BIOSOLUTIONS

REGULATORY SANDBOXES AS A TOOL TO BREAK DOWN REGULATORY BARRIERS

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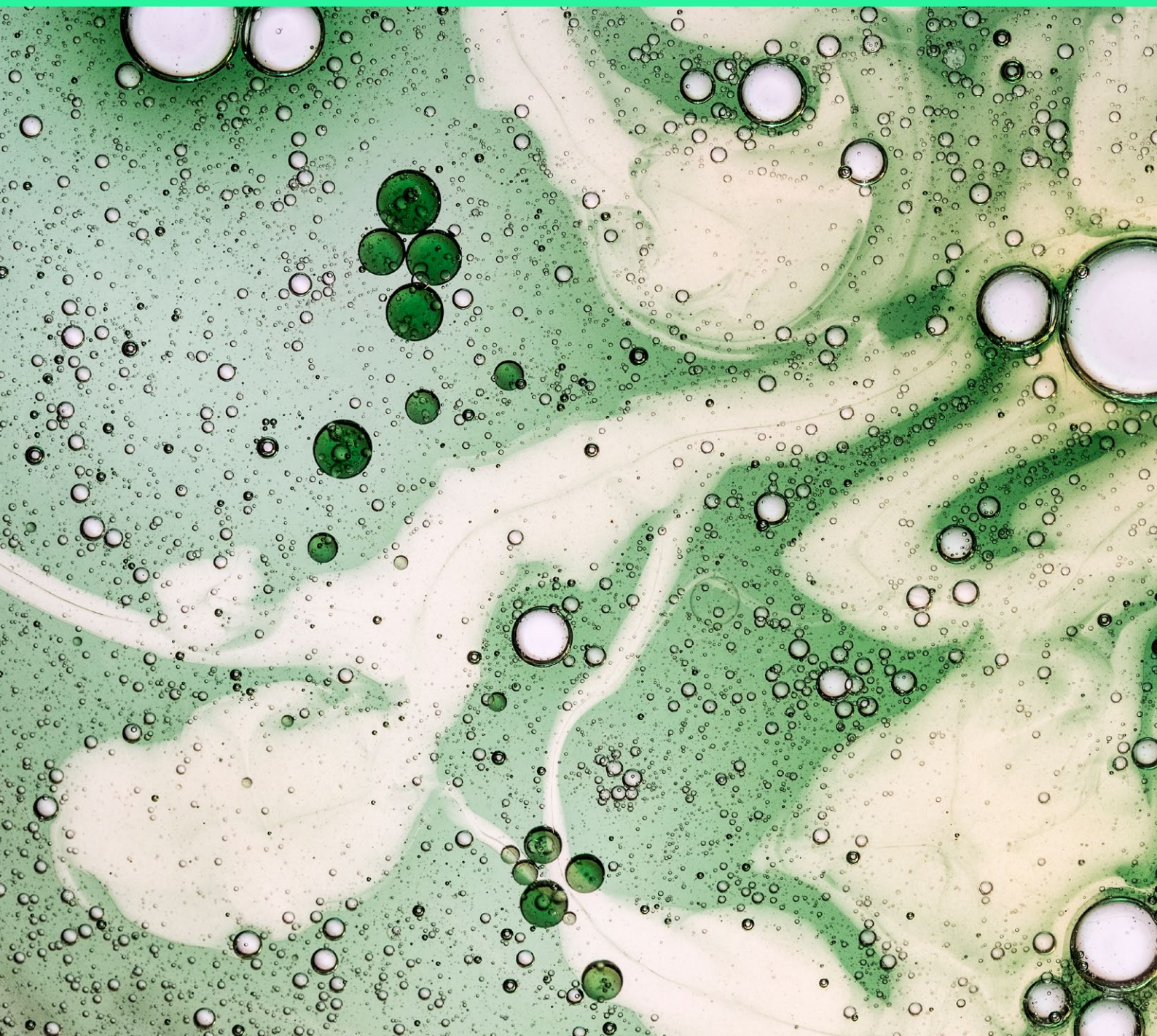

TABLE OF CONTENTS

PREFACE AND OVERVIEW

This report deals with Biosolutions and regulatory sandboxes. As there are no fixed definitions, the report uses the following overall definitions, and specifies different definitions and generations of regulatory sandboxes in part two.

Biosolutions are goods and services derived from combining biology and technology with the ambition of accelerating the green transition.

Regulatory sandboxes are an attempt to remove barriers and increase the speed of the development of innovative solutions. Crucial elements are a structured context for testing, in a limited part of a sector or area, under supervision of a competent authority, and ensuring that appropriate safeguards are in place. The hope is that regulatory sandboxes can create interim solutions, which can help innovation to be tested, scale-up and come faster to market - in a soft, safe and supervised environment.

Biosolutions offer enormous potential, but the current regulatory landscape hinders implementation and scaling of nascent solutions. In addition to frustrating implementation of innovation, EU red tape reduces competitiveness and attractiveness of the region and risks researchers, innovators and companies moving elsewhere. While the EU has acknowledged this risk and expressed a desire to move from “red tape” to “red carpet”, a precise roadmap to achieving this has yet to be confirmed.

This report explores and analyses the potential use of regulatory sandboxes to help achieve the "red carpet" transition.

Regulatory sandboxes are a relatively new phenomenon in the regulatory landscape. The purpose of this report is to investigate the extent to which such sandboxes can help in breaking down regulatory barriers. The focus here is on Biosolutions as the bio-revolution has made legal provisions outdated. The descriptions, analyses and evaluations are all viewed through the lens of Biosolutions, but many elements will apply beyond this field.

The executive summary (p9-21) provides a complete overview of the analysis including establishing the need, introducing the concept of regulatory sandboxes, reviewing historic examples of their implementation, and presenting proposals for the implementation of regulatory sandboxes in three areas – (1) bio-pesticides, (2) novel food/fermentation, (3) GMO/NGT – before summarizing the potential for Denmark in spearheading the idea.

Detailed analyses and recommendations are then provided in three parts to provide more comprehensive information as required:

Part I (p 22-33) places Biosolutions and regulatory sandboxes into context, detailing the need for regulatory sandboxes within Biosolutions in the EU, analyzing current limitations and challenges. The EU's visions for sustainability, innovation and competitiveness are illustrated, as Biosolutions can support these. However, the EU red tape versus US red carpet creates challenges. Regulations prevent progress and there is a risk of the EU being left behind while other parts of the world sprint off at high speed. Regulatory barriers need to be broken down while maintaining safety and EU fundamentals. The regulatory barriers comprise different elements, including complexity and bureaucracy; outdated regulations and long approval times; safety, risks and ethics.

Part II (p 34-87) describes previous variants of regulatory sandboxes in a range of areas (from finance to medicine) at the EU level and globally with analyses of their effectiveness and limitations in each case. They are divided into three different generations: *sandbox classic* (within current regulatory limits); *sandbox with exemptions* (from current regulatory provisions); and *sandbox based on specific EU-regulation* (new trends, AI, blockchain, net-zero industry and act on medicinal products).

Part III (p 88-133) takes the learnings from the analyses presented in Part I and Part II and presents recommendations for establishing regulatory sandboxes and sandbox-enabling initiatives, to establish Denmark as a Centre for Excellence. Recommendations include a one-stop-shop with counselling; Biosolution fora involving different authorities, companies, researchers etc.; competence-building; holistic risk assessments and ethical debates. Specific proposals for regulatory sandboxes in three specific areas are included. Finally, the report includes suggestions on *who could do what* – actors and partnerships, proposals for elements in a *Biotech Act,* Denmark as a *center of excellence* and the way forward – all initiatives to help the transition from red tape to red carpet.

This report makes proposals based on legal analysis. As the proposals deal with science, companies, ministries, authorities etc. I have had fruitful conversations with relevant people, but some checks on my understanding of science and practice may be necessary. I have experience as a law professor, and as a 'lawmaker' having been chairperson/member of 50 law reform commissions, councils, think thanks etc., nationally and internationally, including vice chair/member of the EU's Ethics Committee (EGE) for 15 years and special advisor for EU's Commissioner for education and culture. I also have close collaboration with OECD (Chair of NCP DENMARK on responsible business conduct). My work is often interdisciplinary. I am an expert in Sustainability law and a member of Green Solution Centre (GSR) at the University of Copenhagen. Here, I focus on cooperation with researchers from science, law, ethics and economics regarding BioSolutions.

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EXECUTIVE SUMMARY

BIOSOLUTIONS – POTENTIAL AND VISIONS, RED TAPE AND RISKS

The *potential* of Biosolutions is underlined in a number of reports, stressing that Biosolutions can help reach net-zero in 2050 – saving 700 million tons of CO_2 – while creating growth and jobs.

The EUs *visions* on sustainability and green transition are manifold: Fit for 55, Green Deal, Farm to Fork, etc. Other visions are attached to innovation and competitiveness. This is reflected in many policy papers and strategies.

However, the current regulatory landscape on Biosolutions is characterized by *red tape*. Reality shows reluctance to move from red tape to red carpet – and no regulation is better than its implementation.

The *risk* is that frustrated researchers and companies move elsewhere and the EU is left behind, while other parts of the world sprint off at high speed. Competitiveness is weakened and sustainability suffers – despite the EUs clear ability to create Biosolutions innovation. One of the major problems is regulatory barriers.

The EU acknowledges this risk and there is a strong wish to transform the red tape to red carpet. The Statement by EVP Margrethe Vestager on the European Commission's communication *Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU* is very clear on the desire to unleash the potential of biotech and biomanufacturing. It is underlined that biotech businesses "need active support to overcome the barriers" they face and that "we must simplify the regulatory environment and speed up the application of regulation". The need for speed is also underlined: "We need simplification, faster approvals and faster road to the market". The need for new regulations is also on the agenda: "This year, we will study the best mechanisms to achieve this, including targeted simplifications to the regulatory framework. So as to eventually propose what could become an EU Biotech Act".

This report makes a number of proposals to try to realize this agenda.

REGULATORY BARRIERS, CHALLENGES AND NEED FOR A REGULATORY EVOLUTION

There are many *regulatory barriers* standing in the way of Biosolutions. Regulation is fragmented and silo-oriented, complex and cumbersome, with time-consuming processes on approval and risk assessments, much bureaucracy, capacity shortage etc. It is thus difficult to reap the rewards of the bio-revolution and to break down regulatory barriers, once they are established.

Challenges follow in the footstep of the barriers. While technological and biological revolutions move fast, regulations move slowly. Some innovators see the current regulations as a "showstopper" and prefer to go to other parts of the world where they move fast and roll out the red carpet. The gap is getting bigger every year. Time is ticking. We are looking for new tools, and we are looking for speed.

A *regulatory evolution* is needed. The EU is calling for a predictable, coherent and simplified regulatory environment. This is not an easy task. Law is by nature static, representing former technology and frozen ethics. We are, however, in need of a dynamic tool, to be able to make necessary 'ballet-jumps' into the future, to make regulations fit4purpose and fit4future – without compromising safety issues or EU fundamentals. One of the relatively new legal tools is regulatory sandboxes.

REGULATORY SANDBOXES – 3 GENERATIONS' POTENTIAL AND LIMITATIONS

Regulatory sandboxes are *trending*. They represent a unique approach to regulation that permits selected companies to test and experiment with new and innovative products and services, supervised by a competent authority. Policymakers in various jurisdictions, including the EU and the United States, are using regulatory sandboxes as a tool to foster innovation and develop regulations better suited for innovation.

In the *Biosolution* area, regulatory sandboxes are needed, because the regulatory landscape is complex, fragmented, and partly outdated. The scope is sometimes unclear or does not take new biotechnologies into account; the requested dossiers with documentation are often very comprehensive; the approval procedures are complex, cumbersome and lengthy; and the risk assessments are not necessarily fit for new biotechnologies.

Regulatory sandboxes are an attempt to fill the gap and increase the speed. Crucial elements are a structured context for testing, in a limited part of a sector or area, under supervision of a competent authority, and ensuring that appropriate safeguards are in place. This can translate into quicker approval time and potential cost reduction along with greater access to finance for innovators. The hope is that regulatory sandboxes can create stepping-stone solutions, which can help innovation to be tested, scale-up and come faster to market – in a soft, safe and supervised environment, allowing a step-by-step improvement of regulations to be fit4innovation, fit4purpose and fit4future.

The learnings and potential of the 3 generations of sandboxes can be outlined as follows:

The first generation of regulatory sandboxes: Sandbox classic

Sandbox classic operates within regulatory boundaries. The area is primarily fintech, where the legal basis is the competences of the Financial Supervisory Authorities. The sandbox offers the possibility of small-scale tests before scaling-up and going to market. The primary effects are new knowledge/evidence from supervised testing, legal clarity obtained and mutual learning between innovators and regulators. Innovators learn about regulation and regulatory-thinking; regulators learn about innovations, potential and pitfalls, and an evidence-base is provided, from which to make policy decisions. Sandbox classic has, however, not really made a big difference, and rather than the speed of a racing car, it is the speed of a bicycle.

The second generation of regulatory sandboxes: Sandbox with exemptions

Sandbox with exemptions is rather new and there is little experience on its effects. Most of the exemptions accepted relate to national legislation. These sandboxes can enable the same benefits as generation 1, but they can also make exemptions from current regulations. Their potential is thus much more powerful, if used proactively. However, it is not clear to what extent exemptions and waivers will be accepted in practice. The primary focus seems to be on exemptions in *national* regulation, which limits the potential regarding regulatory areas with much legacy and binding EU regulations.

The third generation of regulatory sandboxes: Sandboxes based on EU-regulation

Sandboxes based on EU-regulation is a new phenomenon, which has been strongly welcomed and seems to be gaining ground. Four prominent and recent examples are the Act on Artificial Intelligence (AI), Act on Blockchain (DLT), Act on Net-Zero Industry (NZIA) and proposal for a Regulation on Medicinal Products. The NZIA primarily regulates clean tech, but the provisions on regulatory sandboxes also include "other innovative technologies", which will include Biosolutions. These sandboxes can provide useful evidence. They differ when it comes to innovation and exemptions. The NZIA enables the competent authorities in the Member States to set up a regulatory sandbox and to make derogations from national regulations but limits their ability to grant derogations from current EU regulations. This may narrow the practical influence of the new regulation, as most Biosolution regulations are detailed, binding EU Regulations. A very proactive interpretation from EU institutions in order to 'play along' and make the NZIA regulation serve its purpose is needed. The sandbox on medicinal products can be initiated by the EU Commission, based on a proposal from EMA, and derogations from the EU law may be accepted. (see below, 10.1-4).

Different potentials

The three generations of regulatory sandboxes thus have *different potentials* in relation to the need emphasized above for Biosolutions. *Generation 1* sandboxes can create constructive testing, legal clarity and mutual learning, but are limited by existing national and EU regulations. *Generation 2*

sandboxes are more powerful and can involve exemptions from current regulation, but these exemptions seem primarily to be used regarding national regulations. *Generation 3* is new and interesting, and the wording of the specific provision establishing a regulatory sandbox is crucial. In contrast to the proposal for medicinal products enabling exemptions from EU law, the act of relevance for Biosolutions – the NZIA – is limited by current EU law, and the effectiveness is therefore very dependent on rather offensive EU interpretations and flexibility.

PROPOSALS FOR DANISH ONE-STOP-SHOP, BIOSOLUTION FORA, ETC.

In order to drive innovation in the area of Biosolutions, it seems fruitful to make a one-stop-shop and other fora and tools to enable the establishment and functioning of Biosolution regulatory sandboxes. This involves a one-stop-shop/single entry point, a Biosolution Forum, a Biosolution Forum+, educating more skilled people, a new risk-assessment scheme, partnerships with co-creation and ethical debates.

One-stop-shop - single entry point

A one-stop-shop creates a 'counselling facility', where the public authorities can help the innovators with the problems of complexity, uncertainty and bureaucracy. It will be a great help for innovators – not least SMEs and start-ups – to get professional help to navigate in the very complex regulatory landscape. The help could include pre-application counselling, counselling during the testing period and helping to scale-up. Inspiration can be found in the NZIA's article 6, specifying what the content of such a one-stop-shop could be. The relevant authority in Denmark could be the Danish Ministry of Industry, Business and Financial Affairs/Danish Business Authority, which could make initiatives in the Biosolution area. Other relevant authorities could be the Danish Environmental Protection Agency (Miljøstyrelsen), the Danish Agency for food (Fødevarestyrelsen) and the Danish Agricultural Agency (Landbrugsstyrelsen). They could benefit from the experiences from the Danish Fintech Lab, the maritime DMA Regulatory Future Lab, and the Danish Agency for Food.

Biosolution Forum and Biosolution Forum+

A Biosolution Forum could enable collaboration between the relevant ministries, for example the Ministry of Industry, Business and Financial Affairs; the Ministry of Food, Agriculture and fisheries; the Ministry of environment – and the relevant agencies mentioned above. The Danish Ministry for Industry, Business and Financial Affairs/Danish Business authority could also be responsible for this Forum: the Biosolution Forum.

A Biosolution Forum+ could also include relevant researchers, Danish companies, including SMEs, industrial organizations, etc. The experience from the AML forum, and AML Forum+ (Hvidvaskforum) could be explored to reap the fruits of their findings. These fora could help tear down possible silos between ministries, companies and researchers and enable fruitful dialogues on barriers, potentials, ways to navigate, etc. A very specific way of making co-creation could be to set down *task forces* to develop proposals for three sandboxes in relevant areas, see below. The Danish Food Administration can contribute with their experiences regarding the Forum for Future Ingredients, see below (9.4).

Competence-building, holistic risk-benefit analysis, ethical debate

Sandbox-enabling initiatives can also be proposed by Denmark. Such initiatives could address the capacity shortage and need for *more skilled people* in the area of Biosolutions. In Denmark, the establishment of Business Lighthouses is interesting, including the new education on Biosolutions starting in Kalundborg in the summer 2024. A consideration could also be to ask all EU member states to find experts for the EU tasks.

When Biosolutions are *risk assessed*, it would be fruitful to make sustainability part of the risk assessment to ensure that the green transition is not neglected. Sustainability is crucial, and the precautionary principle should not be seen in isolation, but in context. In other words, it does not help to be extremely cautious when assessing the risk of a specific pesticide, novel food etc., when it can benefit sustainability if climate change poses a much more serious and general risk but is not taken into account. More of a *risk–benefit* analysis would be in line with the intentions of the NZIA and would make the regulatory approach more purpose-driven. It may even be considered to make a more holistic approach to risk assessment, also taking efficiency and 'better-than' attitude into account. This would be in line with the trend in the pharmaceutical space. In this regard, it can be considered to approach the EU-Commission and EFSA in order to debate a change in EFSAs mandate.

An *ethical debate* would also be relevant, as it seems that ethics and politics in the area of GMO is on the move. The Danish Council of Ethics now sees no ethical objections in the GMO field. They could together with the EGE (European Group on Ethics in Science and New Technologies) initiate an ethical debate, to consider changing the "frozen ethics". It could also be fruitful to have a more extensive ethical debate on risk and risk assessment.

PROPOSAL FOR A REGULATORY SANDBOX ON BIO-PESTICIDES

Bio-pesticides are *important* for Europe, for the green transition and for competitiveness. They are also important for consumers, and they are a Danish stronghold. They are less risky than chemical-based pesticides, which led the EU to introduce initiatives to reduce the use of chemical-based pesticides and promote use of bio-based pesticides. A new regulation on Sustainable Use of Plant Protection Products (SUR) has been introduced, but it has been withdrawn, as consensus about the proposal seemed unrealistic.

The regulation on plant protection products creates *barriers* for bio-based pesticides. This is, among others, due to the fact that the approval

procedure was developed based on chemical plant protection products and therefore contains demands for tests and documentation that are not relevant for Biosolutions. All applications enter the same queue, whether they are chemical or biological. There are too few resources in the different approval fora to process the applications and the case handlers generally have better insights into chemistry than microbiology. The two-step approval procedure, where the EU-Commission approves the active substance, based on a risk assessment made by EFSA, and Denmark then approves the product is bureaucratic and cumbersome, and innovators can expect a timeframe of seven years, involving a cost of approximately 1 million Euro. The proposal in this report tries to address these barriers.

A *regulatory sandbox* on bio-pesticides could be prepared now. The Danish Ministry of Industry, Business and Financial Affairs/the Danish Business Authority (Erhvervsstyrelsen) and the Environmental Protection Agency (Miljøstyrelsen) could collaborate on this sandbox project on bio-pesticides. A potential political strategy may also encourage such an initiative. The purpose and content could be elaborated in the proposed Biosolution Forum and Biosolution Forum+, maybe in a special taskforce, including relevant companies (large companies and SMEs), researchers (for example, Biosolution center at the University of Copenhagen) and the Business Lighthouse Zealand. Contact might also be made to the relevant EU Commission authority and EFSA to enable closer collaboration. Maybe the Netherlands, France and Belgium could be encouraged to join the sandbox.

The aim of a bio-pesticide regulatory sandbox could be to shorten the process from 7–8 years to 3–4 years and to try to make the evaluation process more fit for bio-pesticides regarding the dossier with documentation, and more risk–benefit based regarding the risk assessment and the involvement of other EU countries.

A *fast-track procedure*, could be established in the Danish part of the approval procedure, just as The Netherlands and France have done. Negotiations could also be made with the EU Commission, to try to ensure that the deadlines in the regulation are in fact met, and to suggest a fast-track procedure also in relation to the EU part of the approval process.

EFSA could also be contacted to introduce and discuss a risk–benefit or holistic risk assessment, if the EU Commission is prepared to change its mandate. Educational efforts could be continued and strengthened to ensure competent people to deal with the approval procedure. The testing themes could be determined by the innovators and the regulator (the two Danish authorities) to enable new insights and evidence, making it possible to get faster approvals that still respect relevant safeguards, but speed up the process and make the dossiers more fit for bio-pesticides and implementation. This could hopefully lead to more purpose-driven interpretations of current regulations and updated regulations in the years to come.

PROPOSAL FOR A REGULATORY SANDBOX ON NOVEL FOOD/FERMENTATION

Food and food safety are, of course, of great importance to the EU's citizens along with people worldwide. There is a demand for *novel food* to support the green transition and competitiveness and to produce sustainable, healthier food to the benefit of society and consumers. *Precision fermentation* could be a relevant candidate for a regulatory sandbox. It is a stronghold for Europe and Denmark. Precision fermentation may use GMOs in the process, even if no GMO is present in the final product (e.g., enzymes). A regulatory sandbox could be established to test how to unleash the full potential of fermentation, providing innovative, green solutions for the food value chain.

There are currently many *problems and barriers* in gaining approval from the authorities, which is necessary in order to go to market. It may be difficult to find out which regulations apply, which may limit the interest in starting an approval procedure. Some innovators also find it difficult to have an overview of the approval procedure in practice. To make an application is time-consuming, complex and costly; and it may take several years to obtain an approval. The IRISGROUP also underlines the fact that an approval process cannot be started until the innovator is deep inside the development of a novel food etc., and there are no formal possibilities to get counselling from the authorities at EU-level before and during the assessment of the application.

A *regulatory sandbox on precision fermentation* could be prepared now. The Danish Ministry for Industry, Business and Financial Affairs/Danish Business Authority (Erhvervsstyrelsen) and the Danish Food Agency (Fødevarestyrelsen) could collaborate on this sandbox project. A potential political strategy may also encourage such an initiative. The purpose and content could be elaborated in the proposed Biosolution Forum and Biosolution Forum+ (see above). This might be developed in a special taskforce, including relevant companies (large companies and SMEs), researchers (for example Biosolution center at the University of Copenhagen) and the Business Lighthouse Zealand. Contact might also be made with the relevant EU Commission authorities and EFSA to enable closer collaboration.

A regulatory sandbox on precision fermentation could have as its *aim* to explore whether precision fermentation could be tested in order to generate evidence about safety without stumbling blocks in relation to the documentation (dossier), and the approval procedure with the bureaucracy it entails.

A regulatory sandbox could include comprehensive *counselling*, including both pre-application, during-application and post-application counselling. Danish authorities could help to obtain clarity also on the EU application procedures and the documentation needed (the dossier). This could help the innovators to obtain *legal clarity*. This part of a precision-fermentation sandbox represents sandbox classic and can be established now.

The aim could also include simplifying and easing the cumbersome *approval procedures* and create a simpler procedure with focus on securing safety, but with possibilities to also establish evidence of the benefits of making food using precision fermentation. Thus, it would also be helpful if EFSA could make the *risk assessment* more holistic, including a risk–ben-

efit analysis in relation to the needs of the green transitions, food security etc. This part of a precision fermentation sandbox could be explored and discussed with the EU Commission and EFSA.

It would be extremely helpful if a precision fermentation regulatory sandbox could also include *testing* the safety aspects of approving the *food product* instead of the process, as the current regulation on GMO food embraces not only foods which contain GMOs, but also foods which are produced from or contain ingredients produced from GMOs. Considerations for innovation, sustainability and competitiveness make such arguments valid and proportionate. Making a regulatory sandbox including this aspect would enable developments in the food chain and might also be a test for a shift from a process-orientation in the regulations to a product-orientation, which might bring us nearer to the US regulations without jeopardizing safety aspects. However, this can only take place if the EU-Commission is willing to cooperate with Denmark (and any other member states) on the sandbox project.

PROPOSAL FOR PREPARING A REGULATORY SANDBOX ON GMO/NGT

GMO/NGT (Genetically Modified Organisms/New Genomic Techniques) could also be a relevant candidate for a regulatory sandbox. However, GMO has been a controversial topic in the EU for many years, and a heated ethical debate resulted in a very restrictive regulation in 1991 – a different approach to other parts of the world, for example the US. Now science, the ethical debate and political opinion seem to be changing, but GMOs are still seen as controversial in some member states.

The EU has made a proposal to introduce new regulations on new genomic techniques (NGT). The new NGT proposal focuses on plants, except transgenic plants, and does not deal with microorganisms. It is stressed by the EU that more knowledge is needed.

Probably new knowledge could be provided in connection with a regulatory sandbox. Relevant *testing* seems adequate to obtain the *evidence* that the EU is asking for before making the new NGT regulations cover wider aspects. A regulatory sandbox could explore some of the possibilities and results researchers are working with, including the possibility of GMOs in the open land. In such a case a number of specific safeguards would be needed and could be part of a regulatory sandbox under the supervision of the relevant competent authority.

Perhaps a competition could be established, with a Biosolution Prize to the person or institution finding relevant ways to make safeguards, that could enable new valuable knowledge and evidence in the field of GMO/NGT. This could help develop new products with the benefits such innovations are expected to provide to help the green transition, competitiveness, food security, etc.

As the GMO topic is still controversial in some member states, this must be taken into account. It might be relevant to start a more widespread *ethical debate* on the topic, and maybe on broader topics such as risk assessment seen in light of the climate challenges we face. In their recent report on GMO, the Danish Council of Ethics pointed to the possibility to contribute to such a debate, and the EGE (European Group on Ethics in Science and New Technologies) could also be part of establishing such a debate.

WHO COULD DO WHAT – ACTORS AND PARTNERSHIPS

Denmark can drive initiatives and collaborate with EU institutions and other Member States to make regulatory sandboxes become a powerful tool. As the regulatory sandboxes are a relatively new phenomenon in the EU, Denmark has a sublime opportunity to be *'first mover'* to make proposals for relevant regulatory sandboxes in the area of Biosolutions.

Relevant actors to unfold the potential of Biosolutions regulatory sandboxes include the following.

Ministers and politicians already play a major role in encouraging Biosolutions sandboxes and help break down barriers. Their influence on EU politicians and EU authorities is decisive. Moreover, they can enable collaboration between Danish ministries and agencies and make sure that their policy wishes are implemented. A National Action Plan would be a potent tool. It may be fruitful for relevant politicians to make a research visit to The Netherlands, Belgium, France, the US and maybe Brazil.

Authorities (ministries, supervisory authorities, agencies, etc.) are also crucial actors. It is important that they implement policies and strategies, but also make proposals themselves, which seems to be on the agenda in some ministries and agencies. They can also ensure efficient collaboration with colleagues in other ministries, as well as with companies and researchers. And they can participate in shaping a culture where more flexibility - without jeopardizing fundamental safeguards – is encouraged.

Innovators, for example companies, play a crucial role in making innovative processes and products, pointing to barriers in current regulation and practice and in being part of new regulatory sandboxes, influencing their purpose, testing themes, etc.

Researchers' primary tasks are to use their research expertise to find new methods and conduct basic research, but some collaboration with authorities and companies may also be fruitful. This is taking place to a certain extent already. It is paramount to include research in law, There is a need for three levels of regulatory innovation: New regulations on Biosolutions etc.(EU Biotech act). Regulatory sandboxes, which include both testing new products and testing updated regulation. Purpose-driven interpretation, implementation and enforcement in order to foster better conditions for bringing relevant Biosolutions to market in the EU. Experience from regulatory sandboxes and lawmaking in general is crucial.

Partnerships could also be established as experience from existing regulatory sandboxes in other member states has shown that cooperation with EU authorities and partnerships with other member states may foster regulatory sandboxes. Partnerships should include researchers in

both science and law, which is the whole idea behind the "mutual learning perspective" in the regulatory sandboxes.

Regulators are essential in this respect. The new UK "Engineering Biology Sandbox fund" prescribes in their terms that "UK regulators" are the ones who can apply for funding. It is promising that the Danish Government's plan from June 2024: "A world-class entrepreneurial country" ("Et iværksætterland i verdensklasse") takes this aspect of cooperation between entrepreneurs and authorities into account, when making regulatory sandboxes regarding Biosolutions etc., but broader experience from lawmaking may also be fruitful.

POTENTIAL OF NZIA – AND NEED FOR AN EU BIOTECH ACT

It is a big *step forward* that the *NZIA* creates possibilities to make regulatory sandboxes on Biosolutions. This will enable Biosolutions regulatory sandboxes as the legal basis will then be explicit. Such regulatory sandboxes can foster innovation at some scale, if used to their full potential. The limitations regarding the competence to grant derogations or exemptions regarding EU law, risks, however, scaling down the potential in practice, as most relevant EU Regulations in the area of Biosolutions are binding and detailed. It will be necessary for both national (Danish) and EU politicians and institutions to be very clear about the political agenda to foster simplifications, faster approvals and faster roads to the market. A legal basis has been established, but not necessarily the need for exemptions, which will be deeply dependent on national and EU flexibility.

The constructive way to approach this dilemma seems to be to include the administrative processes, time limits, documentation, dossiers etc. in the tasks for the regulatory sandbox. This is in line with the many "openings" in the different new regulations and EU reports that speak in favor of a flexible attitude to both interpretation and enforcement of law. It is in a way also the reverse, but constructive attitude to timelines, where the timelines stipulated in the current legal provisions often seem to be exceeded in practise, see 13.5 below. Moreover, the purpose of regulatory sandboxes is mutual learning, and this includes both science/innovation on the one hand and regulation/administrative procedures on the other hand. One without the other will only be half a solution. The focus on regulators also underpins the need for regulatory sandboxes to include both innovation and regulation – of course without jeopardizing safety and EU fundamentals, which can be ensured by the supervisory authorities and the collaboration among them.

The need for a *Biotech Act* is still present, as the room for derogation does not necessarily present enough flexibility. An EU Biotech Act could be a rather small act, enabling regulatory sandboxes with exemptions in a number of specific regulations within the area of Biosolutions/Biomanufacturing under certain conditions. There is now a paradigm in the AIA, NZIA etc., but the Biotech Act could focus more on the areas where "regulatory legacy" with old-fashioned, complex and detailed regulation creates massive regulatory barriers. More openings to derogations from both national law and EU law seems necessary. The Relevant conditions in the Act can include the essence of safety measures, including health to humans, animals and environment and EU fundamentals. It would be helpful to widen the risk assessment, including a more holistic view, taking the green transition and "better than" aspect into consideration. Delegated acts could elaborate on specific conditions, tasks and outcomes.

It seems relevant to explore to what extent the national 'France Experimentation' could be an inspiration. Similar solutions in other countries making such a general provision enabling national exemption or collaboration with other countries and/or EU institutions also seem worthwhile to investigate. Some of the elements that might be part of such a Biotech act are proposed in 14.3.

With a longer perspective, the current complex, detailed EU regulatory landscape might also be changed to an *EU framework regulation*, with much more flexibility and agility than the current patchwork. Inspiration may be achieved from the area of products where such a transformation has taken place. Such a framework regulation could cover the whole Biosolution area and make regulations less fragmented and silo based. It could focus on the more principled questions, primarily dealing with safety issues, and not have the variety of complex approval procedures we see now.

In the meantime, it would be useful to create an *overview* of the specific Biosolutions regulations. A comparison on the different safety issues, scopes, approval processes with dossiers, involvement of other EU countries and EFSA, and risk assessments, could make it easier for the innovators, the regulators, the researchers and others to grasp, what the regulation embraces and demands. An AI tool could probably pave the way to such an overview.

DENMARK AS A CENTER OF EXCELLENCE FOR BIOSOLUTIONS

Denmark may become a *Center of excellence for Biosolutions and Biosolution sandboxes*. It seems fruitful for Denmark to take the initiative, as we have strongholds and can be seen as a frontrunner in the Biosolution area. We have excellent research, many large and small companies making Biosolution products and driving bio-innovation. We focus on education and a skilled workforce. Being a small country, we are used to dialogue between different actors, nationally, and we can foster and continue relevant dialogues with the EU Parliament, the EU Commission, different relevant EU authorities, EFSA, etc.

It would be essential to make sure that learnings from Biosolutions and from Biosolution regulatory sandboxes are communicated broadly to the benefit of countries in the EU. In this way, it could be seen as more beneficial to keep the development of BioSolutions and Biomanufacturing within the EU, with Denmark as spearhead, instead of exporting Biosolutions to be made and go to market in other places in the world such as the US, China, the UK, etc. The vision is to keep it simple, but safe, to keep it in the EU and to make a transition from red tape to red carpet.

This ‘golden opportunity’ necessitates a very active effort to be cooperating, co-creating and creative to play a crucial role in reaping the fruits of the bio-evolution and being a frontrunner on Biosolutions.

THE WAY FORWARD

Denmark can set up relevant fora, including a one-stop-shop, a Biosolutions Forum and a Biosolutions Forum+, and can initiate competence-building, ethical debates, etc. Parallel with the Danish initiatives, it could prove fruitful to contact potential partnership countries, ESMA and the EU Commission, the relevant DGs, to introduce ideas and start a dialogue about the establishment and content on Biosolutions regulatory sandboxes. This way - and with the help of Danish and EU politicians etc. - the idea of accepting flexibility also in the EU system, when interpreting and enforcing regulations in the Biosolutions area, could be presented and debated in light of the clear policy visions. Debates may for example be on the question of which safeguards are essential, whether changed administrative processes in the tests in regulatory sandboxes could be accepted, and whether a holistic risk assessment taking into account the need for a green transition can be introduced (see part III).

Denmark could play a role to the benefit of Danish and EU companies and thus help speed up the EU and enable innovation, the green transition and the competitiveness in relation to other countries. This way Denmark could be a strong player in helping the transition from red tape to red carpet.

PART I

BIOSOLUTIONS AND REGULATION

BARRIERS AND CHALLENGES

The EU's visions on enabling sustainability and the green transition, fostering innovation and improving the EU's competitiveness are clear and mirrored in many policy papers, strategies, etc. They express the goals current regulations can be judged against. The EU's regulatory landscape on Biosolutions creates problems for the possibility to reap the full rewards of the bio-revolution. Changes are difficult to obtain. The EU's regulation in some areas seems 'frozen'. The EU risks lagging behind, in need of innovation and competitiveness and not supporting sustainability and the green transition in the way Biosolutions could. This is a challenge calling for an evolution of regulatory tools. Sandboxes may represent an innovative way to ease the regulatory pathway in a dynamic, but soft way.

1 BIOSOLUTIONS POTENTIAL, EU VISIONS AND RED TAPE

1.1 BIOSOLUTIONS POTENTIAL IN THE GREEN TRANSITION

There is no formal definition of Biosolutions,[1] but often the potential impact on the green transition is included in the definition and sometimes the definition also mentions the use of microbes, enzymes, algae and other microbial cultures to transform low grade biomass into industrial products of different kinds, for example bio-pesticides, biobased protein for food and feed etc.

The potential of Biosolutions has been underlined in a number of reports. *Alliance for Biosolutions* in December 2023 made "10 priorities for the EU Biotech and Biomanufacturing Initiative", where they make an "Appeal to the European Commission to develop conducive framework conditions to allow the strong EU Biosolutions sector to become a key driving force of the green transition..." They refer to a study "estimating that the global market potential for Biosolutions in other industries such as transport and the agri-food sector could surge from EUR 240 billion in 2020 to EUR 640 billion in 2030, if optimal frameworks were created." The

1 Related used terms are "Bio-economy" and" Biocontrol".

study also "found the achievable global emission reduction potential of mature, ready-to-deploy Biosolutions to amount to roughly 4,300 million tons of CO2 equivalents towards 2030, corresponding to around 8 percent of current global emissions".

In their press release of 20th March 2024, "*Commission takes action to boost biotechnology and biomanufacturing in the EU"*, the EU characterized the potential of biotech as one of the most promising technological areas of this century:

> "The advances in life sciences, supported by digitalization and artificial intelligence (AI), and the potential of solutions based on biology to solve societal issues, make biotechnology and biomanufacturing one of the most promising technological areas this century. They can help the EU to modernize its agriculture, forestry, energy, food and feed sectors and industry. In addition, these technologies can contribute to a more competitive and resilient EU, that provides better healthcare to its citizens, and succeeds in its green and digital transitions".

The Danish Government has made a Biosolution Initiative. This involves close cooperation across ministries and for example an ingredients strategy and a vision for and partnership with the business lighthouse, Biosolutions Zealand.

1.2 EU VISIONS ON SUSTAINABILITY, INNOVATION AND COMPETITIVENESS

The EU's visions on sustainability, innovation and competitiveness are reflected in many policy papers, etc. Some examples illustrate this, with a focus on areas within Biosolutions.

Back in 2017, the EU introduced the *Innovation Principle*, a tool to help achieve EU policy objectives by ensuring that legislation is designed in a way that creates the best possible conditions for innovation to flourish. The ambition is that the Innovation Principle will ensure that regulations are innovation-friendly and will cover the entire three phases of the policymaking cycle: *Agenda-setting, legislation, and implementation.* In the implementation phase the Commission offers *Innovation Deals* to deal with existing EU rules, identify if an EU rule or regulation is an obstacle to innovation and if so, help to find solutions. In a Communication from 5th July 2022, *A new European Innovation Agenda*, it is underlined, that "Innovation is essential to drive Europe's competitiveness and to ensure the health and well-being of its citizens".

The *green transition and sustainability* is a prominent example of EU's visions. In 2019, *Ursula von der Leyen* introduced "The Man on the Moon" moment presenting the EU's *Green Deal,* followed by an Action Plan and a tsunami of regulations, including taxonomy, disclosure, sustainability reporting and sustainable due diligence. However, the EU acknowledges that these initiatives will not have sufficient effect, unless followed up with research and innovation.

In the EU Green Deal *Farm to Fork Strategy - For a fair, healthy and environmentally friendly food system* (2020), the need for transition to sustainable food systems is underlined. The aim is to accelerate our transition to a sustainable food system, that should have a neutral or positive environmental impact, among other benefits; help to mitigate climate change and adapt to its impact; and reverse the loss of biodiversity.

The European Environment Agency (EEA) made a report (No 14) in 2022: *Transforming Europe's food system - Assessing the EU policy mix*, which stressed that:

> "Sustainability transitions research underlines the need for policies to disrupt and phase out harmful technologies, substances and practices, and even entire socio-technical systems, stringent regulations and marked-based instruments can also incentivize innovation and support the diffusion of more sustainable alternatives. In practice, however, the EU food systems policy is inconsistent, regarding actions to phase out unsustainable activities. ... Successful phase-outs therefore require combinations of policies that support innovation, disrupt established systems, navigate resistance, broker consensus and ensure a fair distribution of costs and benefits". (p. 9).

The *Fit-4-Future Platform* is a high-level expert group established to help the Commission simplify EU legislation[2]. Fit4Future examines whether existing legislation can achieve its objectives effectively when faced with new challenges. The Platform's views are taken into account by the Commission to ensure that EU legislation helps, not hinders, citizens and businesses, especially SMEs. In December 2022, that platform made a number of recommendations to the Commission on how to create a more innovation-friendly regulation of Biosolutions while upholding necessary protections. The report was accepted by all EU-countries, including 10 specific recommendations, which are mentioned below, part III, 11.3. In the EU's *Green Deal Industrial Plan for the Net-Zero Age* from 2023[3] and the *Net-Zero Industry Act (NZIA),* the desire is for "enabling innovation regulation" and "simplified regulatory environment".

> " The objective of the Communication is to ensure a quick transition to carbon neutrality and complement the legislation already in place or under negotiation. The plan is the result of a huge push from member states in response to the US Inflation Act, and to put the attention of the Commission on the potential competitiveness disadvantage Europe would face in the light of new attracting measures coming from the Biden administration". One of the pillars mentioned is a "predictable, coherent and simplified regulatory environment".

In the *State of the Union Speech, September 2023* it is underlined that the EU "will hold a series of Clean Transition dialogues with industry ... and prepare a report on the future of European competitiveness, looking at the challenges facing industry and companies in our Single Market". One of the key priorities will be EU Biotech and Biomanufacturing Initiative.

2 The platform consists of representatives from Member States and individual experts, representing EU's industrial and employer-organizations, NGO's and two European committees. "Dansk Erhverv" is representing Danish industry.

3 EU's Industrial Plan "The Green Deal Industrial Plan for the Net-Zero Age - Speeding up the contribution of Europe's innovative clean tech industries to net-zero" (1.2.2023).

In the *Communication from the Commission to the European parliament, the Council, The European economic and social committee and the Committee of the regions: Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU* from 20th March 2024, a number of proposals deal with the regulatory complexity. Both streamlining and sandboxes are mentioned (p. 12):

> *"Streamlining regulatory pathways, including permitting and authorization:*
> Further action at EU level is needed to improve conditions for moving from "lab to fab" creating a level playing field for companies in the internal market for the commercialization of mature biotech innovation.
>
> The Commission will assess how EU legislation and its implementation could be further streamlined to reduce any fragmentation, explore potential simplification, and shorten the time for biotech innovations to reach the market; as well as regulatory obstacles that arise at national or other governance levels which impede an effective single market. To this end, the Commission will launch a study that will map key current industrial bio-based value chains, analyse the regulatory framework and the impact of relevant legislation, and thereby lay the foundations for a possible EU Biotech Act[4].
>
> In that context, targeted simplifications to the regulatory framework, focusing on specific areas such as harmonized requirements for low-risk biotechnologies and streamlining/simplifying approval processes for certain product categories, will be explored. Issues of implementation will also be considered, for instance, to ensure clarity about applicable regulatory frameworks in fast developing areas or products or technologies that do not easily fit an existing category. This would foster innovation in the EU by improving clarity and predictability for the industry and help to upscale relevant biomass production in the EU. In addition, the adoption of the new Regulation on plants produced by certain new genomic techniques is essential for the EU to benefit from the biotechnology potential in the agri-food area.
>
> The Commission will further promote the establishment of regulatory sandboxes that allow to test novel solutions in a controlled environment for a limited amount of time under the supervision of regulators, as a way of bringing more of them quickly to the market". This has already been proposed for breakthrough therapies under the reform of pharmaceutical legislation.
>
> The Commission will also "work towards establishing an EU Biotech Hub, an operational tool for biotech companies to navigate through the regulatory framework and identify support to scale up".

It is mentioned (p.6), that an example of regulatory complexity is "the approval of a biological plant protection product in the EU ... takes up to three times as long as in the US. Similarly, developers of biotech health products have difficulties in navigating the complex EU and national-level regulatory environment and the intrinsic complexity characterizing those innovative treatments.

4 It is in a footnote mentioned that "One possible question would be the possible generalisation to non-medical biotech of approaches under the Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment, OJ L 458, 22.12.2021, p.1".

1.3 RED TAPE VERSUS RED CARPET

The EU's visions on sustainability, innovation and competitiveness should be seen in the context of the situation in the US. In the US *Inflation Reduction Act* (IRA) billions of USD have been assigned to the green industry. In a commentary on LinkedIn, the Danish Foreign Minister *Lars Løkke Rasmussen* underlined the following in relation to his visit to the US in 2023:

> In many ways good news, because we will not reach the global climate targets without a USA, fully and completely engaging. But it also presents challenges for Europe to step up. If a red carpet is rolled out for the future's green companies in the US, while they are met with red tape in Brussels and the European countries, we will lose the competition regarding the future knowledge-workplaces and welfare. For this reason, the EU is currently working on making a more robust trade- and industrial policy in Europe.

This difference in the approach to green transition and green companies enabling innovation, including Biosolutions, creates a major challenge for EU, including Danish companies. The risk is that research and innovation tend to move to other places in the world, primarily the US. This is bad for Europe.

In Part II the regulatory landscape and regulatory barriers for Biosolutions are described and analysed. Based on this some proposals for breaking down some of the barriers can be made. It is, however, crucial to be aware of what is at stake when dealing with the regulatory barriers etc. and the proposals for rather "offensive" approaches to regulatory sandboxes. In this respect, some more general observations can create a relevant background for the review of the Biosolution regulations and barriers and the need for regulatory sandboxes.

1.4 WHAT IS AT STAKE?

The EU's regulatory landscape on Biosolutions creates problems for the possibility to reap the rewards of the bio-revolution. The consequence is a risk that the EU is lagging behind, needing innovation and competitiveness and not supporting sustainability and green transition in the way Biosolutions could.

EU's Biosolution regulation prevents progress if it is 'frozen' and outdated

Just as was seen in the tech revolution, the bio-revolution creates great potential for innovations to the benefit of societies. It is urgent that regulations support Biosolutions with the potential it offers. This is, however, not necessarily the case (see Part II). There are many barriers and obstacles. It is obvious that regulation should secure safeguards including human health and the environment. But relevant safety issues cannot justify the magnitude, complexity and long timelines of the current regulations. The regu-

lations seem rather often to be made for chemistry-based or fossil-based products and not fit for bio-based products. It is urgent that the regulation is "fit4innovation", "fit4purpose" and "fit4future".

EU risks to be lagging behind – need for speed and a regulatory evolution

While the EU is struggling with inefficient and outdated Biosolutions regulation, much is happening in other parts of the world. There is a risk that research and commercialization will move to the US, where the red carpet is rolled out, while the EU is seen as being a place where red tape is an obstacle and barrier. The innovators are left behind, frustrated, sometimes going to other places more fit-for-innovation. This creates a need to identify the barriers and make proposals for a regulatory evolution - and to do it fast. Current regulations, reflecting former technologies and frozen ethics, are an obstacle for regulatory visions, and changes seem to have a long way ahead. The need for speed is obvious. If we do not use relevant tools, for example sandboxes, for Biosolutions at this stage, but wait 10–20 years for new regulations, there is a risk that red tape will win and competitiveness, sustainability and innovation will lose. The best approach is clearly innovation, but also innovation in regulatory thinking.

Many visions, policy papers etc. call for changes, but reality shows reluctance

The EU has issued many strategies, policy papers and proposals for regulations, presenting their visions for sustainability, competitiveness and innovation. Important examples are Green Deal, Fit-for-55, Farm-to-Fork, Fit4Future, Better Regulation, Innovation Principle, Net-Zero Industry Plan and Net-Zero Industry Act proposal. Proposals for regulations about, for example, Sustainable Use of Pesticides (SUR) and New Genomic Techniques (NGT) have been introduced, but face difficulties - SUR has even been withdrawn in 2023. Despite the good intentions, the realities speak for themselves: Green Deal makes a tsunami of regulations about reporting, information etc., but until now very little innovation. Farm-to-Fork strategy has little chance of reducing pesticides by 50% by 2030 when approvals take 7–8 years. The Innovation Principle seems to have limited success in the area of Biosolutions. SUR regulation and GMO regulations seem to be controversial and face difficult negotiations. This shows that there is a need for new tools to foster quicker solutions.

2 REGULATORY BARRIERS FOR BIOSOLUTIONS

The regulatory landscape regarding Biosolutions is characterized by EU harmonization, fragmented regulations, complex processes on approval and complicated risk assessments, where EFSA plays a major role. It has developed over several years but not necessarily in a way which takes the new Biosolutions and their contribution to sustainability, innovation and competitiveness into consideration. In many ways, it is a reflection of former technology, frozen regulations and frozen ethics. This makes life for innovators complicated to a degree where they sometimes see the current regulation as a showstopper and look elsewhere for their innovations to be approved and brought to market. While this is clearly a problem, at the same time the regulations were made for a reason. It is important to not compromise EU fundamentals or safety issues. Thus, it is important to analyze the regulatory barriers in light of the need for a balance to secure safety and EU fundamentals on one side and welcome and support new developments enabling sustainability, innovation and competitiveness on the other side.

The Biosolution area is generally characterized by a number of characteristics and consequences when it comes to regulation:

1 *Safeguards* are essential. The purpose of the regulations is closely related to safety issues. These are connected to human health, animal health and the environment. The consumers play a crucial role.
2 *Harmonization within the EU* is a general characteristic of many of the areas relevant for Biosolutions. This is important to help the Single Market and create a level playing field but makes rapid changes very difficult in practice.
3 *Approval* from authorities is a condition for placing Biosolutions products on the market. Both the EU and Member States are involved. Part of the approval procedure will be on *risk assessment*, where EFSA plays a major role.

The following description of some of the barriers the companies experience in practice is based partly on interviews with relevant companies, but primarily on a report made by the IRISGROUP[5] documenting in detail the experienced barriers. The description is far from exhaustive, but presents an updated picture of the regulatory barriers, that Danish companies have experienced. The regulatory barriers are "decomposed", to be able to make some general remarks and propositions. This makes it possible to treat them separately and to point to possible ways to overcome or diminish the three different categories of barriers: 1) complexity/bureaucracy elements; 2) outdating and timelines elements; 3) and safety and ethical elements.

2.1 COMPLEXITY, UNCERTAINTY, BUREAUCRACY

Complexity is a general characteristic as the regulations are manifold. The regulatory provisions are not easy to find, read and understand. The regulation is also fragmented and '*silo-oriented',* dealing specifically with many different areas, for example pesticides, stimulants, food, feed, additives, novel food, GMO plants, GMO food, GMO and the environment, etc.

Companies also point to the *uncertainty and lack of legal clarity* as a barrier. It may be difficult to find out *if* a Biosolution product or process is covered by any regulation, *if* a specific regulation or definition is relevant for them, *how* a dossier is to be established, *which* kind of documentation, test etc. is relevant, *which form* the application should have, and *how* the interplay is between different regulations.

5 The IRIS Group has made a report for the Danish Business Authority (Erhvervsstyrelsen) in January 2022 on regulatory barriers for development of Biosolutions - mapping of barriers in Denmark and neighbor check of practice in other EU Member States. "Regulatoriske barrier for udvikling af Biosolutions. Kortlægning af barrierer i Danmark og nabocheck af praksis i andre EU-lande".

Some of these barriers can be overcome by help from authorities to interpret the regulations. Sometimes authorities are, however, not very eager to make very clear-cut interpretations, which may be seen as a 'civil servant precautionary principle' and may leave companies in a vacuum. Besides, the uncertainty is often a reflection of very complex regulation, not taking new Biosolutions into account. It may be seen as more to the point to change that fact instead of making problems for companies and authorities to make difficult and uncertain interpretations.

Bureaucracy can also be seen as a major barrier. The approval processes often involve many authorities and many individuals. National authorities, the EU Commission and EFSA, and other Member States will often have a role to play. When it comes to novel food, a mapping of requests for additional or supplementary information sent by the EFSA is overwhelming. Moreover, public consultation will sometimes also be relevant. Depending on the area, the conditions to obtain the relevant approvals, the documentation and tests and the involvement of both EU and Member States experts may seem overwhelming. The reasoning behind is often that there are many stakeholders who want to have a say, but the procedures may prolong the time-to-market and contribute to the problems regarding bureaucracy. EFSA has published a general overview of the procedure and its phases regarding new pesticide active substances,[6] which is very illustrative - and may take 8 years!

A special obstacle is that approvals in the EU system are often based on the *process* used, not the *product* made. This is different from many other places in the world such as the US, and creates specific obstacles, for example, regarding food.

The barriers regarding complexity, uncertainty and bureaucracy often seem to create stumbling blocks, that go beyond the necessary procedures to secure safety and consumer interests. The fundamental EU values, including the Single Market, can probably also be ensured without the complexity, uncertainty and bureaucracy in the current regulations.

Complexity and uncertainty can be helped by establishing a 'sandbox classic' making counselling, for example as a 'one-stop-shop' (see below, Part III). It would also be helpful to make legal changes to create more clarity and less complexity. Bureaucracy can be diminished by simplifying the approval procedure. This might be helped by a 'sandbox with exemptions' (see below, Part III, 13.2).

2.2 CUMBERSOME OUTDATED REGULATIONS, LONG APPROVAL TIMELINES, COMPETENCES

The bureaucracy leads to major problems with the time it takes to get an approval, which delays time-to-market compared with other places in the world. Innovators experience the approval process in certain areas to take 7–8 years. This may result in innovators going to non-EU countries. Moreover, regulations may be outdated, for example, if based on chemical or fossil methods, not taking the bio-revolution and new bio-based processes and products into account. There is a need to bypass conditions and criteria that are not relevant anymore and make it possible to get to market quicker.

6 General overview of application procedure for approval of new pesticide active substances and amendment of approval conditions.

Outdated regulation is a huge problem, especially regulation based on fossil-based or chemistry-based products, which are not fit for Biosolutions, as many of the conditions and tests will not be relevant. While many new technologies seem to fall outside the scope of traditional regulations, new biological substances are often 'captured' by existing regulation, which is not geared to the new substances and therefore include conditions, risk assessments and tests that are irrelevant. As Biosolutions are gaining ground in research and innovation, the problem will only grow – and will grow rapidly.

Approval timelines are often very lengthy for Biosolutions[7], and much longer than in other places in the world. While the timeline is 2 years in China, 2–3 years in the USA, Canada, India and Australia, it is 5 and even up to 8 years in the EU. The lengthiness of the approval procedure has been criticized immensely by the companies.

It also seems that one of the major problems – apart from the bureaucracy as such – is finding competent people to be Member State Rapporteurs, and finding enough competent staff in the EFSA and member state authorities to approve the applications.

This barrier can be overcome in different ways. One possibility is to employ more people to make the approval procedure faster. Compared with the problems of competing with the rest of the world, including the US and its red-carpet approach, it seems a very low cost to educate and hire some more people in the EU. When thinking how to accelerate this, using universities and potentially companies to help with education, it is important to always secure the independence of the evaluators. Another solution could be to establish lighter-touch procedures in certain appropriate cases.

2.3 SAFETY, RISK, PRECAUTIONARY PRINCIPLE & ETHICS

Safety, risk assessment and ethics should of course play decisive roles but may create barriers. When it comes to *safety* regarding human health and animal health, it is paramount – and generally accepted – that relevant and sufficient safeguards should be secured. The same is the point of departure for safeguarding the environment.

There is a need to evaluate the background, relevance and content of the barriers in light of pressing climate dangers if we do not succeed in the green transition. This is a difficult task, as some of the *risks* are very difficult to assess. It is important to remember that *not* making changes and accepting new solutions also creates a risk – which may turn out to be much more serious than the option of saying 'yes' to new solutions. The precautionary principle should be interpreted in the context of the climate crisis: it may be better to accept minor risks than to give up in relation to climate changes.

If the barrier is due to *ethics* issues, new debates should shed light on recent developments in science and ethics. The present regulation can be seen as 'frozen ethics', mirroring ethical considerations, which were widely accepted when the regulation was enacted, but may be 'overruled' by later ethical common attitudes. Moreover, the present sustainability crisis, including the climate risks, may put former ethics in new light warranting reconsideration. The GMO regulation now seems to be replaced by NGT,

7 International Biocontrol Manufacturers Association.

which is an example of change of ethical worries – also helped by the use during many years in the US.

A tendency to weigh risks against benefits and to include sustainability risks in this balance should be encouraged to support a dynamic regulatory evolution. A *holistic risk assessment* could be encouraged and debates to ensure that Biosolution regulation is both fit-for-purpose and fit-for-future.

2.4 NEED FOR NEW APPROACH TO BREAK DOWN OR DIMINISH BARRIERS

The description of the regulatory landscape and the barriers experienced by the innovators seem to have very strongly indicated a number of problems and challenges regarding the present regulations and practices on Biosolutions.

The *regulatory landscape* in itself creates barriers for Biosolutions. It is very complex, very detailed, very fragmented, very silo-based and very overwhelming. Basic regulations are in place for a number of different areas, but these are spiced up with a number of special regulations for specific processes and products and with numerous Annexes adding to the conditions and complexity.

A number of the regulations and provisions are *outdated* as they are based on chemical or fossil solutions, not Biosolutions. Examples include pesticides, but the (novel) food area and GMO/NGT also seem outdated in a number of ways. Science and technology, experience from other parts of the world and changes in ethical considerations all contribute to the need for regulatory review.

Authorities are also manifold. In Denmark, these include Erhvervsministeriet and Erhvervsstyrelsen, Miljøministeriet and Miljøstyrelsen, Ministeriet for Fødevarer, Landbrug og Fiskeri and Fødevarestyrelsen and Landbrugsstyrelsen, and Undervisnings- og forskningsministeriet, just to name a few. They play an important role in the approval process, but also regarding policy development and implementation and initiatives for actions in the area of Biosolutions and others.

EU authorities also play a crucial role, especially the EU Commission, with different relevant Director Generals (DGs). Special agencies play a crucial role, for example regarding risk assessments, where EFSA is the specialist agency regarding foods. *Other actors* have roles to play, for example researchers in Biosolutions, politicians in Denmark and Europe, big companies, SMEs and other innovators, etc.

Approval procedures are essential for the Biosolutions regulations and for the barriers experienced. Danish companies developing Biosolutions experience that many regulations in different areas appear inappropriate and sometimes slow down their development opportunities. Most of the regulations to which the companies are subject have been developed, where there were no real alternatives to fossil-based or chemical forms of production. This means their new bio-based products and technologies must be tested and approved according to standards developed on the basis of conventional product characteristics and risk assessments.

There is a wish to encourage entrepreneurship and SMEs, but for them to find their way in the regulatory jungle is almost hopeless. The conclusion seems to be that the current regulatory landscape is extremely complex and partly outdated and that the regulatory approval processes are complicated cumbersome and very long. Taken together, the regulations and practice seems not fit4innovation, not fit4purpose, and not fit4future.

There seems to be an urgent need for simpler rules, legal clarity and less bureaucratic procedures. In the Green Deal Industrial Plan, the EU is also calling for a "predictable, coherent and simplified regulatory environment". This is a very relevant but also very ambitious plan.

While we wait, we could try to support the green transition, innovation and competitiveness in a less complex, soft way. It is worth investigating to which extent regulatory sandboxes could ease the regulatory pathway and be able to bridge the gap from frozen regulations to a more dynamic, step-by-step modernization of current regulation and its barriers. In a way, it is quite obvious that technological revolutions and bio-revolutions should be followed by regulatory evolution. An innovative approach to legal tools is necessary, and regulatory sandboxes may prove potent in this respect, if approached with an open mind.

PART II

REGULATORY SANDBOXES

3 GENERATIONS

In this Part, regulatory sandboxes will be described. The definitions and development of such sandboxes are outlined. They are divided into 3 generations: 1) Sandbox classic, normally operating within current regulations and primarily helping to navigate in the regulatory jungle. 2) Sandbox with exemption, allowing temporary exemptions from current – normally national – regulation. 3) Sandbox based on EU regulation, examples being new acts on AI, on blockchain and on net-zero industry and a proposal for an act on medicinal products. A great number of examples, experiences and findings from different reports made by the EU, the World Bank, OECD and Germany are described, including Danish experiences. The sandboxes included in EU regulations/proposals are described in more detail as well as inspiration from EU Better Regulation, EU Commission Recommendations for sandboxes, the Fit4Future Platform, new OECD reports on regulatory experimentation and national examples.

PART II elaborates on regulatory sandboxes as a relatively new phenomenon. The definitions and development of such sandboxes are outlined, and for the purpose of this report, they are divided into three generations with different legal bases and the possibility for derogation from current regulations.

Reports are described to illustrate national, European and global examples of sandboxes. A report from the EU and a report from the World Bank focus on the development of fintech sandboxes. A global report from OECD presents a number of sandbox examples from around the world. A national report from Germany presents yet a broad variety of examples. Two Danish regulatory sandboxes in the Financial Supervisory Authority (Finanstilsynet) on fintech and the Danish Maritime Authority (Søfartsstyrelsen) on what they call Future Lab are also included in the outline, as well as some recent proposals by Danish authorities. Moreover, new sandboxes based on EU regulation are described: the AI Act on Artificial Intelligence, the DLT Act on blockchain, the Net-Zero Industry Act and the proposal on medicinal products. Finally, the EU's tool on sandboxes in their Better Regulation principles and their Guidance on Regulatory Sandboxes are presented, the proposals from the Fit4Future Platform and OECD reports on experimental regulations and some national examples are described.

The description is far from exhaustive, but gives an impression of the development, status, experiences and potential of regulatory sandboxes.

Based on the descriptions, Part III analyses the benefits and challenges of regulatory sandboxes, and reflections are made on what we can learn from the current regulatory sandboxes and what the potential of regulatory sandboxes could be in the future.

3 DEFINITIONS AND DEVELOPMENTS OF REGULATORY SANDBOXES

3.1 DEFINITION OF REGULATORY SANDBOXES

There is no agreed definition of regulatory sandboxes.

The World Bank, in their report on *Global Experiences from Regulatory Sandboxes* p. 65 note 2 defines a sandbox as:

> "A regulatory sandbox is generally defined as a controlled, time-bound, live testing environment, which may feature regulatory waivers at regulators' discretion."

The OECD made the following definition in a policy note from 2020: *The role of sandboxes in promoting flexibility and innovation in the digital age*, p 7:

> "A regulatory sandbox refers to a limited form of regulatory waiver or flexibility for firms, enabling them to test new business models with reduced regulatory requirements. Sandboxes often include mechanisms intended to ensure overarching regulatory objectives, including consumer protection. Regulatory sandboxes are typically organized and administered on a case-by-case basis by the relevant regulatory authority. Regulatory sandboxes have emerged in a range of sectors across OECD and beyond, notably in finance but also in health, transport, legal services, aviation and energy".

The EU has also introduced sandboxes of different kinds. The newest examples, where sandboxes are defined, are the Better Regulation Toolbox, the Guidance on Regulatory Sandboxes, the AI act (AIA) and the Net-Zero Industry Act (NZIA).

In the European Commission's *Better regulation toolbox* 2023 tool #69, p. 597 a sandbox is defined as follows:

> "Regulatory sandboxes are a relatively new policy 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. Although no commonly agreed definition exists regulatory sandboxes can be broadly described as schemes that enable firms to test innovation in a controlled real-world environment under a specific plan developed and monitored by a competent authority. They are usually organized on a case-by-case basis, include a temporary loosening of applicable rules, and feature safeguards to preserve overarching regulatory objectives, such as safety and consumer protection. Two approaches are theoretically possible to set up a sandbox: one where the request (and identification of a regulatory barrier) is initiated by innovator, and another, where the regulator identifies legislative provisions for testing and calls for applications by interested organisations. Additional approaches or a combination of the above may emerge with time".

In the *Guidance on Regulatory Sandboxes*, made by the EU Commission, regulatory sandboxes are defined as follows:

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

In the *AIA* a regulatory sandbox is defined in (article 3(55):

> an AI regulatory sandbox is "a controlled framework set up by a competent authority which offers providers or prospective providers of AI systems the possibility to develop, train, validate and test, where appropriate in real-world conditions, an innovative AI system, pursuant to a sandbox plan for a limited time under regulatory supervision".

In the *NZIA* a regulatory sandbox is defined in article 3(22):

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

In the EU proposal from 26th April 2023 on regulatory sandboxes for medicinal products, the regulatory sandbox is set up by the Commission based on a recommendation from the Agency. The sandbox "may allow targeted derogations to" the regulation. The regulation is described below, 10.4.

> The conditions to set up a regulatory sandbox are a.o that it is not possible to develop the medicinal product in compliance with the requirements applicable to medicinal products "due to scientific and or regulatory challenges arising from characteristics or methods related to the product", and they "positively and distinctively contribute to the quality, safety or efficacy of the medicinal product ... or provide a major advantage contribution to patient access to treatment.

3.2 DEVELOPMENTS OF THE SANDBOX CONCEPT

The main descriptions of regulatory sandboxes are primarily based on papers from EU and the World Bank, an OECD report and a German Handbook for Regulatory Sandboxes.[8] Sandbox reports from the EU Council and an EU Commission Staff Working Document[9] are also included as are some sandboxes described elsewhere and innovation initiatives, which do not present themselves as sandboxes, but have (some of) the same characteristics.

The sandbox concept is quite new. It originated in the *IT industry* to refer to a segregated, isolated environment for testing products or software, thus mitigating risks before products were brought to market. Developers used IT sandboxes to execute suspicious code or check security software for vulnerabilities without risking harm to the host device or network.

Sandboxes have also been used in the *health industry* to identify and experiment with innovative tests and services. For instance, the UK used a sandbox environment to virtually test services and innovations for predictive early detection of neurodegenerative diseases, antidepressant treatment responses, or rare disease scanning, among other medical uses.

Sandboxes made their way into the *financial sector* regulation in 2012, and the term "regulatory sandbox" was popularized by the UK's Financial Conduct Authority (FCA), through its *Project Innovate* which, in 2016, first promoted the sandbox idea to support and enable the environment for fintech. The sandbox frameworks allowed fintech startups to conduct live experiments in a controlled environment under a regulator's supervision. FCA has received over 550 applicants since its launch. The primary areas for the UK sandboxes are new technologies: AI, DLT (blockchain), digital ID, Open Banking, Crypto, ESG, robo advice, RegTech, etc.

Denmark introduced regulatory sandboxes in 2018 in the fintech area by the Danish Financial Supervisory Authority (Finanstilsynet). The Danish Maritime Authority (Søfartsstyrelsen) introduced another regulatory sandbox in 2021 called DMA Future Lab (see below).

Germany has used sandboxes in a number of areas and has made a report on sandboxes: *Making space for innovation. The handbook for regulatory sandboxes* (2019). In this handbook, several sandboxes are mentioned which make exemptions from current national regulations possible.

The *OECD* report from 2020 – *The role of sandboxes in promoting flexibility and innovation in the digital age* – also mentions a number of regulatory sandboxes with exemptions from current regulations.

Over the past years, the sandbox approach has gained considerable traction across the EU as a means of helping regulators address the development and use of emerging technologies – such as *artificial intelligence (AI) and blockchain technologies* – in a wide range of sectors. The European Parliament has also called for introducing regulatory sandbox instruments in several resolutions.

A relevant and recent example is the EU's *Net-Zero Industry Act*. The act points to the net-zero transformation causing huge industrial, economic and geopolitical shifts and the need for the EU to respond to these developments while implementing the energy, climate and environmental transitions. It is underlined that a strong manufacturing base is a key element in securing access to net-zero technologies and quality jobs in Europe. This requires that the Union preserves its competitiveness, including through innovation, and particularly with regard to clean technology. While clean technology is the basis for the provisions in the NZIA, other innovative technologies, including Biosolutions, are also part of the provisions on regulatory sandboxes, (see below, 10.3, where the conditions are described).

8 "Fintech: Regulatory sandboxes and innovation hubs". (JC 2018 74). (ESMA: European Securities and Markets Authority; EBA: European Banking Authority, EIOPA: Europeans Insurance and Occupational Pensions Authority). World Bank Group:" Global Experiences from Regulatory Sandboxes", Finance, competitiveness & Innovation. Global Practise. Fintech Note, No. 8. (2020). OECD: Attrey, A., M. Lesher and C. Lomax (2020): "The role of sandboxes in promoting flexibility and innovation in the digital age", Going Digital Toolkit Policy Note, No. 2 https://going-digital.oecd.org/toolkitnotes/the-role-of-sandboxes-in-promoting-flexibility-and-innovation-in-the-digital-age.pdf. Germany Sandbox handbook, "Making space for innovation. The Handbook for regulatory sandboxes (Federal Ministry for Economic Affairs and Energy, July 2019. "Federal Ministry for Economic Affairs and Energy", "Reallabore. Testräume für Innovation und Reglierung", july 2019.

9 Commission Staff Working Document 29.8.2023: "Regulatory learning in the EU. Guidance on regulatory sandboxes ...".

4 THREE GENERATIONS OF REGULATORY SANDBOXES

Based on the definitions and development this report underlines the existence of three versions of sandboxes:

4.1 FIRST GENERATION: SANDBOX CLASSIC

Regulatory tool allowing businesses to test and experiment with new and innovative products, services or businesses under supervision of a regulator for a limited period of time. The sandbox operates within existing regulations. The main purpose of the sandbox is to enable experiments and testing under the counselling and supervision of a supervisory authority. An illustrative example is the fintech area.

4.2 SECOND GENERATION: SANDBOX WITH EXEMPTION

Regulatory tool allowing businesses to test and experiment with new and innovative products, services or businesses under supervision of a regulator for a limited period of time. This sandbox includes a possibility to make temporary exemptions from existing regulations – normally national regulations. The main purpose is to enable both counselling, supervision and certain specific and well-justified derogations in the interest of society. This version is newer and more nuanced than sandbox classic. illustrative examples are mentioned below.

4.3 THIRD GENERATION: SANDBOX BASED ON EU REGULATION

Regulatory tool allowing businesses to test and experiment with new and innovative products, services or businesses under supervision of a regulator for a limited period of time. This sandbox includes a specific legal basis in the EU regulation. The purpose is to create a framework regulation for a certain area, theme, method or product. This version is a rather new form. Illustrative examples are the EU AI Act on artificial intelligence, the EU DLT Act on blockchain, the Net-Zero Industry Act, and a proposal on medicinal products, see below 10.1–4.

5 EU REPORT ON FINTECH SANDBOXES

The first generation of regulatory sandboxes – sandbox classic – is described in a report from the EU (EBA, ESMA and EIOPA[10]) in the area of fintech (2019), *Fintech: Regulatory Sandboxes and Innovation Hubs*. The

10 The EU Supervisory Authorities ESA's – EBA (European Banking Authority), ESMA (European Securities and Markets Authority) and EIOPA (European Insurance and Occupational Pension Authority).

report contains an Annex B: Principles for establishment and operation of innovation facilitators.[11]

The most dominant 3 features are: a) that no changes to the law are required, but supervisory powers are used; b) that objectives are faster innovation on a case-by-case basis; c) that better mutual understanding between innovators and supervisory authorities can be obtained.

5.1 BACKGROUND AND LEGAL BASIS

These sandboxes do not provide a space for 'light touch' regulation and supervision. Rather, all the 'normal' supervisory powers, procedures and tools apply.

In 2019, the supervisory authorities in the EU regarding the financial area (ESAs) made a comparative analysis of the innovation facilitators established in the EU. They also set out best practices regarding the design and operation of innovation facilitators to promote convergence and thereby protect the level playing field. Moreover, they set out options to be considered in the context of future EU-level work on innovation facilitators.

No changes to the law were required to establish the regulatory sandboxes because each one involves the use of the "general" supervisory powers available to the competent authorities. None of the competent authorities referred to powers directly derived from EU law, nor did any consider that the absence of any such powers represented a direct impediment to the establishment and operation of regulatory sandboxes. They cited their statutory objectives of contributing to financial stability, promoting confidence in the financial sector in their jurisdictions and consumer protection as the foundation for their initiatives.

5.2 CATEGORIES, PURPOSE, BENEFITS AND CHALLENGES

The EU rapport on fintech identifies two main categories of innovation facilitators:

> **Innovation hubs** providing a dedicated point of contact for firms to raise enquiries with competent authorities on fintech-related issues and to seek non-binding guidance on the conformity of innovative financial products, financial services or business models with registration or licensing requirements and supervisory expectations. Innovation hubs vary across jurisdictions. Broadly speaking, two operating models can be observed. Some competent authorities have established dedicated fintech/innovation hub teams, whereas other authorities have adopted a 'hub and spoke' model with a dedicated coordinator drawing on additional expertise throughout the authority.
>
> **Regulatory sandboxes** providing a scheme to enable firms to test, pursuant to a specific testing plan agreed and monitored by a dedicated function of the competent authority, innovative financial products, financial services or business models. Sandboxes may also imply the use of legally provided discretions by the relevant supervisor (with use depending on the applicable EU and national law) but sandboxes do not entail the disapplication of regulatory requirements that must be applied as a result of EU law. When regulatory sandboxes address preparation for testing, the competent authority will seek assurances that appropriate risk-mitigation measures are in place before permitting the commencement of the test.
>
> **Common features.** The nine sandboxes included in the survey have a significant number of common features: A) they are cross-sectoral; B) they are open to both incumbent firms and new entrants and others; C) they are not limited to the testing of regulated financial services, but may also include other products or services that enable or facilitate the provision of regulated financial services by another party; D) they do not allow, even in the testing phase, the carrying out of regulated financial services without a license; E) they do not involve the disapplication of regulatory obligations that are required to be imposed on the participating firms as a result of EU and/or national law, but can involve the exercise of supervisory powers or levers for proportionality already available to the competent authorities in relation to the application of regulatory requirements during the testing phase; F) They provide specific entry conditions against which applicants to participate in the sandbox are assessed in order to determine eligibility; H) They involve the imposition of testing parameters, determined on a case-by-case basis as part of the conditions to enable participation in the sandbox.
>
> **Typically regulatory sandboxes** involve several phases: 1) application, where the firm submits an application, which is judged against publicly available criteria and decision on participation made by the competent authority; 2) preparation, where testing parameters are determined by the competent authority, any appropriate license is applied for, and limitations or restrictions imposed as appropriate pursuant to the testing plan; 3) testing where the firm can test its proposition and the competent authority monitors the testing process; 4) evaluation, where results of tests are reviewed and evaluated, decision is taken on the most appropriate approach to exiting the sandbox and as appropriate removal of limitations and restrictions or discontinuation of license (withdrawal). Objectives are to foster innovation.

The aim is to provide a monitored space in which competent authorities and firms can better understand the opportunities and risks presented by innovations and their regulatory treatment through a testing phase, and to assess the visibility of innovative propositions, in particular in terms of their application of and their compliance with regulatory and supervisory requirements.

11 The Annex includes pre-establishment principle and operating principles, including explanatory notes.

It is thus underlined that the initiatives have the role of facilitating financial innovation, and that the initiatives "are designed to promote greater engagement between competent authorities and firms about financial innovations with a view of enhancing firms' understanding of regulatory and supervisory expectations and increasing the knowledge of competent authorities about innovations and the opportunities and risks they present."

The value for both the firm and the authorities is acknowledged:

"The value for the firms can be found in gaining a better appreciation of the application of the regulatory scheme and supervisory expectations regarding the innovative proposition. Some firms have also reported deriving some benefit, in terms of the interaction with potential investors and consumers, from being able to demonstrate that they have thought out fully, and adjusted to, the regulatory and supervisory approaches in the context of the admission to the sandbox and the testing phase" (p. 28).

The importance of consumer protection and of proportionality and technical neutrality is also underlined:

"From the perspective of those competent authorities reporting regulatory sandboxes, the value of the testing phase can be found in the opportunity to understand the application of the regulatory framework with regard to the innovative proposition and in the opportunity to build in appropriate safeguards for innovative proportions, for example with regard to consumer protection considerations. This may involve a reassessment of the regulatory perimeter (in the context of determining how the proposition fits into the regulatory framework) or a recalibration of the regulatory requirements within the existing framework to ensure proportionality and technical neutrality". (pp.27–28)

5.3 OBSERVED PRACTICES AND NEXT STEP.

The EU report on fintech made a number of findings (p. 33 ff) that may be helpful in relation to the considerations in relation to sandboxes in the Biosolution area. The perceived opportunities are primarily better understanding, including an important issue on potentially undue regulatory barriers to financial innovation:

"The majority of competent authorities reports that innovation facilitators offer opportunities for the authorities to gain better understanding of innovation in financial services, and for firms to understand better the regulatory and supervisory expectations against the backdrop of rapid technological advancement.

In particular, innovation facilitators can help competent authorities to keep pace with developments by gaining near "real time" insights into emerging technologies ... and their application in the financial sector. Competent authorities can apply these insights for the purposes of anticipating regulatory and supervisory issues and responding proactively.

For instance, competent authorities may react by building up supervisory expertise and resources in relevant areas, confirming and clarifying the application of the regulatory framework to financial innovations, and, as appropriate, informing timely updates of regulatory and supervisory practices. In addition, the insights can enable the authorities to adopt a preventive approach, identifying supervisory issues only on such as emerging risks to consumer protection, and to develop a good understanding of potentially undue regulatory barriers to financial innovation.

Innovation facilitators can help enhance the accessibility of competent authorities for firms, particularly for new entrants and technology providers, enabling participants to obtain clarifications regarding regulatory and supervisory issues at an early stage and within a reasonable timeframe. For example, technology providers aiming to offer services..... to regulated entities can obtain clarifications of supervisors' expectations in such contexts. Firms can also use innovation facilitators as platforms to raise policy matters with the competent authorities, for instance regarding areas in which clarifications may be required in the application of the regulatory framework to financial innovations".

The operational challenges or risks are also addressed:

On the whole, competent authorities within innovation facilitators did not identify any issues that differ from those arising in the course of more traditional interactions with firms in the context of performing traditional supervisory tasks. However, some competent authorities felt that some operational challenges or risks could be slightly increased by innovation facilitators. (p. 34 ff). The challenges include keeping pace with industry, domestic coordination and cross-border coordination:

"Keeping pace with industry: Some authorities noted the difficulties in finding and retaining staff with the appropriate knowledge and experience of fintech, noting the pace of change in the financial sector and variety of innovation proposed.

Domestic coordination: some authorities noted that enquiries raised through the innovation hubs and propositions tested in regulatory sandboxes, often involve cross-cutting issues going beyond their direct sphere of responsibility (e.g. queries giving rise to data protection and regulatory perimeter issues). They also noted "challenges in proving complete and prompt responses in this context. Many, in the absence of multi-disciplinary innovation facilitators, referred firms

to other relevant domestic authorities, so firms needed to initiate separate discussions.

"Cross-border cooperation: some competent authorities noted that the current framework guiding interactions between authorities on issues giving rise to cross-border considerations, might not be fully adapted to financial innovations (e.g. where a firm may wish to apply an innovative product or service in more than one jurisdiction and seeks guidance from the competent authorities about the appropriate regulatory treatment in each jurisdiction) and could give rise to delays in providing coordinated and holistic responses."

"Some competent authorities raised concerns about the possibility that propositions tested in a regulatory sandbox may be perceived by consumers and/or the market as "endorsed" by the competent authority, resulting in ..potential preferential access to financing and/or preferential market positioning; and legal risk to the competent authority in the event that consumers were to suffer detriment as result of services provided in the course of sandbox participation."

Competent authorities also cited concerns regarding the impact on level playing field creating two tiers:

"Some competent authorities queried if the active and close monitoring of the participants in the regulatory sandboxes could give rise to level playing field issues, creating two tiers between those firms in the sandbox and those outside it. As for innovation hubs, the need for the public articulation of general policy stances adopted by the competent authorities and wider lessons learned from sandbox test outcomes (e.g, regarding the applicability of a specific legal instrument to an innovative service) is underlined to ensure that all firms can benefit. It is also emphasized that the objective of the regulatory sandboxes and the entry criteria should be clear and made public in order to ensure a high degree of transparency in the entry process". (p. 36)

The need for enhancing cross-border coordination and cooperation between innovation facilitators is also mentioned.

"The reported innovation facilitators currently operate at national level. This is one factor that has the potential to impede the scaling up of financial innovations across the EU – an issue cited by the European Commission, competent authorities and firms. For example, firms may find that different competent authorities adopt different regulatory and supervisory stances towards the same innovation leading to challenges in extending the innovation in more than one Member State. This may also present risks in terms of "forum shopping" and regulatory arbitrage, undermining the level playing field." (p. 37)

The need for enhanced cooperation, coordination and knowledge sharing between relevant authorities (both domestically and across borders) is underlined, including a network of innovation facilitators.

An important note was made regarding the limits of what can be achieved by regulatory sandboxes, pointing to the need for new powers enabling the disapplication or modification of regulatory and supervisory requirements:

"Several competent authorities noted that there are limits to what can be achieved through innovation facilitators. For example, none of the reported innovation facilitators confer new powers enabling the disapplication or modification of regulatory and supervisory requirements under EU law that may not be well adapted, for example, to innovative business models or delivery mechanisms. In turn, some competent authorities observed that further measures may be warranted to help support innovation while balancing other public policy interests (e.g., consumer protection) and these may entail legislative changes even at the EU level, for example by enhancing the levers for proportionality and flexibility applicable in the licensing process" (p. 36).

This emphasis of the limits of classic sandboxes is interesting and leads to the question of new and more nuanced versions enabling exemptions from specific regulatory requirements.

6. WORLD BANK SURVEY ON FINTECH SANDBOXES

The World Bank Group issued a publication in 2020: *Global Experiences from regulatory Sandboxes.*[12]

The World Bank Group underlines that a regulatory sandbox has the potential to meet several objectives, both regulatory and institutional. While regulatory objectives are most commonly limited to financial stability, integrity, consumer protection, inclusion, and, occasionally, competition, institutional objectives may be wider in scope, such as supporting the fintech ecosystem or encouraging engagement with the private sector. ..." (p. 5). It is also underlined (p.26) that a regulatory sandbox can be beneficial, "where regulatory requirements are unclear, or missing, or create barriers to entry disproportionate to the risks", and this is an area showing "the clearest link to direct benefits"(p.26).

6.1 BACKGROUND AND LEGAL BASIS

The report from the World Bank underlines that regulators globally have embraced the regulatory sandbox as a means of providing a dynamic, evidence-based regulatory environment to test and learn from and evolving with emerging technologies."

"The demand for digital financial services has increased significantly in recent years, and that fintech plays a key role in meeting this demand. These technological innovations have been met with policy responses that have the potential to create new opportunities for fintech firms

12 See the World Bank report Finance Competitiveness & Innovation Global Practice. Fintech Note, No. 8 p. 51. The benefits bought about by regulatory sandboxes are analysed in the paper: Global Experiences from Regaulatory Sandboxes(https://documents.worldbank.org/en/publication/documents-reports/documentdetail/912001605241080935/global-experiences-from-regulatory-sandboxes. The research covers the challenges and lesson learned from the implementation of 73 unique fintech sandboxes in 57 countries. More than half of them were created between 2018 and 2019, and a fifth were set up in the first half of 2020 alone.

through targeted regulatory approaches while balancing the potential risks to consumers and firms. One such approach is the "regulatory sandbox", which provides room for experimentation while guiding regulation towards embracing emerging technologies... Using country case studies and analysis of operations and outcomes of fintech sandboxes globally, the report highlights the benefits, challenges, and lessons learned from the implementation experiences of 73 unique fintech sandboxes in 57 countries. The intention is to provide key insights for policy makers looking to establish a new fintech sandbox or to evaluate an existing one. ... The emerging trends and key findings have been structured using the themes of country context; sandbox design; and impact at the level of institution, market, and individual firms".

The *legal basis* is addressed, emphasizing the differences that may exist regarding the regulators power to adjust regulation:

> "No definitive relationship exists between the country's legal system and the efficacy of a regulatory sandbox. ... In some countries, however, the regulators may have greater latitude to implement the sandbox as well as to adjust regulation and the degree of autonomy regulators or supervisors are given to make adjustments to regulations and their interpretation also varies". (p. 19)[13]

> In Germany, the Bundesbank and the Federal Supervisory Authority (BaFin) have taken coordinated steps toward fintech innovation, but, for several reasons, nothing that can be defined as a regulatory sandbox had been set up in Germany by 2020, where the World Bank report was made. It is said that Germany takes an innovation hub approach, as do the majority of the EU's member states[14]. An important institutional consideration was based on their legal mandate.[15]

6.2 COMMON FEATURES

The sandboxes are usually classified into 4 types, based on their objectives:

1 *Policy-focused sandboxes*, where the sandbox process is used to evaluate particular regulations or policies.
2 *Innovation- or product-focused sandboxes*, where the sandboxes encourage innovation by lowering the cost of entering the regulated marketplace, allowing firms to test the market viability of new business models.
3 *Thematic sandboxes*, where focus is on a precise theme with the objective of accelerating adoption of a specific policy or innovation or supporting development of a particular subsector or even of specific products aimed at particular population segments.
4 *Cross-border sandboxes*, where cross-border or multi-jurisdictional sandboxes support firms' cross-border movement and operations while encouraging regulatory cooperation and reducing arbitrage. Objectives include improving cross-border regulatory harmonization and fintech firms' ability to scale more rapidly on a regional or global basis.

Approaches to running a sandbox can differ substantially between countries. The two most common governance models are: (i) the dedicated unit, which requires countries to develop and staff new departments specifically to implement the sandbox – an example of this is the UK FCA (100 staff); (ii) the hub-and-spoke model, only a skeletal permanent staff count is maintained, and expertise is drawn both from within the regulator and from outside, as needed.

The resource intensiveness is also addressed:

> "Sandboxes are highly resource intensive, and different governance models have been adapted for running them. The two most common approaches are the "hub-and-spokes" model .....or the dedicated unit....Sandboxes can also help to build consensus among different stakeholders needed to endorse or support broader regulatory change". "Some evidence shows that well-defined thematic sandboxes can be effective in encouraging particular technologies or products to come to market".

6.3 IMPACT: EVIDENCE SO FAR

The World Bank report on fintech summarizes the impact in 7 themes, with this overall conclusion (pp. X-XI):

> "Taken together, the overall evidence from outcomes observed from fintech sandboxes suggests that they have several benefits for regulators as well as for the financial sector ecosystem as a whole. They can provide an evidence base from which to make policy decisions; influence future supervisory methodology; help to define, create, or amend regulation; and, in some cases, support the regulator's competition mandate. For firms sandboxes have been shown to offer a faster route to market and a better understanding of the regulatory environment, but in some cases, sandboxes prolong regulatory uncertainty. From a more macro perspective, the indirect benefits include spillover effects into the overall fintech ecosystem, spurring consumer-centric products, and signaling that the market is open to innovation".

> "At the same time, implementing a sandbox can pose several risks, particularly when poorly considered and implemented. It can potentially pose unexpected burdens on the regulators and promote risk such as creating level playing fields in the market".

13 In the World Bank report p. 19 it is underlined that the UK FCA created sandboxes under the existing powers of the relevant act under which it was created and "further the sandbox was put in place to directly support the secondary objective of the regulator: to increase competition. This is similar to India and South Africa where regulators had the power to set up a sandbox without needing an explicit law to provide approval".
14 See also the report from the EU ESAs, mentioned above.
15 P. 29. The EU has no single regulatory sandbox, but instead a network "European Forum for Innovation Facilitators (EFIF) was established.

Some of the relevant themes are:

> "Assisting policy makers decisions and effecting regulatory change: While early evidence suggests that sandbox programs can result in regulatory change, interviews with some policy makers suggest that change can be attributed to the open engagement between regulators and innovators. Sandboxes are ..... useful where empirical evidence is needed to support policy development. They can be beneficial where regulatory requirements are unclear or missing or create barriers to entry disproportionate to the risks. Sandboxes can also help to build the consensus among different stakeholders needed to endorse or support broader regulatory change".
>
> "Benefits for regulatory institutions: Sandboxes offer value to policy makers looking to increase their understanding and capacity to facilitate and regulate a range of fintech innovations, particularly where existing policy frameworks can be tested against new technologies and business models. Sandboxes can also help to build internal capacity on different fintech innovations and provide a structured process through which to strengthen dialogue and interaction with the industry".
>
> "Assisting private sector firms: "While sandboxes are often open to both regulated and unregulated firms, some fintech companies have attributed the ability to access markets to their participation within a sandbox. Moreover, some evidence shows that a sandbox has reduced time to market for some firms".
>
> "Fostering partnerships in the market: Sandboxes can help attract and develop marketplace partnerships or even investors ... Specific design features that can encourage partnerships include partnership requirements between a fintech and a licensed firm for eligibility to participate in the sandbox and close associations with industry accelerators that cab provide advice and mentorship from more established players.....".
>
> "Strengthening competition: Policy makers have reported mixed results when assessing if a sandbox has led to an increase in competition in their respective markets..."
>
> "Enabling fintech market development: ..... regulatory sandboxes can provide valuable insights to policymakers and enable innovation. For fintech to thrive, a multi-dimensional approach must be adopted, including a gap analysis of existing laws and regulations combined with an open dialogue between regulators and the industry".

7 OECD REPORT ON THE ROLE OF SANDBOXES

The OECD in their report: *The role of sandboxes in promoting flexibility and innovation in the digital age* (2020) mentions that regulatory sandboxes have become increasingly popular in securing regulatory flexibility. The definition of sandboxes is mentioned above (4.1).

7.1 DEVELOPMENTS

> "While interesting policy experiments have abounded in recent years in response to digital transformation, one increasingly popular mechanism of ensuring regulatory flexibility has been the emergence of regulatory sandboxes. Regulatory sandboxes are a structured form of regulatory flexibility that enables selected firms to test innovative products or services with minimal regulatory requirements. Regulatory sandboxes are typically administered by regulatory authorities. The innovative nature of sandboxes may require approaches and competences that differ from those required for traditional regulatory approaches". (p. 6)

The OECD also mentions "the rise of outcome or performance-based regulation, which specifies required outcomes or objectives, rather than the means by which they must be achieved, potentially enabling firms the freedom to innovate while remaining within the spirit of the law. Australia, for example, has adopted performance-based guidelines for the use of autonomous vehicles" (p. 6). So-called "testbeds" for testing autonomous cars have also emerged in Korea, China and Germany.

7.2 EXAMPLES OF REGULATORY SANDBOXES GLOBALLY

France: Fast track scheme for approval of micro-biological plant protection products
The French Environment and Food Agency has established a fast-track scheme for approval of micro-biological plant protection products (PPP), where the intention is for product approval to take place in 6–8 months (depending on whether other member states need to be consulted) while the intention for traditional chemical products is 12 months case-processing time. The agency has increased the number of employees. (p. 14)

US: the United States Federal Aviation Administration initiated a project on Unmanned Aircraft System Integration Pilot Program in 2018
This program tests the safe application of drones, over a period of 2½ years. Private sector applicants were invited to partner with state, local or tribal governments to apply for a waiver from the US airspace regulation to test drones for a period of 30 months. The data collected from the 10 tests and the lessons learned from the program is intended to help the FAA and the US Department of transport generate new enabling rules related to drones, particularly in terms of privacy and security regulation. (p. 20)

Singapore made a Licensing Experimentation and Adaption Programme in 2028
Singapore's Ministry of Health introduced the programme (LEAP), a regulatory sandbox initiative to enable the experimentation around new and innovative health care services in a manner that safeguards public safety and welfare. LEAP allows the Ministry to closely collaborate with the industry to understand the risks of new care delivery models early, so as to co-create a set of "fit-for-purpose" regulations for such new and innovative healthcare services. For example, in telemedicine, the Ministry sets safety and service standards related to clinical processes, data protection policies, incident reporting and escalation timelines – and works closely with the telemedicine providers to develop the telemedicine regulations under the upcoming Healthcare Services Act. (p. 18)

7.3 APPROACHES AND BENEFITS

The OECD underlines that there are different approaches to regulatory sandboxes across sectors and countries. For example, a financial services sandbox, operated by the Australian Securities and Investments Commission offers a class waiver that allows individuals to seek relief either as an alternative path or in addition to the class waiver, which is characterized as an important regulatory innovation.

Nevertheless, many emerging regulatory sandboxes programs share some common features. The firms applying for regulatory waivers under regulatory sandboxes are often required to demonstrate that their business idea is a genuine innovation. Many sandboxes also require that applicants demonstrate that they need the regulatory exemptions or waivers offered by the relevant sandbox. Most firms are also asked to demonstrate their readiness to begin testing.

Most regulatory sandboxes include safeguards or mechanisms to achieve overarching regulatory objectives, including with respect to consumer protection, safety and data governance.

Some sandboxes also ask applicants to demonstrate identifiable consumer benefit, for instance higher quality or lower prices, or how the business model addresses an otherwise unmet demand.

> For example, France Expérimentation has allowed SEDE Environment and the national Federation of Agricultural Holders' Unions (FINSEA) to tackle depleting natural resources and recycle water by developing an innovative irrigation solution that fertilizes crops by reusing wastewater.[16]

The OECD report mentions a number of benefits and challenges*:*

> "Regulatory sandboxes aim to support competitive innovation in the digital age and enable the entrance of innovative... products and services to the market. For firms, regulatory flexibility can enable live-market testing and market entry that would not have otherwise been possible. This can reduce the time to market for new innovations, driving consumer benefits and broader spillovers in the marketplace. Reduced regulatory uncertainty and the ability to conduct testing can also help to facilitate financing for innovative firms." (p.11)

> "Some jurisdictions have also found that simply developing mechanisms like regulatory sandboxes can help to facilitate dialogue with new players in the market, including those from other sectors. ...Entrepreneurs may be limited in terms of resources and experience when dealing with regulatory authorities and regulatory sandboxes may serve as a mechanism to attract and inform such entrepreneurs". (p. 12)

> "For regulators, regulatory sandboxes can enable a closer relationship with innovative firms. This can help regulators gain insights from frontier innovators, which can in turn inform the process of policy making and regulation." (p. 12).

> The challenges are also mentioned in the OECD report: "for one, early or first-to-market innovations are by definition untested, and their potential risks can be difficult to predict. ... While most sandboxes include extensive safeguards, digital innovations can introduce risks, however small or well-managed, to the market". (p. 12)

> Regulatory sandboxes are also typically developed and administered by regulatory authorities, which may not always be able to devote scarce resources in terms of people and skills to develop and implement a sandbox programme. At the same time, regulators are usually legislatively mandated to enforce regulations, promote competition, and ensure consumer protection in a particular domain. .... Regulatory sandboxes may ... entrench sectoral divides". (p. 13)

In the OECD report a selection of sandbox initiatives is mentioned in an Annex. These include financial services, energy, health, transport and ICT (telecommunication). Cross-sectoral sandboxes are also mentioned:

> **France Experimentation**
> The responsible entity is the French Ministry of Economy and Finance. "France Expérimentation" allows for regulatory exemptions to be made and for legal obstacles to be removed so that projects in any sector may be developed and tested. All innovative products and services are eligible for this sandbox initiative, and not just those based on new and emerging technologies. Projects span a wide range of sectors, including biotechnology, micro-credit, health, energy performance and waste treatment. For example, a firm was allowed to tackle depleting natural resources and recycle water by developing an innovative irrigation solution that fertilizes crops by reusing wastewater. (p. 14)

16 See the OECD report p. 8.

Germany's regulatory sandboxes Strategy
The responsible entity is the German Federal Ministry for Economic Affairs and Energy. "The regulatory Sandboxes Strategy seeks to systematically establish regulatory sandboxes in Germany. It consists of 3 pillars: 1) fostering greater use and development of experimentation clauses; 2) providing information and networking to facilitate the creation of regulatory sandboxes (e.g., by a regulatory sandbox handbook and a regulatory sandbox network); and 3) launching and supporting regulatory sandboxes through competitions or support for specific projects. The strategy does not focus on one specific field of innovation, but rather concentrates on regulatory sandboxes as a cross-cutting instrument useful for different fields of innovation". (p. 14)

8 GERMANY'S HANDBOOK FOR REGULATORY SANDBOXES

8.1 CHARACTERISTICS

In the *Handbook for regulatory sandboxes: Making space for innovation* from 2019, regulatory sandboxes are characterized by three elements: 1) test areas are established for a limited time, covering a limited area, in which innovative technologies and business models can be tried out in real life; 2) sandboxes make use of regulatory leeway via experimentation clauses and other instruments to deliver flexibility; 3) they entail an interest in regulatory discovery and learning for future legislation.
In the handbook there is a chapter on designing regulatory sandboxes.

> *"Experimentation clauses might take the form of an exemption from a prohibition, ... from an approval instrument,... from requirements to provide documentation or deploy certain equipment, or a catch-all clause" (p. 39). "Some experimentation clauses entail an evaluation..."* (p. 43). In that case defining indicators and data sources for evaluations is relevant (p. 55).

> "In many cases, regulatory sandboxes need regulatory leeway. Experimentation clauses are a key legal tool to create this leeway. They offer the administration scope to exercise discretion or even judgment" (p.66).

8.2 EXAMPLES

Regulatory sandboxes are mentioned in the areas of construction law, energy law, trade law, commercial law, media law, transport law and administrative law.
The examples show a tendency to make sandboxes wider and more powerful. They are now found in many areas and with both the encouragement to make them and many forms with important exemptions.

Transport: In a four-year trial period, the Hamburg Electric Autonomous Transportation project (HEAT) is to investigate how fully automated or self-driving electric minibuses can be safely deployed to transport passengers on urban roads. The regulatory sandbox involves an initial stage, where a staff member will be on board. Since the test vehicles are powered with highly/fully automated driving functions, which are to be developed into self-driving vehicles, the implementation of the project and registration of the vehicles necessitates applications pursuant to specific German regulations.

Medicine: The sandbox was made to investigate which fields of medicine and which cases are appropriate to obtain medical advice via video-based surgery. Another question was if doctors and patients respond well to the concept, what barriers exist. Finding the answers to these questions is the shared aim of all the stakeholders in the *Teleclinic in Baden-Württemberg* regulatory sandbox.

9 DENMARK SANDBOXES – FINTECH, SHIPPING, NEW INITIATIVES

In Denmark, fintech labs were introduced in 2016 in the area of financial technologies and with the Danish Financial Supervisory Authority (DFCA) as the authority taking the initiative. The Danish Maritime Authority (Søfartsstyrelsen) also introduced regulatory sandboxes called *DMA Future Lab*. These are described below.
The *Danish governments Biosolutions initiative* from 2021 includes a goal to establish innovation-friendly regulation of new technologies. A one-stop-shop for new green technologies and business models, creating coordinated answers to questions from startups and innovative companies on regulation, also in the Biosolutions sector and cooperation between all relevant ministries are on the agenda. The Danish government will establish 7 regional growth teams to make recommendations for the development of regional 'business lighthouses. The establishment of 'business lighthouses', including *Biosolutions Zealand* is described below.

9.1 DANISH FINTECH LAB (FT LAB)

The legal basis was the tasks and powers of the Danish Financial Supervisory Authority (DFSA – Finanstilsynet). The DFSA underlines: "It is important to note that companies participating in the FT Lab are subject to the applicable law". The FT Lab has as its aim to give selected companies the possibility to test their innovations in a secure environment.
The overall purpose is:

1 Providing a basis for testing innovative financial products and services.

2 Promoting the development of beneficial financial products and services for the customers and society.
3 Enabling the DFSA to better understand fintech.
4 Supporting the use of new technology in the financial sector.

The criteria for being accepted in the FT Lab sandbox are:

- The activity is directly or indirectly embraced by the financial regulation.
- The technology or business model is new.
- The service or product is for the benefit of society or consumers.
- There is a need for access to FT Lab.
- The company is willing to be included in the FT Lab testing process.

The FT Lab is open to three kinds of companies:

- Financial institutions already having a permission according to the financial regulation but wanting to test a new technology or business model.
- Companies, not having the relevant permission according to the financial regulation to offer the desired activity.
- Companies, where it is unclear if the activity demands permission according to the financial regulation.

The reasoning behind the FT Lab is focused on the testing of new technologies faster than the usual procedure:

> "The use of new technology in the financial sector can be difficult to place within the scope of the existing financial regulation. Hence, the FSA Created FT Lab as a place where selected companies can test their technology or business model. FT ensures that companies can test their technologies and business models faster. Testing will always happen with boundaries set by the FSA in collaboration with the company. This approach enables both the companies and FSA to understand the use of innovative technology and business models within the scope of finance. FT Lab will be open to up to five companies at any given time, and it is open to applications from fintech entrepreneurs as well as established companies. The Danish FSA expects a test to run for up to six months depending on the specific agreement between the FSA and the concerned company".

In cooperation with the DFSA, companies can have an efficient process "to clarify whether their activities require a license." The DFSA and the company will create a testing framework to be certain testing is safe and will enter into an agreement outlining the specific limitations. Examples of limitations are number of customers and scope of business.

Example: E-NETTET. The Danish company e-nettet has also been involved in a regulatory sandbox with good results. The focus of the sandbox was machine learning and valuation of owner-occupied homes.

Example: BLOCKCHAIN (February 2022)[17]. In the reporting about the sandbox on blockchain the DFSA underlines that blockchain is gaining traction in the financial field and the potential of the technology is widely recognized. However, with the use of new technology, new risks often also follow, and it can be difficult to determine how to handle services based on blockchain within the existing regulation.

Together with ZTLment Aps (ZTLment) the DFSA examined the use of technology for a specific business model in DFSA's regulatory sandbox, FT Lab. ZTLment's solution facilitates payments with electronic money issued on blockchain. The solution differs from other payment services using the traditional payment infrastructure, which includes operators such as an acquirer, a financial institution and clearing and settlement systems. Many of these operators are not part of the ZTLment solution. Instead, the blockchain technically handles several of the roles filled by these operators.

"The FT Lab test shows that it is possible to make fast, secure and efficient payments on blockchain. The test also shows that blockchain-based payment services have the potential to compete with existing payment solutions that use the existing payment infrastructure. The DFSA expects that we will see several different types of financial business models using blockchain in the future. The test ... is a good example of how FT Lab enables the DFSA to gain further insight into how technology can help optimize existing business models".

The majority of the tests concerned regulatory clarification of the business model and assessing how users are protected compared to traditional payment solutions.

The company's CEO and founder, Mads Stolberg-Larsen says:
"We were in a regulatory grey area before this process. It is kryptonite when working with B2B transactions like we do. Therefore, it is a great relief that we have now gained clarity".

Tobias Thygesen, who is in charge of the DFSA's Fintech Lab says:
"ZTLment's participation in the FT Lab has given the DSFA a good insight into how blockchain can be used in practice to make payments. The DFSA and ZTLment have had a good and constructive process, where both parties learned about the potential and regulation of technology."

17 Memo from the Danish Financial Supervisory Authority 4 February 2022: "Bolckchain technology can provide efficient infrastructure for payment services."

The DFSA underlines:
"This is, as far as DFSA knows, the first time that a supervisory authority in an EU member state carries out this assessment based on a specific business model".

9.2 MARITIME REGULATORY SANDBOXES

With its initiative *DMA Regulatory Future Lab*, the Danish Maritime Authority (DMA - Søfartsstyrelsen) has taken the initiative to become a facilitator and partner for innovative maritime solutions especially in the fields of green tech, decarbonisation and digitalization. The following introduction is available on DMA's website:

> "The Danish Maritime Authority would like to be a facilitator and partner for innovative solutions especially in the fields of green tech, decarbonisation and digitalization. However, regulation can sometimes be a barrier for implementing new ideas. Updating international regulations takes time and industry innovation moves faster. In order to handle industry inquiries that challenge the regulation, The Danish Maritime Authority offers case management in Future Lab.
>
> DMA Future Lab is a matrix organization that handles challenging inquiries that need authority approval or acceptance. The goal is to be an open-minded authority partner that efficiently helps find safe, secure and environmentally friendly solutions. The Lab handles inquiries on various stages in the innovation process. On the one hand, the Future Lab handles inquiries on innovations that are ready to be implemented on commercial vessels. However, the lab can also help with early-stage innovations that need room or geography to test out new ideas.
>
> Each inquiry is unique, and the case management process is tailored individually. The overall process however has some similarities. The first step in DMA Future Lab is to get an in-depth understanding of the project in order to determine if the project challenges regulation and needs management in the Lab. Next step is for DMA to define the approval basis. For new ship design, this could for instance be according to IMO Guidelines for Alternative Design (MSC.1/Circ.1455). For other innovations, the basic regulation may be different. With the approval basis in place, the client and DMA will develop and agree upon a framework for analysis, test or evaluation of the project. A time and process plan will be set. From here, it is an iterative process, where the clients perform their project and analysis and if needed get feedback underway as the project gets more specific and detailed. If there are particularly challenging aspects concerning the regulation or safety, DMA can initiate workshops or sprints in order to crack the nut. When all documentation is in place, the proposal is evaluated for approval.

Criteria for Using DMA Future Lab

- The activity is directly or indirectly covered by SFS legislation and needs handling.
- The project is challenging conventional regulation and case management.
- It is a new innovation e.g. technology, business model or organizational innovation.
- The innovation is a benefit for society users.

Legal basis for approvals in DMA Regulatory Future Lab

The international shipping conventions enable the use of considerations of equivalence in a number of areas. Such examples can for instance be found in the international Convention for the Safety of Life at Sea (SOLAS-Convention). The International Maritime Organization (IMO) has also adopted joint guidelines regarding the risk-based approach to approvals of alternative design and arrangements (MSC.1-Circ.1455), which can be used to demonstrate that an equivalent level of safety is fulfilled.

The international conventions, and their possibilities to use considerations of equivalence, have been implemented in Danish regulations. As an example, the Danish Order on the implantation of the international Convention on safety for humans at sea[18] includes a very interesting provision (5[19]) about equivalence. If the international provisions demand that a specific material, device, etc. must be present in a ship, the Administration may allow that another material or device etc. is present instead, if this through testing or in some other way is proven to be at least as effective as what is required by the regulations[20].

In cases where prescriptive rules may become a barrier for the development and use of new maritime technologies and innovative solutions, that hold the potential to increase safety, efficiency and/or reduce emissions, DMA uses the experiences from the Future Lab to promote necessary adjustments in international regulations for the benefit of the green and digital transition of international shipping.

The DMA Lab has more than 10 projects in the Future Lab. The specific projects are collaborating projects with industry and are treated confidentially. Some of the projects deal with new types of fuel, small autonomous vessels, automatic systems for navigation and alternative design.

19 "Bekendtgørelse om skibes bygning og udstyr m.v., gennemførelse af den internationale konvention om sikkerhed for menneskeliv på søen" (SOLAS) 1974, especially chapter I, art. 5, regarding equivalence

20 A similar solution is known from the "red biotechnology" (health), where the Health Technology Assessment (HCA) include if the new medicine works better, equally well, or worse than existing alternatives and are bases on multidisciplinary process reviewing also social and ethical issues.

9.3 LIGHTHOUSES FOR BIOSOLUTIONS – BIOSOLUTIONS ZEALAND AS EXAMPLE

The consortium behind the Danish business lighthouse for Biosolutions consists of a broad range of ministries, universities, institutions and companies. The vision for Biosolutions Business Lighthouse and their tasks are ambitious:

> "Zealand and the islands must be world leaders in the development of Biosolutions that contribute to solving global and local climate and environmental challenges and at the same time create sustainable growth, jobs and exports throughout Zealand and the islands."

1 A strong and cohesive innovation and entrepreneurial ecosystem
   - Establishment of testing, demonstration and development facilities
   - Launching innovation collaborations
   - Addressing regulatory barriers

2 Good educational opportunities and sufficient supply of highly skilled labor
   - Developing new master's degree and continuing education programs and recruitment of students

3 International initiatives
   - Attraction of international talent, finance and startups, cooperation with knowledge hubs, TDU facilities etc.

The Danish government partnership with the lighthouse is covered by a contract. The purpose of the partnership agreement between the government and the consortium behind the lighthouse is to create a framework for strategic and coordinated development of the business lighthouse in the short and long term. The partnership agreement consists of a strategy for the development of the business lighthouse with guidelines for the work up to 2025 and an action plan with specific initiatives. As a starting point, the partnership meets twice a year and discusses the development of the work with the business lighthouse, including which additional activities may need to be initiated to realise the full potential of the business lighthouse.

In 2024, the University of Copenhagen starts a new two-year education course (kandidatuddanelse) in Kalundborg. The aim is to educate candidates with solid knowledge on sustainable solutions and technologies for the bio-based products of the future. The growing green industry needs specialists in the areas of, for example Biosolutions.

9.4 RECENT INITIATIVES FROM DANISH AUTHORITIES

Close cooperation across ministries could include a number of ministries and agencies: Ministry of Industry, Business and Financial Affairs and Danish Business Authority and the Danish Supervisory Authority; Ministry of Food, Agriculture and Fisheries of Denmark, and Danish Veterinary and Food Administration; Ministry of Environment of Denmark and Environmental Protection Agency; Ministry of Higher Education and Science in Denmark; Ministry of Employment; Ministry of Climate etc.; and Ministry of Foreign Affairs of Denmark.

The Ministry of Food, Agriculture and Fisheries of Denmark has initiated *The Ingredients Strategy* aiming to create better framework conditions for the ingredients industry, including by identifying regulatory barriers to sustainable innovation in the sector. The strategy focuses on ingredients such as additives, cultures, enzymes, flavorings, etc. but also new raw materials such as alternative protein sources and the exploitation of side streams from feed and food production. To strengthen cooperation with the ingredients sector, the Danish Food Administration has established the Forum for Future Ingredients, where representatives from industry organizations, ingredients companies and research institutions discuss topics of relevance to the ingredients industry. Task forces are regularly set up under the forum, where selected members of the forum work in more depth on a topic of particular relevance.

A number of ministries and agencies also work on, and sometimes collaborate on, more specific projects, including regulatory sandboxes. The Danish Ministry of Environment (Miljøministeriet) is also in the process of considering a very specific proposal to amend Regulation (EC) No. 1107/2009, shortening relevant timelines for the Rapporteur member state and the EU Commission (article 11 and 13).

10 SANDBOXES BASED ON EU-REGULATIONS

Generation 3 of sandboxes is gaining ground. Four examples are mentioned: the regulatory sandboxes in the AI act on artificial intelligence; the 'pilot regime' in the DLT Act on blockchain; the Net-Zero Industry Act on cleantech and other innovative technologies; and the proposal on an Act on medicinal products.

These regulations are fundamentally different from generation 1 (sandbox classic) and generation 2 (sandbox with exemptions), as they have a legal basis in EU regulation. They may be seen as examples of following up on the recommendations from the EU Commission and the EU parliament to use sandboxes in a number of areas. Their ability to break down regulatory barriers and support innovation will, to a large extent, depend on the precise wording in the relevant articles. The wording differs quite markedly between the 4 acts described here.

10.1 ARTIFICIAL INTELLIGENCE ACT (AIA) – PROVISION ON SANDBOXES

The EU Commission's AI act on Artificial Intelligence (AIA) is the first legal framework on AI, which addresses the risks of AI and aims to position Europe to play a leading role globally.[21] The AIA is applicable to all AI systems placed on the market or used in the Union. The AI Act aims to foster the development and uptake of safe and trustworthy AI applications across the EU's single market. At the same time, it aims to ensure respect of fundamental rights of EU citizens and stimulate investment and innovation in artificial intelligence in Europe.

The legal framework introduces a classification for AI systems with different requirements and obligations tailored on a "risk-based approach". Some AI systems presenting "unacceptable risk" will be prohibited. A wide range of "high risk" AI systems will be authorized, but subject to a set of requirements and obligations to gain access to the EU market. Those AI

21 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial Intelligence.

systems presenting only "limited risks" will be subject to very light transparency obligations. A new governance architecture is also introduced.

> In the Press release 409/24 the need for innovation is stressed: "The adoption of the AI act is a significant milestone for the European Union. This landmark law, the first of its kind in the world, addresses a global technological challenge that also creates opportunities for our societies and economies. With the AI act, Europe emphasizes the importance of trust, transparency and accountability when dealing with new technologies while at the same time ensuring this fast-changing technology can flourish and boost European innovation."
>
> "The AI act provides for an innovation-friendly legal framework and aims to promote evidence-based regulatory learning. The new law foresees that AI regulatory sandboxes, enabling a controlled environment for the development, testing and validation of innovative AI systems, should also allow for testing of innovative AI systems in real world conditions".

The AIA introduces the concept of an "AI regulatory sandbox", which is defined[22] as

> "a controlled framework set up by a competent authority which offers providers or prospective providers of AI systems the possibility to develop, train, validate and test, where appropriate in real-world conditions, an innovative AI system, pursuant to a sandbox plan for a limited time under regulatory supervision;"
>
> A "sandbox plan" means "a document agreed between the participating provider and the competent authority describing the objectives, conditions, timeframe, methodology and requirements for the activities carried out within the sandbox;"
>
> "Testing in real-world conditions" means the temporary testing of an AI system for its intended purpose in real-world conditions outside a laboratory or otherwise simulated environment, with a view to gathering reliable and robust data and to assessing and verifying the conformity of the AI system with the requirements of this Regulation and it does not qualify as placing the AI system on the market or putting it into service within the meaning of this Regulation, provided that all the conditions laid down in article 57 or 60 are fulfilled."

According to *Chapter VI Measures in support of innovation*, article 57, *AI regulatory sandboxes*, a system is set up that obliges the Member States to set up regulatory sandboxes, which is a new approach to regulatory sandboxes.

In the following some of the details about AI regulatory sandboxes are elaborated from the legal text, as they may provide inspiration for other regulatory sandboxes:

22 AIA, article 3, (55), (54) and (57).

"Article 57: AI regulatory sandboxes

1. Member States shall ensure that their competent authorities establish at least one AI regulatory sandbox at the national level, which shall be operational by 2 August 2026. That sandbox may also be established jointly with the competent authorities of other Member States. The Commission may provide technical support, advice and tools for the establishment and operation of AI regulatory sandboxes.

The obligation under the first subparagraph may also be fulfilled by participating in an existing sandbox in so far as that participation provides an equivalent level of national coverage for the participating Member States.

1 Additional AI regulatory sandboxes at regional or local level or established jointly with the competent authorities of other Member States may also be established.
2 The European Data Protection Supervisor may also establish an AI regulatory sandbox for Union institutions, bodies, offices and agencies, and may exercise the roles and the tasks of national competent authorities in accordance with this chapter.
3 Member States shall ensure that the competent authorities ... allocate sufficient resources to comply with this article effectively and in a timely manner. Where appropriate, national competent authorities shall cooperate with other relevant authorities, and may allow for the involvement of other actors within the AI ecosystem. This article shall not affect other regulatory sandboxes established under Union or national law. Member States shall ensure an appropriate level of cooperation between the authorities supervising these other sandboxes and the national competent authorities.
4 AI regulatory sandboxes ... shall provide for a controlled environment that fosters innovation and facilitates the development, training, testing and validation of innovative AI systems for a limited time before their being placed on the market or put into service pursuant to a specific sandbox plan agreed between the providers or prospective providers and the competent authority. Such sandboxes may include testing in real world conditions supervised therein.
5 Competent authorities shall provide, as appropriate, guidance, supervision and support within the AI regulatory sandbox with a view to identifying risks, in particular to fundamental rights, health and safety, testing, mitigation measures, and their effectiveness in relation to the obligations and requirements of this Regulation and, where relevant, other Union and national law supervised within the sandbox.
6 Competent authorities shall provide providers and prospective providers participating in the AI regulatory sandbox with guidance on regulatory expectations and how to fulfil the requirements and obligations set out in this Regulation.

Upon request of the provider or prospective provider of the AI system, the competent authority shall provide written proof of the activities successfully carried out in the sandbox. The competent authority shall also provide an exit report detailing the activities carried out in the sandbox and the related results and learning outcomes. Providers may use such documentation to demonstrate their compliance with this Regulation through the conformity assessment process or relevant market surveillance activities. In this regard, the exit reports and the written proof provided by the national competent authority shall be taken positively into account by market surveillance authorities and notified bodies, with a view to accelerating conformity assessment procedures to a reasonable extent.

8 ...

9 The establishment of AI regulatory sandboxes shall aim to contribute to the following objectives:

Improving legal certainty to achieve regulatory compliance with this Regulation or, where relevant, other applicable Union and national law;

a supporting the sharing of best practices through cooperation with the authorities involved in the AI regulatory sandbox; fostering innovation and competitiveness and facilitating the development of an AI ecosystem;

c contributing to evidence-based regulatory learning;

c facilitating and accelerating access to the Union market for AI systems, in particular when provided by SME's, including start-ups.

10 ...

11 The AI regulatory sandboxes shall not affect the supervisory or corrective powers of the competent authorities supervising the sandboxes, including at regional or local level. Any significant risks to health and safety and fundamental rights identified during the development and testing of such AI systems shall result in adequate mitigation. National competent authorities shall have the power to temporarily or permanently suspend the testing process, or the participation in the sandbox if no effective mitigation is possible .... National competent authorities shall exercise their supervisory powers within the limits of the relevant law, using their discretionary powers when implementing legal provisions in respect of a specific AI regulatory sandbox project, with the objective of supporting innovation in AI in the Union.

12 Providers and prospective providers participating in the AI regulatory sandbox shall remain liable under applicable Union and national liability law for any damage inflicted on third parties as a result of the experimentation taking place in the sandbox. However, provided that the prospective providers observe the specific plan and the terms and conditions for their participation and follow in good faith the guidance given by the national competent authority, no administrative fines shall be imposed by the authorities for infringement of this Regulation ...

13 The AI regulatory sandboxes shall be designed and implemented in a way that, where relevant, facilitates cross-border cooperation between national competent authorities.

14 – 17. ..."

Article 58: Detailed arrangements for, and functioning of, AI regulatory sandboxes

"1.In order to avoid fragmentation across the Union, the Commission shall adopt implementing acts specifying the detailed arrangements for the establishment, development, implementation, operation and supervision of the AI regulatory sandboxes. The implementing acts shall include common principles on the following issues:

a eligibility and selection criteria for participation in the AI regulatory sandbox;

b procedures for the application, participation, monitoring, exiting from and termination of the regulatory sandbox, including the sandbox plan and the exit report;

c the terms and conditions applicable to the participants.

2 The implementing acts .. shall ensure:

a that AI regulatory sandboxes are open to any applying provider or prospective provider of an AI system who fulfills eligibility and selection criteria, which shall be transparent and fair, and that national competent authorities inform applicants of their decision within three months of the application;

b that AI regulatory sandboxes allow broad and equal access and keep up with demand for participation; providers and prospective providers may also submit applications in partnerships with deployers and other relevant third parties;

c that the detailed arrangements for, and conditions concerning AI regulatory sandboxes support, to the best extent possible, flexibility for national competent authorities to establish and operate their AI regulatory sandboxes;

d that access to the AI regulatory sandboxes is free of charge for SMEs, including start-ups, without prejudice to exceptional costs that national competent authorities may recover in a fair and proportionate manner;

e that they facilitate providers and prospective providers, by means of the learning outcomes of the AI regulatory sandboxes, in complying with conformity assessment obligations under this Regulation and the voluntary application of the codes of conduct .....

f that AI regulatory sandboxes facilitate the involvement of other relevant actors within the AI ecosystem, such as notified bodies and standardization organizations, SMEs, including start-ups, enterprises, innovators, testing and experimentation facilities, research and experimentation labs and European Innovation Hubs, centres of excellence, individual researchers, in order to allow and facilitate cooperation with the public and private sectors;

g that procedures, processes and administrative requirements for application, selection, participation and exiting the AI regulatory sandbox are simple, easily intelligible, and clearly communicated ...

h that participation in the AI regulatory sandbox is limited to a period that is appropriate to the complexity and scale of the project and that may be extended by the national competent authority;

i that AI regulatory sandboxes facilitate the development of tools and infrastructure for testing, benchmarking, assessing and explaining dimensions of AI system relevant for regulatory learning, such as accuracy, robustness and cybersecurity, as well as measures to mitigate risks to fundamental rights and society at large.

3 Prospective providers in the AI regulatory sandboxes, in particular SMEs and start-ups, shall be directed, where relevant, to pre-deployment services such as guidance on the implementation of this Regulation, to other value-adding services such as help with standardization documents and certification, testing and experimentation facilities, European Digital Innovation Hubs and centres of excellence.

4 where national competent authorities consider authorizing testing in real world conditions supervised within the framework of an AI regulatory sandbox to be established under this Article, they shall specifically agree the terms and conditions of such testing and, in particular, the appropriate safeguards with the participants, with a view to protecting fundamental rights, health and safety. Where appropriate, they shall cooperate with other national competent authorities with a view to ensuring consistent practices across the Union."[23]

It is interesting that AI regulatory sandboxes are introduced in order to foster AI innovation. As the regulation in the AIA is totally new, the aim is not to accept derogations from this regulation but to ensure compliance with the new regulation and create legal certainty. This is mentioned in recital 138-139 in the AIA:

> "AI is a rapidly developing family of technologies, that requires regulatory oversight and a safe and controlled space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that promotes innovation, is future-proof and resilient to disruption, Member States should ensure that their national competent authorities establish at least one AI regulatory sandbox at national level to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service. ..... AI regulatory sandboxes could be established in physical, digital or hybrid form and may accommodate physical as well as digital products. Establishing authorities should also ensure that the AI regulatory sandboxes have adequate resources for their functioning, including financial and human resources.
>
> The objectives of the AI regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AY systems with this Regulation and other relevant Union and national law. Moreover, the AI regulatory sandboxes should aim to enhance legal certainty for innovators and the competent authorities' oversight and understanding of the opportunities, emerging risks and the impacts of AI use, to facilitate regulatory learning for authorities and undertakings, including with a view to future adaptations of the legal framework, to support cooperation and the sharing of best practices with the authorities involved in the AI regulatory sandbox, and to accelerate access to markets, including by removing barriers for SME's, including start-ups ... The participation in the AI regulatory sandbox should focus on issues that raise legal uncertainty for providers and prospective providers to innovate, experiment with AI in the Union and contribute to evidence-based regulatory learning...".[24]

The description of the AIA shows, *that* a new, risk-based system is set in place with different requirements, *that* innovation is supported with a new regulatory tool, *that* regulatory sandboxes are seen as so important that it is mandatory, to establish one in 2026 and *that* a very detailed system regulating these regulatory sandboxes is set in place. The latter can be an inspiration for other regulatory sandboxes, but with due consideration for the differences of the specific areas of regulation. In this respect, it is paramount that the AIA regulates an area with no former regulation – in contrast to Biosolutions, which are covered by very detailed regulation that creates the barriers for innovation.

10.2 PILOT REGIME FOR DISTRIBUTED LEDGER-TECHNOLOGY (DLT) MARKET INFRASTRUCTURE

In relatively new EU regulation from 2022[25] a 'pilot regime' for market infrastructures based on distributed ledger technology is introduced.

The overall objective is to remove regulatory hurdles to the issuance, trading and post-trading of financial instruments in crypto-asset form and for regulators to gain experience on the application of DLT in market in-

23 The topics of the next Articles are as follows: Article 59: Further processing of personal data for developing certain AI systems in the public interest in the AI regulatory sandbox. Article 60: Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes. Article 61: Informed consent to participate in testing in real world conditions outside AI regulatory sandboxes. Article 62: Measures for providers and deployers, in particular SME', including start-ups.

24 Preamble (142) focuses on sustainability: "To ensure that AI leads to socially and environmentally beneficial outcomes, Member States are encouraged to support and promote research and development of AI solutions in support of socially and environmentally beneficial outcomes, such as AI-based solutions to increase accessibility for persons with disabilities, tackle socio-economic inequalities, or meet environmental targets, by allocating sufficient resources, including public and Union funding ....."

25 (EU) 2022/858 of 30. May 2022.

frastructures. The pilot regime therefore allows for the development of crypto-assets that qualify as financial instruments, and for the development of DLT. At the same time the wish is to preserve a high level of investor protection, market integrity, financial stability and transparency and to avoid regulatory arbitrage and loopholes.

In the "whereas" of the regulation, this is elaborated:

"(1) It is important to ensure that Union financial services legislation is fit for the digital age and contributes to a future-proof economy that works for citizens, including by enabling the use of innovative technologies. The Union has a policy interest in exploring, developing and promoting the uptake of transformative technologies in the financial sector, including the uptake of distributed ledger technology (DLT)..."

"(2) Most crypto-assets fall outside the scope of Union financial services legislation and create challenges in terms of, among other things, investor protection, market integrity, energy consumption and financial stability. Such crypto-assets therefore require a dedicated regulatory framework at Union level..."

"(4) Union financial services legislation was not designed with distributed ledger technology and crypto-assets in mind and contains provisions that potentially preclude or limit the use of distributed ledger technology in the issuance, trading and settlement of crypto-assets that qualify as financial instruments. Currently, there is also a lack of authorized financial market infrastructures which use distributed ledger technology to provide trading or settlement services, or a combination of such services, for crypto-assets that qualify as financial instruments. The development of a secondary market for such crypto-assets could bring multiple benefits, such as enhanced efficiency, transparency and competition in relation to trading and settlement activities."

"(5) At the same time, regulatory gaps exist due to legal, technological and operational specificities related to the use of distributed ledger technology and to crypto-assets that qualify as financial instruments. For instance, there are no transparency, reliability or safety requirements imposed on the protocols and "smart contracts" that underpin crypto-assets that qualify as financial instruments..."

The pilot regime allows for certain DLT market infrastructures to be temporarily exempted from some of the specific requirements of Union financial services legislation that could otherwise prevent operators from developing solutions for the trading and settlement of transactions in crypto-assets that qualify as financial instruments, without weakening any existing requirements or safeguards applied to traditional market infrastructures. DLT market infrastructures and their operators should have in place adequate safeguards related to the use of distributed ledger technology to ensure the effective protection of investors, including clearly defined chains of liability

to clients for any losses due to operational failures. The pilot regime should also enable EU's financial supervisory body, ESMA to draw lessons from the pilot regime and to gain experience of the opportunities and specific risks. The experience gained should help identify possible practical proposals for a suitable regulatory framework in order to make targeted adjustments to Union law as regards the issuance, safekeeping and asset servicing, trading and settlement of DLT financial instruments (whereas 6).

When applying the regulation, the principles of technology neutrality, proportionality, the level playing field, and 'same activity, same risk, same rules' should be taken into account to ensure that other participants have the regulatory space to innovate, in order to uphold the values of transparency, fairness, stability, investor protection, accountability and market integrity etc. (whereas 10).

Since the pilot regime involves temporary exemptions from certain provisions of existing Union legislation, they should cooperate closely with the competent authorities and ESMA during the period in which their specific permission is valid. They should inform of any material changes to business plans, risk etc. (whereas 50).

The Regulation on DLT market infrastructures establishes requirements for acquiring a permission to operate a DLT market infrastructure, sets limitations on the transferable securities that can be admitted to trading, and frames the cooperation between the DLT market infrastructure, competent authorities and the European Securities and Markets Authority (ESMA). The proposed regime concerns a limited set of assets and transactions.

The Regulation mandates ESMA to carry out a review on the application of the pilot regime three years after its entry into force. All participants will also have to provide a clear exit strategy, to ensure smooth transitions once the pilot period is over.

Article 1: Subject matter and scope:

This Regulation lays down requirements in relation to DLT market infrastructures and their operators in respect of:

a Granting and withdrawing specific permissions to operate DLT market infrastructures in accordance with this Regulation;
b Granting, modifying and withdrawing exemptions related to specific permissions;
c Operating DLT market infrastructures;
d Supervising DLT market infrastructures; and
e Cooperation between operators and DLT market infrastructures, competent authorities and the European Supervisory authority .....ESMA."

26 Regulation (EU) 2024/1735 of the European Parliament and of the Council of 13 June 2024 on establishing a framework of measures for strengthening Europe's net-zero technology manufacturing ecosystem and amending Regulation (EU) 2018/1724.

The description of the Regulation shows, *that* this DLT Regulation has characteristics similar to regulatory sandboxes even if called a pilot regime, *that* it aims at supporting innovation, *that* it allows for derogations from current regulations, *that* it is quite detailed regarding specific areas and *that* it fosters cooperation.

10.3 EU'S NET-ZERO INDUSTRY ACT (NZIA)

In Regulation (EU) 2024/1735 of 13 June 2024[26]- NZIA - the EU introduced the possibility of "regulatory sandboxes" in light of the need for enabling innovation regulation.

> In the EU's Green Deal Industrial Plan on Innovation from 2023 the background for the proposed Net-zero Industry act is presented:
>
> "The objective of the Communication is to ensure a quick transition to carbon neutrality and complement the legislation already in place or under negotiation. The plan is the result of a huge push from member states in response to the US Inflation Act, and to put the attention of the Commission on the potential competitiveness disadvantage Europe would face in the light of new attracting measures coming from the Biden administration". One of the pillars mentioned is a "predictable, coherent and simplified regulatory environment".

The general objective of the Industry Act (Chapter I, article 1) is to improve the functioning of the internal market by establishing a framework in order to ensure the Union's access to a secure and sustainable supply of net-zero technologies. This includes scaling up the manufacturing capacity of net-zero technologies and their supply chains to safeguard their resilience while contributing to achieving the Union's climate targets and climate neutrality objective. The objective is also to contribute to quality jobs in net-zero technologies, and thereby also improve the competitiveness of the Union.

One of the measures to achieve this goal is supporting innovation through the creation of net-zero regulatory sandboxes[27].

In the preamble (whereas 100) it is said that Net-zero regulatory sandboxes can be an important tool to promote innovation in the field of net-zero technologies and regulatory learning. Innovation needs to be enabled through experimentation spaces as scientific outcomes need to be tested in a controlled real-world environment. Net-zero regulatory sandboxes should be introduced to test innovative net-zero technologies *or other innovative technologies*[28] with the potential to enable the transition to a climate neutral, clean economy and to reduce strategic dependencies, in a controlled real-world environment for a limited amount of time, thus enhancing regulatory learning and potential scaling up and wider deployment. It is appropriate to strike a balance between legal certainty for participants in the Net-Zero regulatory sandboxes and the achievement of the objectives of Union law. Member States should be able to provide for *derogations of net-zero regulatory sandboxes in national law* while *ensuring compliance with Union law* and with the essential requirements on net-zero technology laid down in national law[29].

The NZIA, Chapter VI on Innovation, article 33, Net-Zero regulatory sandboxes includes provisions regulating their establishment, conditions etc. and the role of the supervisory authorities.

During the negotiations about the NZIA it has been decided to include not only net-zero technologies, but also "other innovative technologies" which will include Biosolutions. Moreover, it has been decided to accept derogations from national law, but not Union law. The provision on regulatory sandboxes is found in Article 33:

> NZIA article 33 on regulatory sandboxes
>
> "1. By 30 March 2025, Member States shall, when setting up net-zero regulatory sandboxes, establish or designate one or more contact points. A sole contact point shall be responsible for each request to establish a net-zero regulatory sandbox pursuant to this article.
>
> 2. Member States, together with local and regional authorities and other Member States where appropriate, may at their own initiative establish net-zero regulatory sandboxes. Member States shall establish net-zero regulatory sandboxes, in close collaboration with industry and, where relevant research institutes, the social partners and civil society, in accordance with paragraph 1 at the request of any company, organization or consortium developing innovative net-zero technologies that fulfils the eligibility and selection criteria laid down in paragraph 3, second subparagraph, point (a), and that has been selected by the competent authorities following the selection procedure referred to in the paragraph 3, second subparagraph, point (b).
>
> 3. The arrangements and the conditions for the establishment and operation of the net-zero regulatory sandboxes pursuant to paragraph 2 shall be adopted by means of implementing acts. Those arrangements and conditions shall support flexibility of the competent authorities with regard to prioritising between and approving applications for net-zero regulatory sandboxes. They shall foster innovation and regulatory learning and shall particularly take into account the special circumstances and capacities of participating SMEs and start-ups.
>
> Those implementing acts shall include common main principles on the following issues:
>
> a The eligibility criteria and selection procedure for participation in the net-zero regulatory sandboxes;
> b The procedure for the application, participation, monitoring, exiting from and termination of the net-zero regulatory sandboxes;
> c The terms and conditions applicable to the participants.
>
> Those implementing acts shall be adopted in accordance with examination procedure referred to in article 45(2).
>
> 4. Participation in the net-zero regulatory sandboxes shall not affect the supervisory and corrective powers of the authorities supervising the net-zero regulatory sandbox. The testing, development and validation of innovative net-zero technologies or other innovative technologies shall take place under the supervision and with the support

27 These are in article 3 defined as a scheme that enables undertakings to test innovative net-zero technologies and other innovative technologies in a controlled real-world environment, under a specific plan, developed and monitored by a competent authority.

28 These are in article 3(13) defined as energy or climate related technologies with proven potential to contribute to decarbonisation of industrial or energy systems and to reduce strategic dependencies, that comprise genuine innovations that are not currently available on the Union market and that are advanced enough to be tested in a controlled environment. The general view is that Biosolutions are covered by this definition.

29 Reference is made to the Commission's "Guidance for sandboxes" from 2023 (mentioned below 11.2).

of the competent authorities. The competent authorities shall exercise their supervisory powers in a flexible manner within the limits of the relevant law, adapting existing regulatory practices and using their discretionary powers when implementing and enforcing legal provisions to a specific net-zero regulatory sandbox project, with the objective of removing barriers, alleviating regulatory burden, reducing regulatory uncertainty, and supporting innovation in net-zero technologies or other innovative technologies.

5. For the purpose of achieving the objective of this Article, the competent authorities shall consider whether to grant derogations or exemptions in national law to the extent allowed by the relevant Union law. The competent authorities shall ensure that the sandbox plan respects the requirements of Union law and the key objectives and essential requirements of national legislation. Competent authorities shall ensure that any significant risk to health, safety or the environment identified during the development and testing of innovative net-zero technologies or other innovative technologies is publicly communicated and results in immediate suspension of the development and testing process until such risk is mitigated. Where competent authorities consider, that the proposed project raises exceptional risks for the health and safety of workers, of the general population, or of the environment, in particular because it relates to testing, development or validation involving particular toxic substances, they shall only approve the net-zero regulatory sandbox plan, provided that they are satisfied that adequate safeguards commensurate with the exceptional risk identified have been put in place.

6. Participants in the net-zero regulatory sandbox shall remain liable under applicable Union and Member States' liability law for any material harm inflicted on third parties as a result of the testing taking place in the net-zero regulatory sandbox.

7. The duration of the net-zero sandbox may be extended through the same procedure upon agreement of the national competent authority.

8. The net-zero regulatory sandboxes shall be designed and implemented in such a way that, where relevant, they facilitate cross-border cooperation between the national competent authorities. Member States that have established net-zero regulatory sandboxes shall coordinate their activities and cooperate within the framework of the Platform with the objective of sharing relevant information with other Member States. The Platform may invite companies that have participated in a net-zero regulatory sandbox to share their experience of the process. The Commission shall, on the basis of information provided by the Member States and the discussions held in the Platform, report regularly on the results of the implementation of net-zero regulatory sandboxes, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application within the net-zero regulatory sandbox of this Regulation and other Union law in a manner adapted for the purposes of the net-zero regulatory sandbox."

Article 34: Measures for SMEs and start-ups
"1. Member States shall:

a provide SMEs and start-ups with priority access to the net-zero regulatory sandboxes to the extent that they fulfil the eligibility conditions laid down in article 33;
b organise awareness raising activities about participation to the net-zero regulatory sandboxes by SMEs and start-ups;
c where appropriate, establish a dedicated channel for communication with SMEs and start-ups to provide guidance and respond to queries about the implementation of article 33.

2. Member States shall take into account the specific interests and needs of SMEs and start-ups and provide adequate administrative support to take part in the net-zero regulatory sandboxes. Without prejudice to the application of articles 107 and 108 TFEU, Member States shall inform SMEs and start-ups of available financial support for their activities in the net-zero regulatory sandboxes".

Articles 36-37 contain rules on the establishment of the Strategic Energy Technology (SET) Plan Steering Group, the tasks of the SET Plan Steering Group and the structure and functioning of the Group. Chapter VII on Governance contains provisions on the establishment and tasks of the Net-Zero- Europe Platform.

Section II: Streamlining administrative and permit-granting processes, contains provisions on "Single point of contact". These imply obligations for net-zero technology manufacturing projects[30] and may be an inspiration for the Danish agencies responsible for permit-granting in the area of Biosolutions.

NZIA article 6 on Single point of contact

"1. By 30 December 2024 Member States shall establish or designate one or more authorities as single points of contact at relevant administrative level. Each single point of contact shall be responsible for facilitating and coordinating the permit-granting process for net-zero technology manufacturing projects, including for net-zero strategic projects, and for providing information on streamlining the administrative process in accordance with Article 7, including information on when an application is considered to be completed in accordance with article 9(10).

2. Where a Member State establishes or designates more than one single point of contact pursuant to paragraph 1 of this Article the Member State shall provide tools to help project promoters identify the

30 These are in article 3(16) defined as a planned commercial facility or an extension or repurposing of an existing facility to manufacture net-zero technologies or an energy extensive industry decarbonisation project". Net-zero technologies aredefined in Article 3(1) and listed in article 4. They are focused on clean-tech, wind, energy, carbon capture and storage, alternative fuels, biotech climate and energy solutions, nuclear technologies etc.

appropriate established or designated contact point on the online web page set up in accordance with Article 7.

3. A single point of contact established or designated pursuant to paragraph 1 shall be the sole point of contact for the project promoter in the permit-granting process for a net-zero technology manufacturing project, including a net-zero strategic project. It shall coordinate and facilitate the submission of all relevant documents and information and shall notify the project promoter of the outcome of the comprehensive decision.

4. Project promoters shall be allowed to submit any documents relevant to the permit-granting process in electronic form.

5. The competent authorities shall ensure that any relevant studies carried out, or permits or authorisations issued, for a given project are taken into account and that no duplicate studies, permits or authorisations are required, unless otherwise required under union or national law.

6. Member States shall ensure that applicants have easy access to information on and procedures for the settlement of disputes concerning the permit-granting process including, where applicable, alternative dispute resolution mechanisms, if such procedures are provided by national law.

7. Member States shall ensure that the single point of contact and all competent authorities responsible for any step along the permit-granting processes, including all procedural steps, have a sufficient number of qualified staff and sufficient financial, technical and technological resources necessary, including, where appropriate, for up-skilling and re-skilling, for the effective performance of their tasks under this Regulation.

8. The Platform referred to in Articles 38 and 39 shall periodically discuss the implementation of this section and Articles 15 and 16 and share best-practices for organizing single points of contact.

9. The authorities involved in the permit-granting process and other authorities concerned shall specify and make available to the single point of contact concerned, the requirements and extent of information requested of a project promoter before the permit-granting process commences."

The description of the NZIA regulation shows *that* innovation is supported and *that* the provisions on regulatory sandboxes include Biosolutions as "other innovative technologies". The regulatory sandbox includes possibilities for derogation of national (Danish) law, but explicitly excludes the derogations from current Union law. This may turn out to be an important obstacle in practice, as the Biosolution area is covered by extensive and detailed EU regulations.

10.4 THE EU'S PROPOSAL FOR A REGULATION ON MEDICINAL PRODUCTS

This EU proposal for a regulation on medicinal products is interesting as it provides a very flexible third generation of regulatory sandboxes, opening up for derogations also from EU law. The sandboxes may be set up by the EU Commission based on a recommendation of the EMA agency.

The EU Commission proposed a revision of the pharmaceutical legislation[31] that includes elements to ensure that the EU regulatory system is flexible enough to accommodate new innovative biotechnological medicines that are safe and effective. The proposal includes new provisions such as regulatory sandboxes

> The proposal on medicinal products introduces sandboxes to test new regulatory approaches for novel therapies in real-world conditions, for example when a medicinal product is at a very early stage of development. This can be important in the face of high uncertainty and disruptive challenges, as well as when preparing new policies, which is relevant in the context of digitalization or the use of artificial intelligence and machine learning in the life cycle of medicinal products, from drug discovery and development to the administration of medicinal products.
>
> The sandbox provisions cover the development phase prior to the authorization, the authorization of the medicinal product itself and the subsequent placing on the market. The establishment of a regulatory sandbox will be based on a Commission decision following a recommendation of the European Medicines Agency (EMA). This decision will be based on a detailed plan outlining the particular features of the sandbox as well as describing the products to be covered. The EMA is acting as the health agency, working in collaboration with agencies in Member States. To qualify, the medicinal product must meet eligibility criteria and conditions, among other that the characteristics or methods will positively and distinctively contribute to the quality, safety, or efficacy of the product, or provide a major advantage to patient access or treatment. A regulatory sandbox may be terminated at any time for public health reasons. Medicinal products developed under a regulatory sandbox may be authorized subject to specific conditions and subsequently placed on the market. The learning stemming from a regulatory sandbox should inform future changes to the legal framework to fully integrate the innovative aspects into the medicinal product regulation.

The proposal from 2023[32] includes provisions in article 113–115 on regulatory sandboxes:

31 https://www.health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en

32 Proposal for a Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency (EMA), 26 April 2023. (COM, 2023, final).

Article 113:

1 The Commission may set up a regulatory sandbox pursuant to a specific sandbox plan, based on a recommendation of the Agency and pursuant to the procedure set out in ... where all the following conditions are met:

   a it is not possible to develop the medicinal product... in compliance with the requirements applicable to medicinal products due to scientific or regulatory challenges arising from characteristics or methods related to the product;
   b the characteristics or methods ... positively and distinctively contribute to the quality, safety or efficacy of the medicinal product ... or provide a major advantage contribution to patient access to treatment.

2 The regulatory sandbox shall set out a regulatory framework, including scientific requirements, for the development and, where appropriate clinical trials and placing on the market of a product referred to in paragraph 1 under the conditions set out in this Chapter. The regulatory sandbox may allow targeted derogations to this Regulation, ... under the conditions set out in article 114.
A regulatory sandbox shall take effect under direct supervision of the competent authorities of the Member States concerned with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member State legislation concerned by the sandbox. .....

3 The Agency shall monitor the field of emerging medicinal products and may request information and data from marketing authorisation holders, developers, independent experts and researchers ... and may engage with them in preliminary discussions.

4 ...

5 The Agency shall be responsible for developing a sandbox plan based on data submitted by developers of eligible products and following appropriate consultations. The plan shall set out clinical, scientific and regulatory justification for a sandbox....

Article 114:

Products developed under a sandbox

1 When authorizing a clinical trial application for products covered by a regulatory sandbox, Member States shall take the sandbox plan .. into consideration.

2 A medicinal product developed as part of a regulatory sandbox may be placed on the market only when authorized in accordance with this Regulation....

3 In duly justified cases, the marketing authorisation of a medicinal product developed under the regulatory sandbox may include derogations from the requirements set out in this Regulation ... Those derogations may entail adapted, enhanced, waived or deferred requirements. Each derogation shall be limited to what is apt and strictly necessary to attain the objectives pursued, duly justified and specified in the conditions of the marketing authorisation.

Article 115:

1 The regulatory sandbox shall not affect the supervisory and corrective powers of the competent authorities. ....

2 Participants in the regulatory sandbox... shall remain liable under applicable Union and Member States liability legislation for any harm inflicted on third parties as a result from the testing taking place in the sandbox....

The description of this proposal shows *that* innovation is supported, *that* regulatory sandboxes are introduced, *that* this proposal explicitly enables derogations from the Regulation and *that* this is in an area with great emphasis on safety and a well-known and detailed regulatory legacy.

11 INSPIRATION ON REGULATORY SANDBOXES

Some recommendations. etc. can be found in the EU's toolbox for regulatory sandboxes, the EU Commission's Guidance on regulatory sandboxes and the Fit4Future platform's recommendations.

11.1 EU BETTER REGULATIONS RECOMMENDATIONS – TOOL FOR SANDBOXES

The definition of a regulatory sandbox in the Better Regulation context from November 2021 is mentioned above (4.1).

It is said (p. 597) that current regulatory sandboxes tend to share the following characteristics:

→ **Genuine innovation:** the products services/business models admitted to a sandbox should represent a genuine innovation, not currently available in the market. A new use of an existing technology can also qualify;

→ **Societal and/or consumer benefit:** these innovations are expected to deliver consumer and/or wider societal benefits, for instance by addressing unmet social needs or by contributing to policy objectives on e.g. environmental protection, financial stability, competitiveness, and so on;

→ **Readiness for testing:** an innovation is advanced enough to be tested in a controlled environment/market and the legislative is identified; theoretical links between an innovative idea and existing rules are not sufficient to set up a sandbox.

→ **Defined scope and time:** the boundaries of a regulatory sandbox may be grounded in law (e.g. an experimentation clause), In any event, boundaries are established ex ante and usually clarify the

legislation and sector(s) covered by the test, its duration and exit conditions. This approach ensures legal predictability and facilitates measuring and evaluating sandbox outcomes;

→ **Safeguards:** the purpose of a sandbox is not deregulation. Hence, even in a controlled setting, appropriate safeguards to preserve policy objectives and legal requirements apply (e.g., safety when testing self-driving vehicles).

In the Better Regulation Tools recent examples of regulatory sandboxes at EU-level are mentioned: Artificial Intelligence Act and Pilot Regime for Distributed Ledger Technology (DLT) market infrastructures (see above, 10.1 and 10.2). Moreover, examples from Germany, France and a Pan-European blockchain regulatory sandbox are mentioned:

Germany: Transport of medical samples by drone

The regulatory sandbox Medifly Hamburg allows for the transportation of sample tissue between hospitals located in the same urban area. The sandbox is backed by the Hamburg Authority for Economy, Transport and Innovation, and involves Hamburg's aviation authority and the relevant air traffic control office. The participating consortium, led by the Centre for Applied Aeronautical Research, includes a research institution, software companies, and a drone operator. The sandbox is based on an experimentation clause in section 21b subsection 3 of the Rules of the Air Regulations. Six test flights were successfully carried out in February 2020.

France: Facilitating innovative projects for collective self-consumption of electricity

France has made a derogation two articles L.315-2 and L 315-3 of their Energy Code in order to facilitate the development of innovative projects in the area of collective self-consumption of electricity. The derogation widens the boundaries of collective self-consumption so that local facilities, larger than those originally permitted under the Energy Code, can fall under the self-consumption definition. The experiment may also remove the 100kW threshold (article L.315-3 of the Energy Code) linked to the applicable tariff for the use of public electricity networks. The sandbox runs for five years and is operated under France Experimentation, an initiative by the French Ministry of Economy and Finance. Regulatory sandboxes in the energy sector are also emerging in Germany and United Kingdom.

Pan-European blockchain regulatory sandbox

The EU Member States, Norway and Lichtenstein signed a Declaration creating the European Blockchain Partnership to establish a European Blockchain Services Infrastructure (EBSI) and support the delivery of cross-border digital public services, with the highest standards of security and privacy. In cooperation with the European Commission, the European Blockchain Partnership has been planning a pan-European regulatory sandbox to become operational in 2021/2022. Use cases covered by the sandbox may include data portability, B2B data spaces, smart contracts, and digital identity (Self-Sovereign Identity) in the health, environment mobility, energy and other key sectors.

It is underlined that "regulatory sandboxes present both advantages and difficulties for all parties involved. Provided the concerned firm(s) can meet the requirements to take part in a sandbox, advantages include the possibility to test own innovations in a real-life setting, and gaining a better understanding of applicable rules, particularly when these fall in the remit of different regulators. Participation in a sandbox may also facilitate access to finance and reduce time-to-market for the innovator".

"From a regulator's perspective, sandboxes allow some degree of flexibility without giving up regulatory standards; they facilitate learning, keeping up with developments in the sector, and highlight the implications of existing rules on cross-sectoral innovation and on innovation happening in the 'periphery' of the regulator's competence. They strengthen ties between regulators from different policy fields, overall, these features can contribute to resilient and relevant legislation. On the downside, regulatory sandboxes may alter the level-playing field in the market; and can increase risks of market fragmentation and 'regulatory arbitrage' if sandboxes for the same rules/innovation lead to results across the EU. They also require significant resources and time, as well as dedicated skills, that are also needed for 'core' regulatory functions. "

It is also underlined that "other forms of experimentation are available and may be more appropriate for a specific case, for instance when a clarification of how existing legislation applies to an innovation can be provided through interpretive guidelines and without additional testing. In fact, sandboxes may be the follow-up to other, looser forms of experimentation, if these did not yield the desired clarity on the link between an innovation and the existing regulatory framework."

The Better Regulation toolbox introduces elements to consider before setting up a regulatory sandbox. Among these are the principles of proportionate analysis. A valuable starting point would be to draw a list of existing experimentation tools in the policy field under consideration, including examples at national level. Such a stocktaking exercise can already shed light on potential frictions between legislation and selected innovations. It may well be that guidelines would already reduce regulatory uncertainty, without the need for temporary exemptions or testing. At the EU level, another potentially source of evidence are innovation deals (see tool 22), if any have been concluded in the policy field concerned. Similar initiatives also occur at national level, for instance through innovation hubs.

It is noted that existing regulatory sandboxes are limited to specific policy areas (e.g., financial services, energy, digital technologies) and usually implemented locally, as this is where the regulator can more easily control the parameters of the sandbox experiment. One of the main difficulties of a regulatory sandbox is in scaling-up the results observed in the testing environment to the wider market. At the EU level, an additional challenge is worth mentioning: the impact on the Single Market and the risk of fragmentation if sandboxes for the same innovation are implemented in an un-

coordinated manner in different member states. This risk is already known to regulators, and various approaches are being considered to mitigate it.

For further guidance, Table 1 in the Better Regulation tool includes a number of questions to consider before deciding whether to establish a regulatory sandbox. It is not exhaustive and will be completed with practice in the future.
The Table 1:

Innovation and the market:	Which features of the product qualify as a genuine innovation? What alternatives exist – are they comparable? Main competitors – fairness to those not being in a sandbox? Which criteria to establish that the innovation is beneficial?
Applicable rules and flexibility	Which body of regulation is relevant? Is it a cross-sectoral sandbox? Is the regulatory barrier for testing precisely identified? Who establishes which regulatory barriers/requirements will be covered by the sandbox? Are these chosen by the regulator or identified exclusively by the applicant? What are the objectives of the relevant legislation that need to be safeguarded during implementation. What is the scope for making regulatory requirements more flexible? Which form should they take? Are there risks of fragmentation for the EU Single Market?
Access to sandbox	How will the selection criteria be outlined in an unambiguous way in the application form? How is fairness in access ensured for all applicants? What mechanisms are needed to ensure that selection criteria are applied consistently? Is there a standstill period for unsuccessful applications to contest the decision leading to their non-admission to the sandbox? Is there any form of support (guidance, funding, mentoring) envisaged for applicants?
Design and implementation	What are the goals of the sandbox? Limitations and indicators used to monitor progress and correct course if needed? How many companies/innovations can be meaningfully observed in the sandbox? What happens in case of exit before the end? What criteria will be used to close/exit the sandbox. What could be the possible consequences on the market. E.g. if a product is discontinued?
Evaluation and learning	What will success look like? What if the results can be scaled up, beyond the controlled environment? What risks could materialize when scaling up and how can they be mitigated?
Time and resources needed?	Is there any experience (EU or national level) with a sandbox in this area? If so, can the findings be used as a starting point? Are sufficient resources available to set up, run and exit the sandbox? Is coordination with other entities needed? What are the resources implications of coordination? Are all the parties involved equally equipped to sustain the necessary effort over time?

In the EUs *Principles for better regulations - tool for sandboxes* (p. 602) - it is emphasized how sandboxes can be relevant in cases of specific regulatory barriers:

"If available at early stages of policy preparation, the findings of a regulatory sandbox can be used - together with other sources of evidence - to inform impact assessments and in particular the problem definition and the baseline scenario. Insofar as they provide indications on how a given innovation interacts with applicable legislation, the results of a sandbox may also be used to estimate impacts of policy options affecting the regulatory environment (e.g. relaxing certain licensing requirements). When doing so, it is important to always consider whether the indications provided in the sandbox remain true when scaling-up. If potential new risks and positive/negative impacts are likely to derive from scaling-up or from an EU-wide application, these should be factored in the analysis.

Regulatory sandboxes may also be useful for an evaluation or fitness check, when specific regulatory barriers to innovation have been signaled during public consultation, through the Fit-for-Future Platform and other channels (e.g. innovation deals). In this case, the regulatory sandbox can inform possible future approaches to tackle these barriers and make the corresponding rules more adaptive and future-proof".

11.2 EU COMMISSION *GUIDANCE ON REGULATORY SANDBOXES*

In the Commission Staff Working Documents *Regulatory learning in the EU. Guidance on regulatory sandboxes, testbeds, and living labs in the EU, with a focus section on energy* 29th August 2023, regulatory sandboxes are defined, examples are presented both at EU level, national level and outside the EU, conclusions are drawn and the way forward described. The aim is to support regulators and innovators in their approach to experimentation in the EU.

It is underlined that innovators face the challenge of fitting their innovative solutions into relevant laws, policies, standards, rules etc., set by regulatory authorities. "Disruptive innovations can be subject to outdated

regulatory frameworks ... which may slow down the development and deployment of innovation and may undermine investor and consumer confidence." "Regulators establish and enforce policies and legislation, and balance different objectives. ... Put simply, the public sector faces two main welfare-decreasing risks when it comes to innovation: under- and over-regulation. Lenient legal frameworks (under-regulation) can leave society and the environment vulnerable to the moral hazards of market players. Overly stringent regulation (over-regulation) and regulatory uncertainty can deter investment and stifle innovation and business activity. Furthermore, regulators have to be mindful of the need to create and maintain a level playing field for innovators and to mitigate market fragmentation risks."

A new term used is "experimentation spaces" which allows innovators and regulators to explore the link between innovation and regulation by using a combination of experimentation tools. Regulatory sandboxes are examples of such types of experimentation.

Legal basis

In the working paper the difference between unregulated fields and already regulated fields is underlined. In a regulated field the need for a legal basis is underlined:

" ... different approaches to experimentation is possible. To use them, however, and particularly in already regulated fields, the competent authority needs to be able to do so, either through a legal basis in the legislation applicable, or if its mandate features the possibility to support innovation, including through experiments or a degree of flexibility in applying existing rules." [33]

"Competent authorities may also dispose of a certain degree of flexibility within the limits of the law and margin of appreciation on how to apply the legal requirements in a proportionate and context specific manner. When derogation from existing legislation is foreseen by a regulatory sandbox, a specific experimentation clause in legislation is required and serves as the legal basis for the sandbox. This binding legal basis must exist for the competent authority to be able to exercise the necessary degree of flexibility to derogate from applicable legislation. In some sectors such as energy ... a regulatory sandbox can also be based on a derogation from ordinances of regulatory authorities, if the competences of the regulator so allow..." (p.11)

"Innovation deals are mentioned as another way to address existing regulatory barriers to innovation in EU legislation. They are voluntary agreements with stakeholders: innovators, civil society, national, regional or local authorities and the Commission. Such innovation deals may result in a revision of EU rules, following established decision-making procedures. It consists of a) the definition of the regulatory problem encountered by innovators and b) (p. the identification of a solution to this problem in cooperation with the innovation deal team. (p. 13).

33 P 9, note 8, it is underlined that not all national mandates of competent authorities provide such flexibility and legislative changes may be necessary to empower regulators to employ regulatory experimentation. France is mentioned in connection with their change of mandate of the energy regulator, while in Italy the energy regulator's existing competences have been broad enough to apply regulatory experimentation tools. It is p. 11 underlined that the presence of a derogation is not a necessary element of regulatory sandboxes, but that the involvement of a competent authority is necessary.

Examples at the EU level

AI, DLT and NZIA acts – energy and environment

Recent examples are the AI act, the DLT act and the Net-Zero Industry act. Moreover, in the *energy sector* the Commission Recommendation on speeding up permit-granting procedures for renewable energy projects etc. was issued 18th May 2022. On the topic on *environment* article 15(5) of the Industrial Emissions Directive (IED) includes a mechanism to support innovation through the concept of "emerging techniques". The Commission proposal to amend the IED adopted 22nd April 2022, puts forward a number of measures to facilitate testing and deployment of emerging techniques with improved environmental performance, for example enabling the operator to derogate from certain emission levels for 2 years for the purpose of testing a new technique. (pp. 17 &21).

Example: Blockchain

A European Blockchain Regulatory Sandbox was launched under the digital Europe Programme. The sandbox is governed by the Europeans Blockchain Partnership (EBP). Legal uncertainty was present as governance is shared between many actors. To increase legal certainty, the sandbox addresses the need for enhanced dialogue between innovators and regulators by providing a trusted environment in which they can engage with another. The sandbox runs from 2023 to 2026 and will support 20 projects annually. (p. 30)

Example: Products

The New Legislative Framework (NFL) is a general regulatory framework for EU product legislation, containing a toolbox, a model for future and revised product legislation. The provisions are repetitive in every single piece of NFL-aligned product legislation and therefore divergences are reduced. The NFL is based on the new Regulatory Approach, the main principle of which is that product legislation should, wherever possible, avoid going into technical details, but only contain essential requirements in relation to issues such as health, safety consumer protection and the protection on the environment leaving detailed technical aspects of implementation to the development of non-mandatory harmonized standards. This approach allows a flexible legal framework, which is technology neutral and serves as a catalyst for innovation and growth. It has allowed keeping legislation slim, without frequent adaptation to technical progress, which is an important factor in a business environment characterized by fast developing technologies (p. 21).

General findings on regulatory sandboxes include (p. 38):

a a clear focus on regulatory learning;
b a structured approach to testing innovation, in a controlled real-world environment under supervision by one or more competent authorities;

c an explicit link with legislation through a legal base;
d possible flexibility within the law in applying legal requirements in a proportionate and context specific manner and temporary derogations and exemptions from those parts of the legislation that are relevant for a specific sandbox;
e and the use of appropriate safeguards.

Sandboxes can serve *different purposes*. It is underlined that "when a sandbox is established in an already regulated field, the purpose of the sandbox is to provide legal certainty on how existing rules apply, experiment, test and understand whether an adaptation of the legislative framework would make sense, under what conditions and with which requirements. A sandbox could also help the regulator understand new risks and impacts. This could ultimately lead to a change in the legislation or to a different interpretation, and ensure it remains fit for purpose and future proof based on operational evidence. A sandbox could also be used to develop the implementing rules and guidelines ..." (p. 39).

"Both academic and government publications emphasis the need to start each regulatory sandbox project with a hypothesis to test, a rigourous plan for collecting and analyzing key data... and wide dissemination of the results..." (p. 39)

11.3 FIT4FUTURE PLATFORM RECOMMENDATIONS ON BIOSOLUTIONS

This platform is a high-level expert group established to help the Commission simplify EU legislation[34]. They have established *Alliance for Biosolutions* in the EU. The platform examines whether existing legislation can achieve its objectives effectively when faced with new challenges. The Platform's views are taken into account by the Commission to ensure that EU legislation helps, not hinders, citizens and businesses, especially SMEs. In December 2022, that platform made recommendations to the Commission on how to create a more innovation-friendly regulation of Biosolutions, while upholding necessary protections. The report was accepted by all EU-countries, including 10 recommendations regarding simplifications of regulations and reduction of burdens for the sector:

1 "Modifications of the current regulatory framework to speed up the authorisations of microbiological and low-risk products within Regulation (EC) 1107/2009."

The expected benefits are primarily shortening of approval timelines, especially those related to prioritization of applications and evaluations carried out by a group of biocontrol experts. The whole procedure is expected to be shortened with a maximum of 6 years to an average of 4 years, which is a considerable improvement compared with the present period of app. 8 years (and up to 10 years). The benefits include a.o. an increase in the usage of innovative, low-risk microbial and sustainability enabling pesticides and benefiting the environment when substituting chemical pesticides.

2 "Further develop legally binding data requirements for other biological control categories than microbial products, namely semiochemicals, natural substances within Regulation (EU) 283/2013 and Regulation 284/2013 setting the data requirements under Regulation (EC) 1107/200.9 ".
3 "Adopt fast-track approval procedures for innovative, low-risk biological and sustainability enabling pesticides."
4 "Allow extension of the use on one crop to all other crops without the addition of upfront efficacy data for biological control products under Regulation (EC) 1107/2009."
5 "Further develop the regulatory framework for biological control products."

Expected benefits are a.o. to facilitate the creation of dedicated regulatory body for biological control solutions at Member States level, to promote and assist applicants in applying for biological control products and a permanent network of experts within the Member States to ensure quicker and better evaluations.

6 "Analyse opportunities and challenges when revising existing relevant legislation to focus on the potential risk pertaining to the product itself rather than the production process employed."
7 "Support adoption of novel food products while ensuring food safety."
8 "Improve the harmonization of the use of the term (probiotics" in the context of the health claims across the EU Member States to provide clarity for industry and consumers."
9 "Develop industry guidelines for food cultures as food ingredients".
10 "Update EU NACE codes."

11.4 INSPIRATION FROM OECD ON AGILE AND EXPERIMENTAL GOVERNANCE

In this section some recent examples from OECD reports on agile governance, regulatory experimentation and anticipatory governance are outlined.

In a *report from 2021 on Agile Regulatory Governance*[35] the OECD seeks to provide a conceptual framework and relevant guidance for using and adapting regulatory policy and governance in the face of the regulatory challenges and opportunities arising from innovation. The Recommendation are organized around four main pillars:

- Adjusting regulatory management tools to ensure regulations are fit for the future;

34 The platform consists of representatives from Member States and individual experts, representing EU's industrial and employer-organizations, NGO's and two European committees. Danish Industry is represented by the Danish ... (Dansk Erhverv).

35 "Recommendation of the Council for Agile Regulatory Governance to Harness Innovation. OECD/LEGAL/0464".

- Laying institutional foundations to enable co-operation and joined-up approaches, both within and across jurisdictions;
- Developing or adapting the governance frameworks to enable the development of agile and adaptive regulation;
- Adapting regulatory enforcement activities to evolving needs.

In the report OECD recognizes

- the need to ensure a regulatory environment that minimizes barriers for innovative entrepreneurs and their access to markets and resources;
- the need for holistic, open, inclusive, adaptive, and better-coordinated governance models that enhance systemic resilience by enabling the development of agile, adaptive regulation that upholds fundamental rights, democratic values and the rule of law.; and
- that, while innovation-related challenges will often require more flexible and adaptive regulatory frameworks, increased flexibility may lead to more discretion in decision-making and case-by-case trade-offs for which creating societal buy-in by demonstrating that the selected approaches are evidence-based, fit for the future, and trustworthy, including through broad-based and continuous public stakeholder engagement and close monitoring of outcomes, will be crucial.

To support the implementation of the recommendations, the RPC has developed "Practical Guidance of Agile Regulatory Governance to Harness Innovation", which provides more detailed information on concrete ways in which Adherents could implement the provisions of the Recommendation in practice.

In *a report from 2024 on Regulatory experimentation*[36] the OECD aims to help governments develop regulatory experimentation constructively and appropriately as part of their implementation of the 2021 OECD Recommendation for Agile Regulatory Governance to Harness Innovation. It is underlined that regulatory experimentation can help promote adaptive learning and innovative and better-informed regulatory policies and practices. The policy paper examines key concepts, definitions and constitutive elements of regulatory experimentation. It outlines the rationale for using regulatory experimentation, discusses enabling factors and governance requirements, and presents a set of forward-looking conclusions.

Regulatory sandboxes are acknowledged with their growing recognition of its potential and increasing uptake across countries, but despite this, it is underlined that effective adoption of experimentation by the regulatory community is still relatively limited. Moreover, it varies considerably across sectors and jurisdictions in terms of focus, scope and level of ambition.

Regulatory sandboxes are mentioned (p.14) as derogation-based approaches to regulatory experimentation. "A regulatory sandbox typically involves a limited form of regulatory waiver or flexibility so that new products, services or business models can be tested under reduced regulatory restraints. The purpose of regulatory sandboxes is to learn about the opportunities and risks that a particular innovation carries and to develop the right regulatory environment to accommodate it".

It is pointed out,[37] that a shift in regulatory *culture* is needed. Experimentation requires a culture favouring innovation and the scientific evaluation of public policies' results. "While the notion of successful outcome has traditionally been associated with laws, regulations or processes "that work", effective regulatory experimentation involves recognizing failure as an ally: "When taking an experimental approach, good failure is an unavoidable part of the learning process, and bad failure is a preventable failure that doesn't result in new learning". Regulatory decisions should not be thought of as final events, but as open-ended and highly contingent choices that form one stage in a longer process. Regarding innovation, the shift involves a shift from rules to principles. "Reframing regulation in this way and adopting a principle-based approach facilitates action and allows future revisions in the regulatory regime to be based on the incorporation of new knowledge or subsequent discoveries." In this respect, the growing use of EU Regulations, which are directly applicable, instead of Directives, which give Member States more leeway for implementation, seems problematic.

In the OECD report on anticipatory governance[38], the OECD aims to equip governments, other innovation actors and societies to anticipate and get ahead of governance challenges and build longer-term capacities to shape innovation more effectively. Five interdependent elements and associated government tools are presented:

1 guiding values
2 strategic intelligence
3 stakeholder engagement
4 agile regulation, and
5 international cooperation.

The recommendation on agile regulations consists of five key actions:

→ Implement adaptive and iterative regulatory assessment cycles, respond to stakeholder and public concerns, and coordinate across regulatory silos
→ Use experimentation tools like testbeds and regulatory sandboxes for adaptive policy learning
→ Use out-come based approaches that can prove more effective in new policy areas where limited evidence is available, such as emerging technologies
→ Consider non-binding governance approaches (high-level norms, principles and guidelines, technical and normative standards, codes of conduct and by-design approaches) as complementary approaches to public governance
→ Engage and incentivize the private sector for responsible innovation early on. This requires a new set of policy perspectives and tools, like the "ethics-by-design" paradigm and the Responsible Business Conduct approaches.

36 "Regulatory Experimentation: Moving ahead on the Agile Regulatory Governance Agenda", OECD Public Governance Policy Papers, April 2024.

37 The OECD report on Regulatory experimentation p. 31-32 refers to a French sociologist Michel Callon.

38 "Framework for anticipatory governance of emerging technologies", OECD, April 2024, No. 165.

11.5 INSPIRATION FROM OTHER COUNTRIES

In this section some examples[39] are outlined which may offer inspiration for Danish initiatives in the area of Biosolution sandboxes.

The Netherlands introduced so-called "Green Deals" enabling exemptions from regulatory barriers. The purpose is to create room for innovation and green transition by removing bottlenecks in laws and regulations, support market development, provide solid information and ensure optimal partnerships. Companies, non-profit organizations, local and regional authorities etc. can cooperate with the government to break down barriers for innovation and green transition in a specific area. By entering into an agreement, the government undertakes to support, without financing the project itself. The agreement includes purpose, actions and the stakeholders' respective contributions. The agreement normally lasts 2–3 years and is terminated when the defined goals have been achieved. Since 2011, when the program was initiated, about 300 agreements on green deals have been concluded.

France: One example is an accelerator program for producers of bio-pesticides, offering investment grants for equipment, enabling reduced use of chemical plant protection products, and improving framework conditions for bio-pesticides in regulations on future farming, food etc. In regulation from 2014, microbiological plant protection products (Biocontrole) were defined as methods using products that can be found in nature but can be made using biotechnology. This definition focuses on the product, not the process. Moreover, ANSES receives applications on approval of microbiological plant protection products on an ongoing basis, while booking is needed, if the application concerns chemical products. Counselling can present an initial assessment of the chance for approval. The application is evaluated by a "Green Team" with expertise in microbiology, plant extraction or the like (in 2022 20 experts were available after training and education. Cross-national workshops have been established and exchange of experiences, resulting in an increased number of applications.

In **Brazil**, the evaluation and regulation of bio-pesticides is controlled by 3 government agencies: National Health Surveillance Agency, the Brazilian Institute of the Environment etc., and the Ministry of Agriculture etc., – the last being the authority that grants pesticide registration. Biological products have priority in the registration queue. All three authorities have created special routes to evaluate registrations. Differentiation in the regulation of biological products occurred through the Ministry of Agriculture's Joint Normative Instructions, which except them from some requirements from those requested for products of 100% chemical origin and established different protocols for each group of bio-defensive products (micro-biological, bio-chemical etc.). The Normative Acts make it possible to register biopesticides by biological target (pest) and thus, once registered, they can be used in any crop in which the pest is present. Brazil is the largest producer and user of biocontrol products (612 biological products are registered).

US GRAS PROCEDURE: The US Food and Drug Administration (FDA) regulates approximately 80% of the US food supply and is involved with many facets of food safety. One of them is "generally recognized as safe" – GRAS – which is relevant for food ingredient regulatory classification. Ingredients are embraced by regulation requiring premarket approval for new uses of food additives. Congress stated that "substances that are generally recognized, among experts qualified by scientific training and experience to evaluate their safety as having been adequately shown ... to be safe under the conditions of their intended use" are excluded from the definition. Put simply, substances that are GRAS under conditions of their intended use are not food additives and do not require premarket approval by FDA.

EU has created Innovation Testbeds, that can notably be used to experiment with new solutions simulating their effect on the digital systems of public administrations. The innovation testbeds are programs that provide access to physical or virtual environments in which companies or public sector stakeholders can test, develop, and introduce new products, services, regulatory processes, organizational solutions and business models, typically in collaboration with multiple stakeholders. Testbeds can a.o serve as an instrument to co-develop the very rules and regulations needed to cope with new technologies and to gauge which existing regulations might be detrimental to adoption.

Canada has established a "Centre for Regulatory Innovation" (CRI) and is considering setting up a whole-of government framework for experimentation as a complement to existing mandates and responsibilities held by individual regulators. **Germany** has been exploring whether a general experimentation clause and a federal experimentation act should be established. **France** has the possibility of resorting experimentation enshrined in the Constitution. **Sweden** has established a Committee for Technological Innovation and Ethics (Komet). **Portugal**'s energy sector, ERSE, has developed or overseen a number of regulatory experimentation initiatives in the Portuguese energy sector. These include regulatory sandboxes in the gas sector to facilitate the use of hydrogen; establishing a regulation on time-limited projects of 3 years in electric mobility; and improving rules for time-limited pilot projects with dynamic tariffs – made possible by the regulatory discretion granted to ERSE and allowing for the amendment of regulations that apply to the energy sector[40].

39 The examples from The Netherlands and France are described by the IRIS Group in a report they made for the Danish Business Authority (Erhvervsstyrelsen) in January 2022 on regulatory barriers for development of Biosolutions - mapping of barriers in Denmark and neighbor check of practice in other EU Member States. "Regulatoriske barrier for udvikling af Biosolutions. Kortlægning af barrierer i Danmark og nabocheck af praksis i andre EU-lande".

40 The examples are mentioned in the OECD report on regulatory experimentation, see above.

PART III

PROPOSALS FOR BIOSOLUTION REGULATORY SANDBOXES

Regulatory sandboxes are gaining ground in the EU. They provide a structured context for testing innovations under the supervision of a competent authority ensuring that appropriate safeguards are in place. Sandboxes may function as steppingstones to obtain authorizations by testing and using the evidence in a later approval process - and at the same time enabling greater access to finance.

The experience from existing sandboxes (generation 1) has been positive, both in terms of legal certainty obtained by counselling and in terms of mutual learnings between innovators and regulators but can only operate within current regulations. Newer sandboxes (generation 2) have accepted exemptions from current regulation, primarily national regulations, but the legal basis may create problems. The potential of the newest regulatory sandboxes (generation 3) is promising, but dependent on the framework made in the specific act establishing the legal basis for the sandbox. Challenges are primarily the limitations in the acts to make exemptions from current regulations. The net-zero industry act includes Biosolutions regarding establishment of regulatory sandboxes, creating a legal basis for regulatory sandboxes made by member states, but lack of competence to make exemptions from current EU regulations, may limit the use in practice – depending on EU flexibility.

Proposals are made for Danish initiatives: a one-stop-shop/single entry point ensuring counselling etc.; a Biosolution Forum, where relevant authorities can meet, exchange experiences and make proposals for regulatory sandboxes; and a Biosolution Forum+, where innovators/companies, researchers and others are also invited to contribute to exchange of experiences and proposals for regulatory sandboxes. Moreover, proposals are made for national competence-building and more holistic risk-benefit analysis as sandbox enabling initiatives.

Specific sandboxes are proposed for further considerations in the areas of bio-pesticides and novel food/fermentation and some remarks are made regarding potential sandboxes in the area of genetically modified organisms (GMO) and New Genomic Techniques (NGT).

12 REGULATORY SANDBOXES: EXPERIENCES, BENEFITS, CHALLENGES

The experiences from the current landscape for regulatory sandboxes, described in Part II, are important in order to transform these learnings into the recommendations for new Biosolutions regulatory sandboxes. The different regulatory sandboxes present different purposes, legal bases, conditions, contents and power to make changes. The EU guidance on regulatory sandboxes is described in order to create the basis for the proposals on regulatory sandboxes in Denmark. As an introduction some more general benefits and challenges regarding regulatory sandboxes are briefly outlined.

12.1 GENERAL BENEFITS AND CHALLENGES REGARDING REGULATORY SANDBOXES

Benefits
Generally speaking, benefits of regulatory sandboxes may include:

- Reducing the time and, potentially, the cost of getting innovative ideas to market.
- Enabling greater access to finance for innovators by reducing regulatory uncertainty.
- Enabling more products to be tested, and, thus, potentially introduced to the market.
- Ensuring that appropriate safeguards regarding human and animal health, the environment and consumer protection are built into new products and services and are being monitored during the testing period.
- Fulfilling a need for flexibility and innovation-friendliness.
- Enabling specific testing in a controlled real-world environment.
- Creating room for counseling innovators.
- Creating room for mutual learning between innovators and regulators.
- Maybe leading to more agility in the acceptance of new products etc., being temporary and specific.

Challenges
The challenges seem to be concentrated on risks regarding level playing field in connection with the EU's Single Market and the risk of regulatory arbitrage. These challenges follow from the choosing of participants to regulatory sandboxes. These risks are important but must be balanced against the benefits.

Balancing
When the benefits are *balanced* against the challenges, it seems that the benefits outweigh the challenges. Risks for the EU's Single Market and risk of regulatory arbitrage are relevant, but when competitiveness suffers and there is a risk, that companies and researchers move to other countries with 'red carpet', it seems important to try to prioritize the need for innovation and competitiveness – without jeopardizing EU fundamentals. Regulatory arbitrage is a problem within the EU, but in the current situation, regulatory arbitrage may lead to research and business moving to countries *outside* the EU and not *within* EU. It seems far more problematic to see export of important people and businesses to the US, China, UK and other places, than minor problems within the EU.

12.2 LEARNINGS FROM REGULATORY SANDBOXES, GENERATION 1

Regulatory sandboxes do not have one agreed *definition*, but they represent a wish to introduce flexible regulation, being fit4innovation and fit4future, at the same time respecting necessary safeguards and EU fundamentals. These basic elements must be respected when evaluating regulatory sandboxes and when proposing specific regulatory sandboxes for Biosolutions.

> Crucial elements are that regulatory sandboxes represent a structured context for testing innovative technologies, products, services or approaches, for a limited time, in a limited part of a sector or area, under supervision of a competent authority, ensuring that appropriate safeguards are in place.

As sandboxes are relatively new in the area of regulatory models, their novelty limits the comparability of existing experience and learnings. Experiences are mostly described regarding regulatory sandboxes generation 1, sandbox classic, within existing regulatory limits. Practice since 2012 has especially been in the fintech area, designing new financial services (for example, blockchain). They are normally operated by Financial Supervisory Authorities (FSA), and their legal basis is often the competence of the supervisory authorities.

In *Denmark* the Danish Financial Supervisory Authority (*Finanstilsynet)* has made regulatory sandboxes in the area of fintech, for example on blockchain, with good results, using their supervisory competences as their legal basis. The Danish Maritime Authority (*Søfartsstyrelsen)* in 2021 initiated a Regulatory Future Lab where they make use of provisions in a global guideline on shipping to demonstrate that an equivalent level of security is fulfilled by using alternative designs regarding for example green technologies. (see above, 9.1 and 9.2.) The Danish Food Administration also made a Forum for Future Ingredients.

The main experience in the EU has been legal certainty and the mutual learning between regulators and innovators:

> **Legal certainty** can be obtained in areas where it may be difficult to decide which regulations – if any – are relevant for the products, methods etc., being tested. Clarity can be obtained, via counselling by the supervisory authority helping innovators to navigate in the complex regulatory jungle.

> **Regulators** can acquire a better understanding of the innovative products, which allows them to develop adequate rulemaking, supervision and enforcement policies. A wide range of actors - including developers, regulators, experts, and consumers of innovative products - may interact in a sandbox. This fosters communication between all interested parties and helps support regulatory learning, i.e., the formulation of experimental legal regimes to guide and support busi-

nesses in their innovation activities under the supervision of a regulatory authority. In practice, the approach aims to enable experimental innovation within a framework of controlled risks and supervision, and to improve regulator's understanding of new technologies.

Innovators can obtain a better understanding of supervisory expectations. Moreover, for innovators, testing in a controlled environment also mitigates the risks and unintended consequences when bringing a new technology to market, and can potentially reduce the time-to-market cycle for new products. Regulators can offer guidance on how specific rules would apply to the new products and, in some cases, provide for derogation, from regulatory frameworks or waivers. From the innovators' perspective one of the main benefits is the ability to test new technologies without having to meet all regulatory requirements normally applicable in a specific area, which is particularly useful for addressing innovations that do not readily fit an existing framework. The sandbox thus fosters *business learning*, i.e., the development and testing of innovations in a real-world environment.

However, restrictions attached to keeping within current regulations, limit the scope and tools of sandbox classic, which has led to the developments of generation 2, regulatory sandbox with exemptions and generation 3, regulatory sandbox based in EU-regulation.

12.3 POTENTIAL FOR REGULATORY SANDBOXES GENERATION 2 AND 3

Potential for regulatory sandboxes generation 2, with exemptions

Regulatory sandboxes generation 2 – with exemptions – allow temporary exemptions from existing regulation and are much more powerful than sandbox classic. The focus is primarily on new technologies, but also other areas have used second generation sandboxes. Examples are primarily found in national regulations where regulatory sandboxes have emerged as testbeds in transport (e.g., for autonomous cars or drones), energy (e.g., for smart meters), telecommunications (e.g., for 5G deployment) and health (e.g., for services and innovations for predictive early detection of diseases) [41].

However, there are also examples where the EU is more directly involved, which are of special interest. The challenge regarding generation 2 sandboxes is primarily the legal basis. It is clear that it is possible to make specific exemptions in order to enable experiments and tests, which are not bound by all regulatory provisions, but it is less clear, what this entails; and it is not always clear if exemptions can go beyond national regulations and include EU regulations. The need for derogation is, however, very often underlined.

41 "The role of sandboxes in promoting flexibility and innovation in the digital age", OECD, 2020: and "Global experiences from regulatory sandboxes", World Bank Group, 2020.

Potential for regulatory sandboxes generation 3, based on EU-regulations

Regulatory sandboxes, generation 3 – sandbox based on EU-regulation – is so new that we do not yet have any experiences, but the introduction shows a wish from the EU to encourage regulatory sandboxes. In these cases, the legal basis is explicit and clear, and the specific provisions in the new acts set the framework for the regulatory sandboxes.

The areas covered by the Acts are, however, restricted (see 10.1–10.4). The AI act covers *artificial intelligence* and stipulates that Member States shall ensure at least one AI regulatory sandbox at national level. Directions for the establishment and operation are part of the provisions (article 53-54). The DLT Act covers *blockchain* and enables "pilot regimes" allowing for certain DLT market infrastructures to be temporarily exempted from some of the specific requirements of Union financial services legislation (article 10).

The draft *pharmaceutical* legislation on medicinal products also contains provisions on regulatory sandboxes. The proposed set-up is that the EU Commission may set up a regulatory sandbox on a recommendation from the European Medicines Agency (EMA), and these sandboxes are supervised by competent authorities in the member states (article 113–115). The proposed regulation explicitly accepts derogations from the law, which is interesting as 'red biotech' is normally seen as an area where extra caution is crucial.

The *Net-Zero Industry act (NZIA)* has as its scope clean tech. Regulatory sandboxes may be established in these new areas and the regulation creates a framework for their content. During the negotiations it was decided to include "other innovative technologies" to be covered by the new provisions on regulatory sandboxes in article 33-34. The legal basis for regulatory sandboxes regarding Biosolutions is thus clear. The provisions in article 33-34 will constitute the framework for Biosolution regulatory sandboxes. The modalities and conditions for the establishment and operation of the net-zero regulatory sandboxes shall be adopted through implementation acts. The testing, development and validation shall take place under the direct supervision and guidance of the competent authorities. This means that a Danish competent authority can make Biosolution sandboxes. However, the NZIA limits the possibility for the competent authority to make derogations, as they according to article 33(5) can "grant derogations or exemptions in national law to the extent allowed by relevant Union law....". The role of the supervisory authority is expanded in Article 33(4) emphasizing two important aspects of the task for the supervisory authority:

> "...The competent authorities shall exercise their supervisory powers in a flexible manner within the limits of the relevant law, adapting existing regulatory practices and using their discretionary powers when implementing and enforcing legal provisions to a specific net-zero regulatory sandbox project, with the objective of removing barriers, alleviating regulatory burden, reducing regulatory uncertainty, and supporting innovation in net-zero technologies or other innovative technologies"

> For the purpose of achieving the objective of this article, the competent authorities shall consider granting derogations or exemptions in national law to the extent allowed by relevant Union law. The competent authorities shall ensure that the sandbox plan respects the requirements of Union law and the key objectives and essential requirements of national law."

During the negotiations, derogations from national law have been accepted, but not derogations from relevant Union Law. This may create *problems* in the area of Biosolutions, as the regulatory landscape on pesticides, novel food, additives, genetically modified organisms, new genomic technologies etc. are characterized by very detailed, complex and binding EU regulations. There seems to be little room for derogations or exemptions. Even if a (Danish) competent authority would try to live up to the provision on flexibility, using their discretionary powers, removing barriers, alleviating regulatory burden, and supporting innovation, this may prove very difficult. They can help create legal clarity but will need assistance from EU authorities to establish the flexibility needed. The situation may seem a bit 'frozen'. The only possibilities to enable innovation to the extent wished for, seems to be efforts to find loopholes with flexibility and room for purpose-driven interpretation in the current EU regulations and try to persuade relevant EU authorities to 'play along' and be constructive and innovative in the efforts to be flexible.

Thus, the potential of generation 3, sandboxes based in EU regulation, is dependent on the specific wording of the provision dealing with the regulatory sandboxes in the act and the characteristics of the regulatory landscape it covers. While the pharmaceutical proposal seems very open to targeted derogations, also regarding part of Union Law, this is not the case in the Net-Zero Industry Act. This situation calls for innovative, future-oriented interpretations and thorough decisions on how to create agility and use existing tools to allow rapid testing and disruptive innovation for Biosolutions.

12.4 THE EU COMMISSION GUIDANCE ON REGULATORY SANDBOXES

In the EU Commission Staff Working document 29th August 2023 on *Guidance on regulatory sandboxes, testbeds, and living labs in the EU*, new tendencies on experimentation spaces is underlined (p. 6):

> "Regulatory learning is increasingly organized in 'experimentation spaces[42]' to gather evidence in a more systematic and structured manner on the need to adapt or introduce regulation, while ensuring a level playing field and competitive developments. In an EU context, all forms of experimentation will be in line with existing Treaty rules.
>
> The term 'experimentation spaces' is relatively new. Most notably, it is mentioned in the European Commission's New Europeans Innovation Agenda. Experimentation spaces allow innovators and regulators to explore the link between innovation and regulation by using a combination of experimentation tools. Three types of experimentation tools (regulatory sandboxes, testbeds and living labs) are commonly in use ...".

42 See also the OECD reports, mentioned in section 11.4.

In the EU report the role of regulatory sandboxes is stressed (p. 6)

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

Regarding legal certainty it is emphasized that a balance is needed (p. 7-8):

> "Once innovations are close enough to the marketing stage, the question on how they link with regulation automatically arises. This often creates legal uncertainty for all actors involved. It is also at this stage that regulators need to strike the right balance between (i) regulatory flexibility and learning (where needed) and (ii) preserving regulatory certainty, predictability and appropriate safeguards for public interest policy objectives.
>
> Frameworks for regulatory experimentation can increase legal certainty for the different actors:
>
> a For regulators and other competent authorities, by empowering them to support innovation and to use regulatory experimentation tools because this might otherwise not be among their competences;
> b for innovators they provide reassurance that an innovative activity can fit within the existing regulatory framework or that it would be appropriate to provide temporary derogations for testing;
> c for all market participants, by levelling the playing field and avoiding or minimizing any competition distortion effect and by sharing the learning outcomes;
> d for consumers and the public through appropriate safeguards and protection measures put in place".

It is underlined that the need for legal certainty will vary depending on whether innovations occur in a new and therefore unregulated field or in a regulated sector. In a regulated field - like the Biosolution area – innovators often require clarity, and advice on interpretation. In some instances, however, "an innovation will stretch the boundaries on the applicable regulatory framework, raising the question of whether it is still fit for purpose or would

need some adaptation to continue serving its intended policy objectives. (e.g., consumer protection), while accommodating new developments in the sector. Experimentation spaces can in those cases help all actors involved to identify a way forward." (pp. 8–9)

> Some advisory services in the EU are mentioned, for example "the Enterprise Europe Network, (for SMEs), the "Horizon Results Booster" and the "European Cluster Collaboration Platform".

It is stressed that different approaches are possible, but a legal basis is often necessary: (pp. 9–11).

> " .. particularly in already regulated fields, the competent authority needs to be able to (use the different approaches to experimentation) either through a legal basis in the legislation applicable to the innovation at stake, or if its mandate feature the possibility to support innovation, including through experiments or a degree of flexibility in applying existing rules[43]".''When derogation from existing legislation is foreseen by a regulatory sandbox, a specific experimentation clause in legislation is required and serves as a legal basis for the sandbox. This binding legal basis must exist for the competent authority to be able to exercise the necessary degree of flexibility to derogate from applicable legislation."

It is underlined that competent authorities "may also dispose of a certain degree of flexibility within the limits of the law and margin of appreciation on how to apply the legal requirements in a proportionate and context specific manner".

In this respect it is important that when a sandbox has the Net-Zero Industry act article 33 as its legal basis, the article emphasizes the need for the competent authority to be extremely flexible, see above. In order to reap the fruits of the bio-revolution it will also be essential, that the *EU authorities* in the same way are flexible, using their discretionary powers when implementing and enforcing legal provisions in the Biosolution area, with the objective of removing barriers, alleviating regulatory burden, reducing regulatory uncertainty and supporting innovation. If a relevant co-creation can be established between Danish and EU competent authorities, the Biosolution sandboxes can support innovation in a constructive way.

13 PROPOSALS FOR REGULATORY SANDBOXES

The framework for the specific proposals on Danish sandboxes in this report is the policy framework, the practical framework, and the possible purpose and content of Biosolutions regulatory sandboxes. Based on these frameworks specific proposals are made on a one-stop-shop/Single Entry Point (sandbox generation 1, sandbox classic); a Danish Biosolution Forum and Forum+; sandbox-enabling activities in the form of competence-building, a broader, holistic risk assessment, ethical debates and partnerships, including EU involvement. Three specific areas have been chosen for more detailed considerations and proposals: a Biosolution sandbox on Bio-pesticides; a Biosolution sandbox on novel food/fermentation; and considerations on genetically modified organisms (GMO)/new genomic technologies (NGT).

43 It is stressed that not all frameworks or national mandates of competent authorities provide such flexibility. Legislative changes may be necessary to empower regulators to employ regulatory experimentation. A similar issue may also arise at the level of EU agencies. Another approach is to rely on experimentation clauses in legislation.

13.1 POLICY FRAMEWORK AND PRACTICAL FRAMEWORK FOR REGULATORY SANDBOXES

The specific proposals for Biosolution sandboxes operate within specific political and practical frameworks.

Policy framework for Biosolution regulatory sandboxes

EU policymakers and the EU Commission are increasingly favoring a more agile approach to innovation and regulation and use regulatory sandboxes as a relevant tool. The development and trends show the *willingness* to make not only counselling and learnings but also more flexible regulation. The new tendency to make sandboxes part of regulations is primarily used regarding new technologies, where regulation is scarce. The interesting question is, to what extent this new possibility for regulatory sandboxes can have influence in the area of Biosolutions, where regulations, especially EU regulations, are overwhelming – and to what extent it will create problems that the Net-Zero act does not provide for exemptions from relevant EU law.

The many binding regulations create judicial obstacles and are difficult to change. The necessity for tools to overcome these problems is, however, obvious. With the current lack of speed, the EU will stand more or less still, entangled in outdated, complex regulations and barriers in the years to come, while other parts of the world will sprint off at high speed. The costs may be huge in many ways. It is crucial to make regulatory sandboxes an accepted tool, enabling a 'ballet jump' from outdated regulations with too many barriers to fit4purpose and fit4future regulations.

It is therefore urgent that the regulatory sandboxes and other tools are used in a *constructive way* to help Biosolutions become a potent tool in the EU's green transition and harsh competition with other parts of the world. In EU's better Regulation Tool for sandboxes, it is acknowledged that sandboxes are usually organized on a case-by-case basis, include a temporary loosening of applicable rules, and feature safeguards to preserve overarching regulatory objectives, such as safety and consumer protection. Many of the examples mentioned in Part II, 8 and 9, have accepted such sandboxes – mostly regarding national legal provisions. As much regulation today in the area of Biosolutions is EU-based, and the challenge is the great difficulties in speeding this up to date, the need for close cooperation with EU politicians and institutions will be essential.

The hope is that the EU's policy goals about innovation, sustainability and competitiveness, described in Part I, will be reflected in implementation and practice. Such acceptance of tools in the area of Biosolutions will be beneficial for EU Member States. However, it necessitates close cooperation with the EU-Commission, EFSA etc. and an "open mind" for

all involved in order to reap the fruits of the Biosolutions. Dialogue and cooperation between national and EU authorities, politicians etc. will be both necessary and helpful. Only if all actors play along in the same flexible and innovation-oriented way as the regulators ask for, we can reap the fruits of the technology-revolution and the Bio-revolutions in order to achieve the purposes, that is hoped for.

It seems adequate to *encourage the EU authorities* to have the same attitude and willingness to make changes, as the regulation obliges the Member States' competent authorities to do, see above regarding the proposed article 33 in the NZIA. This entails flexibility, using their discretionary powers, when implementing and enforcing legal provisions to a specific regulatory sandbox project with the objective of removing barriers, alleviating regulatory burden, reducing regulatory uncertainty and supporting innovation.

Practical framework for regulatory sandboxes - establishment, purpose, content

This section illustrates possibilities for establishment, purpose, and content of regulatory sandboxes across various elements.

Establishment of Biosolutions regulatory sandboxes

The *initiative* to create a sandbox can come from politician(s), from a competent authority, or from an innovator. Examples of relevant competent authority could be the Ministry of Industry, business and Financial Affairs (Erhvervsministeriet)/Danish Business Authority (Erhvervsstyrelsen), the Danish Environmental Protection Agency (Miljøstyrelsen), the Danish Food Agency (Fødevarestyrelsen) and the Danish Agriculture Agency (Landbrugsstyrelsen).

> NZIA article 33 obliges the member states to designate or establish one or more contact points at relevant levels of member state administration, see article 6. According to article 33 member states may at their own initiative establish sandboxes, allowing for the development, testing and validation of innovative technologies in a controlled real-world environment for a limited time before their placement on the market or putting into service. Member states establish regulatory sandboxes, in close collaboration with industry and where relevant research institutions, social partners and civil society. At the request of any company, organization or consortium developing innovative technologies, which fulfils the eligibility and selection criteria, and which have been selected by the competent authorities following a selection procedure.

The legal basis will normally be EU-based, based on national regulation or based on the supervisory authority of an agency, for example the Financial Supervisory Authority. The legal basis may provide specific limitations, for example on the area for the sandbox, the conditions or the consequences. An example is the possibility of making an exemption from national or EU law.

The supervisory authority decides the *conditions* for applying to participate in the sandbox. Inspiration can be found in the Danish experience from regulatory sandboxes or from the EU better regulation paper or from the implementing acts following the net zero- industry act.

Purpose of the Biosolutions regulatory sandboxes

The purposes fall in four different categories: a) the concept of a sandbox; b) purposes encouraged by EU policies; c) other purposes of relevance; d) the reasoning behind the wish to make a specific regulatory sandbox.

A *The conditions* following the concept of a regulatory sandbox:
- An innovation, for example an innovative technology.
- Willingness to temporary testing.
- A supervisory authority to monitor the sandbox and ensure safeguards.
- A limited part of a sector.
- A limited period.
- Specific conditions follow from the legal basis.

B Purposes encouraged by EU policies:
- Foster *innovation.*
- Support *sustainability.*
- Ensure better *competitiveness.*
- To the benefit of society or consumers/users.
- The innovation is low risk.

C Other purposes of relevance:
- The sandbox can create new knowledge and/or products using evidence-based tests, needed for new or updated regulations.
- The sandbox can create mutual learning between innovators and regulators and this way maybe contribute to better regulation more fit4purpose.
- The regulatory sandbox is needed because of regulatory uncertainty or inappropriateness.
- Crucial elements of current regulations are *bureaucracy*, time-consuming elements of regulation etc. creating stumbling blocks, disproportionate to safety issues.

D Reasoning behind the proposal for a regulatory sandbox:
- Areas where new relevant evidence, science, knowledge etc. can be delivered through sandbox testing.
- Areas where irrelevant documentation can be left out.
- Areas where proposals for new regulations are under negotiations but are not yet implemented or are delayed because it is difficult to reach consensus.
- Areas where new ways of risk assessment seem feasible, for example based on new knowledge, new technology etc.
- Areas where more flexible administrative processes are needed.

- Areas where timelines could and should be shortened - fast track etc.
- Areas where a holistic risk-benefit assessment could be tested.
- Areas where ethical worries seem to have diminished, which may create room for regulatory sandboxes – GMO is a relevant example.

Content of Biosolutions regulatory sandboxes

The content is made by the politicians wishing a specific area to be tested, the competent authority or an innovator, who provides the thesis, documentation etc. regarding the process or product being tested. It may be different processes or products within the area of Biosolutions, for example bio-pesticides, bio-stimulants, additives, novel food, genetically modified food, genetically modified plants, new genomic techniques etc.

13.2 PROPOSAL FOR SANDBOX CLASSIC IN DENMARK – ONE-STOP-SHOP

A one-stop-shop (single entry point) is a crucial element for necessary initiatives and could be part of a potential Danish national action plan on Biosolutions. One for Denmark and for each agency.

Sandbox classic can deal with the barriers on complexity, uncertainty and bureaucracy. It can help companies, especially SMEs, to navigate in the very complex regulatory landscape and make sure that they know what is expected from them to live up to the relevant regulation. The task of the one-stop-shop could include a pre-application meeting, which in the Netherlands has proven to be effective in terms of increased quality of applications and supporting of a faster process. Counselling could also be relevant during the testing period and when scaling up. A one-stop-shop on ingredients has been made in the Danish Food Agency. The proposal for a Net-Zero Industry Act contains rather detailed provisions on a one-stop-shop (article 6, see 10.3).

The one-stop-shop can create a clear point of contact to raise visibility of the enquiry function to firms that may not have a high degree of familiarity with the competent authorities. It may also be supported by specialist resources relating to innovative propositions that create efficiencies in responding to enquiries. The competent authorities this way can devise specific testing parameters, scrutinize the test and develop lessons learned from the test outcome from a specialist perspective. These lessons learned may be applied for the benefit of the competent authority and industry.

13.3 PROPOSAL FOR A DANISH BIOSOLUTION FORUM AND BIOSOLUTION FORUM+

In order to foster collaboration and co-creation, exchange of experiences and inspiration, it may be fruitful to create a special forum, where important actors in the field of Biosolutions meet. Inspired by the Danish AML-forum (Hvidvaskforum), the Biosolution Forum could consist of relevant ministries and authorities, having a place to exchange experiences and set out principles for relevant sandboxes. These could include purposes accepted, topics that can be included (for example innovation and administrative procedures,) relevant tests, documentation and communication of results etc.

Competent authorities could also engage with other relevant domestic authorities in a common forum underpinned by memoranda of understanding (MoU). Several key advantages could be achieved. Automatic sharing of information with all relevant authorities facilitates efficiency in responding to incoming enquiries. The common platform also enables all relevant authorities to keep track of the type of questions that arise within the industry and can adopt a consistent approach to providing responses. Moreover, joint initiatives enable cross-sectoral issues to be more efficiently monitored and facilitate the effective monitoring of the regulatory parameter.

A Biosolution Forum+ could also - inspired by AML Forum+ - be established with a broader range of participants. Members could include industrial organizations, representatives for large companies and SMEs, and research experts in relevant areas – both science and law. Inspired by the Netherlands one could consider making innovation contracts between government, industry and research actors, including targets regarding green-strengthened competition and new business opportunities via trans-sector alliances.

Sandboxes consist of *testing* of new products, and a *framework* for criteria, processes and consequences. While the testing is in the hands of the innovators and companies, the framework is in the hands of authorities and politicians. The framework is important to make the sandboxes attractive to innovators. Initiatives to encourage counselling and cooperation are important. They represent the classic sandbox and lie within the competence of Danish politicians and authorities.

This framework can thus be 'enabling and enhancing' the existence and fruitful outcome of sandboxes. The enabling measure may be just as important as the tests themselves. It is therefore important both to find processes and products where testing is relevant and to make the framework they shall fit into. The results we hope for are new, innovative products, enhancing sustainability and competition and at the same time securing safety – normally in relation to human health, animal health and the environment.

13.4 COMPETENCE-BUILDING, HOLISTIC RISK ASSESSMENT, ETHICAL DEBATE AND CO-CREATION

To establish relevant Biosolutions regulatory sandboxes, some sandbox-enabling activities can be helpful, for example competence-building, more holistic risk assessments and ethical debates.

Competence-building

There is a capacity shortage and need for more professional skills in the areas of Biosolutions. In Denmark, a Business Lighthouse, Knowledge Hub Zealand has been established and a new education in Biosolutions

will start in Kalundborg in 2024, which is very promising. The Netherlands established a dedicated professional "Green Team" with expertise in microbiology, plant extraction etc., to assess applications in the area of pesticides. In Denmark, a team on ingredients is established in the Food Agency. There might also be need for a debate on the 'culture' of civil servants making approvals and a debate on the pros and cons regarding 'panels' with different expertise like in the health area to make the decisions – thereby also enabling a more holistic risk assessment. Shortage of capacity when it comes to experts that can evaluate product applications could be addressed through obligations to Member States to appoint experts.

Regulatory approach should make sustainability part of the assessment
The assessment of Biosolutions should take sustainability benefits into account. This is a crucial part of the NZIA, and it is important to see the innovative Biosolutions in the context of the need for green transition. The regulatory approach should be more 'purpose-driven' and less process-driven. We could learn from the area of Health Technology Assessments (HCA). These include if the new medicine works better, equally well, or worse than existing alternatives and are based on multidisciplinary processes, including reviewing social and ethical issues. The sustainability aspect should also be included in the risk assessment, as it is also a risk to delay processes and products that could speed up the green transition. A risk–benefit analysis is needed. A change of EFSA's mandate could be debated with EFSA, the EU Commission and other Member States. Debates on risk assessments and the precautionary principle in today's society could also be helpful.

The current regulation on Biosolutions only deals with risks, the precautionary principle and ethics, but does not take benefits regarding sustainability, innovation and competitiveness into account. Many other areas, for example, health also include effectiveness and a broader social and ethical evaluation. Regulatory sandboxes are defined by their sustainability potential, and can help initiate such a risk-based, but balanced approach to the benefit for sustainability, the green solutions, etc. This should be supported. It is paramount that regulatory sandboxes are used beyond the first generation – sandbox classic – within the regulatory barriers in current regulations.

Ethical debates and debates on risk assessments, GMOs etc.
Some regulations reflect 'frozen ethics' where developments in science, ethics, and policy are 'on the move'. A classic example is genetically modified organisms (GMO). This has led to a proposal for new regulation on NGT – New Genomics Techniques – but the proposal is controversial, and it may be difficult to obtain consensus. The Danish Council of Ethics in their report, *GMO and Ethics in New Times,* from 2019, underlines that the time has come where new ethical debates are needed regarding GMO. A unanimous Ethics Council finds that it is ethically problematic to reject GMO plants if they can contribute to solve essential problems, and there are no solid arguments to make a rejection. The Council underlines that their new position may influence the ongoing considerations to change the EU's approval system for GMO. Debates would also be fruitful in the area of risk assessments, where there are many 'loose ends' and the need for a holistic approach.

Co-creation: Partnerships in Denmark and with EU-involvement
Cooperation and co-creation will be necessary ingredients in the establishment and development of Biosolution regulatory sandboxes, including cooperation between the innovator and the regulator (competent authority). The Net-Zero industry act proposal also includes a one-stop-shop solution involving the competent authority. The proposal above for a Biosolution Forum and a Biosolution Forum+ will (if established) lead to including more relevant people in the exchange of experiences and the fostering of ideas for Biosolution regulator sandboxes. These co-creation possibilities can take place in a Danish context.

The experiences from existing regulatory sandboxes in other Member States have shown that cooperation with EU authorities and partnerships with other Member States may enable establishment of a regulatory sandbox. An example is a Pan-European regulatory sandbox on blockchain. Such cooperation could be encouraged by politicians and authorities. Other forms of cooperation with EU authorities and other Member States also seem worthwhile.

As the Biosolution area is characterized by comprehensive, detailed EU regulations, it will be crucial to involve dialogue and close cooperation with EU authorities to enable innovation regarding Biosolutions. Regulatory legacy with its entangled regulation often stands in the way for innovation and there is a need to explore possibilities of making purpose-driven interpretations to pave the way for Biosolution sandboxes. This is not an easy task, but the arguments in favor of Biosolutions regulatory sandboxes are manifold.

The topics for regulatory sandboxes should be chosen with care, in areas where the importance is clear, the problems are substantial, and the possible solutions well-argued and realistic. There follow some suggestions in three Biosolution areas, but they include uncertainties regarding the legal framework for regulatory sandboxes, as the interpretation is not yet clear.

13.5 PROPOSAL FOR A REGULATORY SANDBOX ON BIO-PESTICIDES

The proposal will include remarks on a) the importance of the area; b) the barriers experienced in practice; c) possible solutions. The proposed solution for further consideration includes questions as to 'what is the purpose?', 'who should take an initiative?' and 'on what legal basis and framework, who can apply and on what conditions, and what can the content of a regulatory sandbox on bio-pesticides look like?'

The area of bio-pesticides is important
Plant Protection Products (PPP) are essential for farmers and for societies to protect plants against pests or diseases, including weeds, at the same time improving plant production and making sure that pesticides take safety aspects into account. Bio-pesticides are explicitly preferred by the EU be-

cause they are less risky than chemical- based pesticides. This is stressed in the EU Farm to Fork strategy. Moreover, they can help the green transition, and they are beneficial for consumers. Bio-pesticides are important for Europe, including Denmark, given the strongholds in the area.

Problems in practice - current regulations and practices complex and outdated

However, PPP regulation creates barriers for bio-based pesticides. To illustrate practice, the regulation on pesticides is briefly outlined and some barriers are mentioned.

Purpose of current pesticides regulation - safety and EU fundamentals

The *purpose* of the regulation on PPP is primarily *securing safety and EU fundamentals.* Safety includes securing human health, animal health and the environment. The functioning of EUs internal market is also a matter of concern.

> According to regulation 1107/2009, article 1, (3,) the purpose is to "ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through harmonization of the rules on the placing on the market of plant protection products, while improving agricultural production." [44]

Development in current regulation on pesticides

Regulation on plant protection products was developed in 1991 – 33 years ago – where it was based on chemical pesticides and their risks. The basic regulation now is from 2009, 1107/2009 as regards placing pesticides on the market and approval processes, and 2009/128 as regards their sustainable use. The regulation enables a simpler process for low-risk active-substances[45].

The European Commission announced pesticide reduction targets as part of the "Farm to Fork Strategy" in 2020. Target 1 is to reduce by 50% the use and risk of chemical pesticides by 2030. In 2022, The EU Commission introduced legally binding targets, that the Member States will have to set their own reduction targets within clearly defined parameters. The Commission also introduced strict new rules to enforce environmentally friendly pest control, IPM (Integrated Pest Management), in which all alternative methods of pest control are considered first, before chemical pesticides can be used as a last resort measure. These rules are laid down in a regulation, and the EU refers to the Green Deal, the Farm to Fork Strategy, the risk to the health of citizens linked to the use of chemical pesticides and the Sustainable Use of Pesticides Directive (SUD), which has proven too weak and has been unevenly implemented.

In 2023, the Danish Environmental Protection Agency (Miljøstyrelsen) issued a 143-page long *Evaluation Manual for the Authorization of Microbial pesticides according to Regulation (EC) 1107/2009* including general concepts and principles of the risk assessment. It is underlined that the regulation "states that a plant protection product can only be authorized when the active substance has been approved, the product is sufficiently

44 According to preamble 8-10 and 35 to the 1107/2009 regulation priority should be given to non-chemical and natural alternatives wherever possible and the precautionary principle should be applied.

45 Regulation (EC) No 1107/2009 article 22 and Annex II, point 5.

effective, and use of the product does not have harmful effects on human health and have no unacceptable effects on the environment. These conditions should be met for all Plant Production Products independent of the type of the active substance (microbial or chemical)." It is also stressed that the Manual aims to provide an interpretation to the new implementing Regulations. Moreover, assessments of biological entities are seen as "inherently complex", the hazards will depend on the characteristics of the micro-organism, and there is no quantitative threshold to determine what should be considered a foreseeable risk, so it will in most cases be a qualitative assessment, often using a weight-of-evidence approach.

The EU Commission has made a *proposal for a Regulation* on the Sustainable Use of Plant Protection Products[46] (SUR). Its overall objective is to increase the availability of biological control and other non-chemical alternatives to pesticides, and to strengthen IPM strategies (Integrated Pest Management) to minimize the use of chemical plant protection products and the creation of advisory systems for farmers to support their uptake of non-chemical plant protection products. The proposal was negotiated but has been withdrawn as it was not possible to reach consensus.

To sum up: The regulation from 2009 seems outdated, the SUD regulation on sustainable use of pesticides seems inefficient and the SUR regulation has been withdrawn, due to lack of consensus.

Processes in current pesticides regulation

The regulation on PPP is complex, and the bureaucracy attached to the regulation seems *overwhelming.* The basic system is that the EU approves the active substance used, while the Member States approve the plant protection product as such. There are 5 actors at play: the company making an application, the rapporteur member state, the EU Commission, EFSA, the other Member States and the member state approving the product.

> The roles of the five involved entities are primarily the following:
>
> **The innovator/company** wanting to make an application is obliged to find and present – in a dossier – all relevant scientific information, studies etc. to substantiate the application. This is not an easy task.
>
> **The Rapporteur Member State** shall make an initial screening of the application. Where a hazard has been identified, the assessment should conclude on whether this hazard leads to a foreseeable risk. In practice it may be difficult to find a Rapporteur Member State.
>
> **The EU** approach has been to secure *harmonized rules* for approval and placing on the market, including rules of the mutual recognition of authorizations. A *detailed procedure* is set out to assess the application, and there are strict deadlines for the different procedural steps. The EU Commission performs risk management of the active substance, based on a risk assessment made by *EFSA* (European Food Safety Authority) performing an independent scientific review.

46 Proposal for a regulation on the sustainable use of plant protection products, 22.6.2022.

Each active substance has to be proven *safe* in terms of human health, animal health and impact on the environment.

Other Member States are also involved in the process. Denmark is part of the *Northern zone*, which is cooperating to evaluate applications for approval of pesticides. A draft approval is sent to EFSA, which is responsible for a risk evaluation, which is sent to all other countries in the zone for comments. The evaluation must be finished within 6 months, and the registration report is sent to all EU Member States, who have 4 months to finalize their evaluation nationally and decide on approval or denial. The member states in the relevant zone have 1 year from the application date to reach a decision – unless it has been necessary to ask for further information – in which case the period is prolonged to 1½ year (clock stop). Then the different countries in the zone have a possibility to accept the evaluation with or without changes; or to deny approval.

Of great importance is that *authorization* for a *Plant Protection Product as such* is granted by Member States, as they can be formulated in many ways and used on a variety of plants and plant products, under different, agricultural, plant health and environmental (including climatic) conditions.

EFSA has also issued a "General overview of application procedure for approval of new pesticide active substances and amendment of approval conditions." The overview is divided into four phases: pre-submission phase; submission phase and completeness check; risk assessment phase; and post-adoption phase. The process includes potential applicant pre-submission advice (optional); potential applicant notified studies; applicant submits dossier; Rapporteur Member State performs admissibility check and verifies notified studies. EFSA publishes non-confidential dossier and launches public consultation; Rapporteur Member State makes a draft assessment report; EFSA examines the report and launches public consultation; EFSA performs peer review in consultation with Member States experts; EFSA drafts and finalizes conclusion taking into account the comments received; EFSA publishes the final conclusion; EC prepares draft Review Report and Regulation; Standing Committee on Plants, Animals, Food and Feed opinion.

Regulatory barriers for bio-pesticides – slow and cumbersome processes[47]

The *IRISGROUP* underlines that worldwide more bio-based than chemistry-based pesticides are developed today, but the sale of bio-based pesticides are less than 5% of the total sale of plant protection products. The experienced barriers are especially:

A The approval procedure was developed based on chemical plant protection products and therefore contains demands for tests and documentation, which are not relevant for Biosolutions.

47 The Danish Business Authority (Erhvervsstyrelsen) has asked the "IRISGROUP" to make a report. This report from January 2022 has not been published, but it maps out a number of specific barriers and makes a number of recommendations about harmonization, influencing EU regulation etc. The relevant specific proposals regarding pesticides, novel food and NGT plants will be outlined below. (IRISGROUP)

B All applications come in the same queue, whether they are chemical or biological.

C There are too few resources in the different approval fora to process the applications and the case handlers generally have better insights into chemistry than microbiology.

This matches with the experience from some Danish companies that the two-step approval procedure is bureaucratic and normally takes 7 years, involving a cost of approximately 1 million Euro.

> Companies underline these timelines: Step 1 including approval of the "active substance" in the EU, involving an evaluation by EFSA should take 2–3½ years, but normally takes 4 years. Step 2 involving approval of the product in Member States, involving cooperation between Member States in the Northern, Central or South zone, where one country in the relevant zone makes the evaluation on behalf of the zone, should take 1½ years, but normally takes 3 years.

Moreover, Danish companies argue that there is a long waiting list in Member States and a lack of resources and limited experience assessing biological products, creating difficulties for applicants to find a suitable Rapporteur Member State. Consequently, European farmers wait longer for new biological products to reach the market, as the approval procedure stands out compared to other countries/regions, such as the US, Brazil etc., who all have significantly faster processes.

Despite a clear strategy from the EU to reduce the chemical-based and use more bio-based plant production products, the reality is that with the duration of getting an approval often being 7 years, it will be very difficult to reach the Farm-to-Fork goal of diminishing the chemical pesticides by 50% before 2030, 6 years from now.

Proposal: Regulatory sandbox on bio-pesticides, including fast track:
When considering making a regulatory sandbox on biopesticides, it seems relevant to include, 'what is the purpose of such a sandbox?', 'who should take the initiative?', 'what is the legal basis?', 'what conditions should be made for being included in the sandbox?' and 'what should the content of a sandbox be?'.

Purpose of a bio-pesticides regulatory sandbox

The purpose could be introducing new innovative bio-pesticides solutions, which are low risk, supporting sustainability, the green transition and the EUs competitiveness and as part of the sandbox speed up and simplify the approval process. It will be in line with the EU's innovation principle, Farm-to-Fork strategy and better regulation proposals to simplify regulations. The purpose includes ensuring the safety issues, but disregarding processes which are disproportionate to safety issues and EU fundamentals. Simplifying regulations is in line with EU policies and strategies, and to make better use of bio-based pesticides is beneficial for innovation, sustainability and competitiveness.

Initiative to make a bio-pesticides regulatory sandbox

The initiative could be taken politically as part of a political strategy – maybe part of a National Action Plan for Biosolutions. If a national one-stop-shop/single point entry is made[48], it seems relevant to include this in the initiative. This could for example be the Danish Business Authority (Erhvervsstyrelsen). Together with the Environmental Protection Agency (Miljøstyrelsen), they could collaborate as "competent authorities" on this sandbox project on bio-pesticides.

They could discuss the Bio-pesticides regulatory sandbox in the proposed Biosolution Forum with other agencies and use the experiences obtained from the Danish Financial Supervisory Authority (Finanstilsynet) and the Maritime Authority (Søfartsstyrelsen). Moreover, the project could be discussed in the proposed Biosolution Forum+ (see above, 9.1 and 9.2) with relevant companies (large companies and SMEs), researchers (for example Biosolution center at the University of Copenhagen) and the Business Lighthouse Zealand.

Maybe the Netherlands, France and Belgium could be encouraged to join the sandbox.

The legal basis and framework for a bio-pesticides regulatory sandbox

The *legal basis* creates the framework for the regulatory sandbox. As the Net-Zero Industry Act includes Biosolutions in their provisions on regulatory sandboxes, this will constitute the legal basis. As the Net-Zero act does not enable derogations from EU law, it may be necessary to use purpose-driven interpretation of current Danish and EU regulations as the legal basis. Other options could also be explored.

The legal framework for the Bio-pesticides sandbox is dependent on the legal basis for it. The new EU trend to include provisions on regulatory sandboxes in new acts, entails that some conditions are in the acts. These conditions may concern the establishment, including who is to take the initiative and who supervises the sandbox. They may also concern the competences of the regulatory sandbox, including to which extent exemptions and derogations can be made regarding national regulation and regarding EU regulation. As the Net-Zero act does *not* allow derogations from EU law, this outdated regulation still creates the framework, and the challenge is to find ways to allow constructive solutions within the current EU regulations. This is not an easy task, but can be helped by purposedriven interpretations and implementation.

The *Danish* part of the process, described above, can in principle be changed, as derogations from national law are allowed in the legal framework NZIA. The process could thus be made faster and less cumbersome in a number of ways. A fast track could be made, see below. It could be explored if the Danish manual from 2023 could be simplified. It could also be explored whether the risk analysis could include a more holistic approach, taking for example effects on the green transition, the effect compared to chemical pesticides etc. into account. Finally, it could be explored how to ensure more staff skilled in Biosolutions, including the potential in the new Kalundborg education.

48 Article 6 in the Net-Zero Industry act, see 10.3.

The *EU part* of the process, described above, adds complication as changes to EU regulations normally cannot be made. It would be beneficial in order to speed up procedures to make efforts to live up to the timelines in the current binding regulations. Otherwise, it does not make sense to have strict deadlines in the binding regulations. Moreover, it could be explored how to make a fast-track solution also for the EU part of the approval procedure. It could be explored if some of the discretionary "openings" in the current regulation could be used in order to enable relevant sandboxes on bio-pesticides. Of relevance could be the EU 1107/2009 Regulation, article 22, on low-risk substances, article 30 on provisional authorizations and article 54 on research and development. Especially article 30 on authorizations for a limited period could be of interest, especially if bio-pesticides could be taken to the market for a limited period and in this period be monitored.

> Article 22 creates a lighter procedure regarding low-risk active substances. Article 30 creates a possibility for Member States to "provide authorizations for a limited period" under certain conditions. Article 53 may enable prioritized sandboxes if there are no alternatives available in the market to control a specific pest or crop. Article 54 on research and development may create opportunities for a regulatory sandbox on experimentation without an authorization, "if the Member State in whose territory the experiment or test is to be carried out has assessed the available data and granted a permit for trial purposes..."

Conditions and arguments for making a biopesticides regulatory sandbox

Conditions for a regulatory sandbox is primarily established in NZIA, article 33-34 and implementing acts attached to NZIA. Inspiration to be used in the implementation can also to a certain degree be found in the current Danish regulatory sandboxes in Finanstilsynet and Søfartsstyrelsen or sandboxes in other countries, for instance the UK FSA on fintech or other of the examples, mentioned in Part II above.

Conditions would primarily include that an innovative technology is included, that the applicant is willing to undergo supervised testing, and that the application to be part of a regulatory sandbox is approved. The applicant can make arguments for the sandbox: that the regulatory sandbox can include learning between the innovator and the regulator and maybe lead to better regulation; that the sandbox can support sustainability and competitiveness; that the testing will benefit society or consumers; that the innovation is low risk; and that the sandbox is relevant, because crucial elements of current regulations are outdated, and legacy therefore create stumbling blocks for no reason, and because bureaucracy and time-consuming elements of regulation, etc. create barriers disproportionate to the safety issues.

Content of a bio-pesticides regulatory sandbox – testing, fast track, etc.

The basic content of the regulatory sandbox is *testing the bio-based pesticide*. The content of this is primarily produced by the innovator. It could, however, also be fruitful to address the speed, the complex procedure and the outdated provisions as part of the sandbox.

Testing themes for a bio-pesticides regulatory sandbox

The innovator is responsible for proposing the testing themes. This may include the benefits of bio-pesticides compared with chemical-based. The innovator must address the risks and safety for human health, animal health and the environment, and this must be supervised by the supervisory authority: the Danish Environmental Protection Agency (Miljøstyrelsen).

Fast track for a bio-pesticides regulatory sandbox

An important barrier is that case handling times are very long, which is underlined by companies, the IRISGroup and others. The Fit for Future Platform proposed a fast track for innovative, low-risk biological and sustainability enabling pesticides shortening approval timelines to an average of 4 years (instead of 8 years). A fast-track procedure would be helpful.

However, there is also another path to take at the same time. As part of the fast-track procedure, it seems evident to ask the EU Commission and EFSA to *live up to the timelines* in the current regulation and ask the Member States to do the same. This may be problematic in practise due to lack of competent personnell in the relevant areas and may thus neccessitate ensuring enough competent persons to deal with the applications, see 13.4 on competence-building.

As part of the regulatory sandbox, the Danish Environmental Protection Agency (Miljøstyrelsen) can establish a fast-track procedure, just as The Netherlands and France have done. In France an approval is expected within 6–8 months, dependent on whether other Member States need to be consulted, and 12 months regarding traditional chemical pesticides. A Danish fast-track solution may help the approval of bio-pesticides in Denmark. However, as described above, the EU procedures also create a barrier. Contact could be made with the EU Commission and/or other relevant EU authorities regarding fast track in the EU procedure on making a risk assessment and approving the active substance. The Danish Ministry of Environment (Miljøministeriet) has issued a very specific proposal to amend Regulation (EC) No 1107/2009, shortening relevant timelines for the Rapporteur Member State and the EU Commission (article 11 and 13). This would bring the timelines nearer the rather short timelines in the new Net-Zero Industry act for clean-tech approvals.

Risk assessment etc. for a bio-pesticides regulatory sandbox

In the risk assessment involving Danish authorities, it could be explored to which extent a more holistic risk assessment could take place.

A crucial part of the approval procedure is, however, the risk assessment, etc. taking place in the EU. Contact may be made to the relevant EU Commission Authority and EFSA to introduce a more holistic assessment by EFSA, taking also the benefits of the green transition into account. It will probably necessitate that the EU Commission is prepared to change EFSAs mandate, which would be in better line with risk assessments in the health area and new trends in risk assessments. It must be kept in mind, that there is also a risk *not* taking initiatives and implement new solutions supporting sustainability and the green transition and thus helping societies.

Testing of simplifying and updating the approval process for bio-pesticides

The testing of bio-pesticides might also include making specific simplifications of the approval process and updating. These initiatives could help provide evidence that these '*modernization effort*' can happen without jeopardizing safety issues and EU fundamentals. Innovators and authorities could consider making this as a co-creation project as part of the bio-pesticides regulatory sandbox.

It may be possible to point to a number of tests and data, not being proportionate to the safety issues, and thereby *simplifying* procedures – which is also a policy and strategy for the EU. This will necessitate close scrutiny of the regulations to find ways to make a more fit4purpose interpretation of current regulations. Relevant may be guidelines, manuals etc., not being binding, and existing exemptions in the Regulations. This is necessary because the regulations are complex, extremely detailed, etc.

Updating could also be an issue for testing. If it can be documented or made probable, that some regulatory provisions are outdated, and a regulatory sandbox can identify such outdated obligations and allow neglecting these documentations etc., it could prove beneficial for the approval procedure.

> A regulatory sandbox could also allow *extension* of the use on one crop to all other crops without the addition of upfront efficacy data for biological control products. Brazil can be used as inspiration. The Brazilian Ministry of Agriculture's Joint Normative Instructions establishes different protocols for each group of bio-defensive products (bio-based, chemicals etc.) and makes it possible to register bio-pesticides by biological target (pest) and thus, once registered, they can be used in any other crop in which the pest is present.

It could be explored if some of these initiatives are possible, based on a new and purpose-driven interpretation of current EU regulations.

The process on a regulatory sandbox on bio-pesticides, including a fast-track procedure and a debate could start now, with the aim to shorten the approval process from 7–8 years to 3–4 years by making a fast track and perhaps to include simplification, updating and relevant extensions of approval. Maybe the Netherlands, France and Belgium could be encouraged to participate.

Such a bio-pesticide regulatory sandbox may enhance the dialogue and mutual learning process between innovators and regulators, both in Denmark and in the EU, and thus hopefully lead to better regulation in the field of pesticides.

To sum up: Bio-pesticides are important for Europe, including Demark, and a *regulatory sandbox* on bio-pesticides could be prepared now. The Danish Business Authority (Erhvervsstyrelsen) and the Environmental Protection Agency (Miljøstyrelsen) could collaborate on this sandbox project on bio-pesticides. A potential political strategy may also encourage such an initiative. The purpose and content could be elaborated in the proposed Biosolution Forum and Biosolution Forum+, maybe in a special taskforce, including relevant companies (big and SMEs), researchers

(for example Biosolution center at the University of Copenhagen) and the Business Lighthouse Zealand. Contact might also be made with the relevant EU Commission authority and EFSA to enable closer collaboration. Maybe the Netherlands, France and Belgium could be encouraged to join the sandbox.

The aim of a bio-pesticide regulatory sandbox could be to shorten the process from 7–8 years to 3–4 years and to try to make the evaluation process more fit-for-bio-pesticides regarding the dossier with documentation, and more risk-benefit based regarding the risk assessment and the involvement of other EU countries.

A *fast-track procedure*, could be established in the Danish part of the approval procedure, just as The Netherlands and France have done. Negotiations could also be made with the EU Commission, to try to ensure that the deadlines in the regulation are in fact met, and to suggest a fast-track procedure also in relation to the EU part of the approval process.

EFSA could also be contacted in order to introduce and discuss a risk–benefit or holistic risk assessment by EFSA, if the EU Commission is prepared to change their mandate. Educational efforts could be continued and strengthened to ensure competent people to deal with the approval procedure. The testing themes could be determined by the innovators and the regulator (the two Danish authorities) to enable new insights and evidence making it possible to get faster approvals, that still respect relevant safeguards, but speed up the process and make the dossiers more fit for bio-pesticides. This could hopefully lead to more purpose-driven interpretations of current regulations and updated regulations in the years to come.

13.6 PROPOSAL FOR A REGULATORY SANDBOX ON NOVEL FOOD/FERMENTATION

The proposal will include remarks on a) the importance of the area; b) the barriers experienced in practice; c) possible solutions. Possible solutions will include 'what is the purpose?', 'who should take an initiative?' and 'on what legal basis and framework?', 'who can apply and on what conditions?' and 'what can the content of a regulatory sandbox on novel food/fermentation look like?'.

The area of novel food/fermentation is important

While *food* is, of course, important, food safety is essential. Sustainable food systems are desired to reduce the environmental and climate impact on, e.g., food production, reducing waste and the use of land. Obtaining proteins and other food ingredients without requiring agricultural production systems is a challenge.

Along with food production, *fermentation* represents one of Denmark's and Europe's absolute strengths.

Conventional fermentation refers to traditional methods of fermentation that have a long history as an old, well-known and safe method to keep food fresh and safe for longer (cheese, yoghurt, fish, salami, beer, wine, etc.). Fermented food is normally seen as safer and healthier, while combating food waste and reducing unwanted chemicals. New methods are being developed that can be characterized as *novel food.*

Precision fermentation can be used to produce proteins for nutrition and food. *Precision fermentation* is a catch-all term for large scale fermentation, where the purpose is to produce one specific compound rather than altering a whole food. It combines the principle of fermentation, biotechnology and genetic engineering to optimize and control metabolic pathways of microorganisms to produce desired molecules. Using genetically modified bacteria and fungi, such fermentation processes are already widely used in pharma (e.g., insulin production) and in the industrial production of enzymes. In the future, precision fermentation might provide key food nutrients that traditionally could be derived from animals (with a significant carbon footprint), or from plants (with, e.g., excessive irrigation and land use). Examples of specific compounds that could be of interest are specific proteins in milk without cows, essential vitamins (B12), etc. Precision fermentation includes using genetically modified organisms (GMOs) in the process, but any trace of GMO-organisms is normally removed during the process, which means that the *product* does *not* contain GMO[49].

Research is made in this area of food production, and Denmark is home to several companies in the field. This stresses that fermentation technology is now ready to be scaled for industrial production in Europe and beyond.

Problems in practice – current regulations and practices complex and outdated

Fermentation is not a theme for a specific regulation, but interpretations of current complex regulations on food, additives, novel food and GMO food will be necessary to provide legal certainty, as the scope of these special regulations is very broad. They are all about safety for consumers, but they differ when it comes to criteria, procedures and risk assessment. The basic regulation is a general food regulation, another is about food additives, a third about novel food, and a fourth on GMO food. This may create complicated interpretations as to which regulation(s) should be taken into account. The purpose, scope and processes regarding additives, novel food and GMO food will be briefly outlined in order to illustrate the barriers innovators in the field are faced with.

Purpose of current regulation on food - safety, consumer interests and EU fundamentals

Safety is crucial in all food regulations, including the rules in the G*eneral Food Law*[50], the rules on additives, the rules on novel food and the rules on GMO food. Consumer protection and EU fundamentals also play a role.

Additives: The regulation on additives[51] from 2008 focus on safety and consumer protection, not to mislead consumers and also as the first purpose ensuring the internal market:

> **Article 1: Subject matter:**
> "This regulation lays down rules on food additives used in foods with a view to ensure the effective functioning of the internal market whilst ensuring a high level of protection of human health and a high level of

49 From a production point of view (and maybe also from a sustainable viewpoint), it will be easier just to "ferment and eat" like we do with e.g. youghurt, but it may be seen as problematic?

50 The General Food Law Regulation sets out certain procedures relating to food safety. In particular, it provides for a) The establishment of the Rapid Alert system for Food and Feed (RASFF), b) the establishment of the standing committee on Plants, Animals, Food and Feed (PAFF Committee), c) the adoption of emergency measures and d) the establishment of a general plan for crisis management.

51 Regulation (EC) No 1333/2008 on food additives.

consumer protection, including the protection of consumer interests and fair practices in food trade, taking into account, where appropriate, the protection of the environment."

In this regard it is interesting that the US has made a special principle to guide their approval of additives: GRAS, Generally Considered as Safe.

Novel food: The rules laid down for the placing of novel food[52] on the market in EU, are designed to provide a high level of protection for human health and consumer's interests.

Article 1: Subject matter and purpose

"This Regulation lays down rules for the placing of novel foods on the market within the Union.

The purpose ... is to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumer's interests."

The *underlying principles* underpinning Novel Food regulation in the EU are that novel foods must be

a Safe for consumers - not pose a risk to human health, on the basis of scientific evidence.
b Properly labelled - not to mislead consumers, especially when it is intended to replace another food and there is a significant change in nutritional value.
c Not be nutritionally disadvantageous for the consumer, when replacing another food under normal consumption.

GMO food: The purpose of the regulation on genetically modified food and feed (1829/2003) is somewhat broader, based on considerations for human and animal health, the environment, consumer interests and EU's internal market.

"Article 1: The objective of this Regulation... is to:

a provide the basis for ensuring a high-level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market;
b lay down Community procedures for the authorisation and supervision of genetically food and feed;
c lay down provisions for the labelling of genetically modified food and feed".

Scope and processes of current regulations on food

Food additives: These are regulated[53] in a way, where all additives in EU must be authorized before they can be used in foods. The approved additives are listed with conditions of use in the EU's positive list.

52 Regulation (EC)2015/2283 on novel foods.
53 Regulation EC 1333/2008.

According to article 5 "No person shall place on the market a food additive or any food in which such a food additive is present if the use of the food additive does not comply with this Regulation."

The scope of the regulation is food additives (article 2), as defined in article 3, which as a point of departure embraces "any substance not normally consumes as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value...". The regulation does not apply to food enzymes falling within the scope of Regulation 1332/2008 on food enzymes.

The authorisation procedure starts with submission of a formal request to the European Commission consisting of an application dossier on the substance, containing scientific data on its proposed uses and use levels. EFSA evaluates the safety of new additives or proposed new uses of existing food additives, based on a) a safety assessment; b) the technological need; and c) ensuring that use of the additive will not mislead consumers. All additives are identified by an E number.

Food additives are always included in the ingredients lists of food in which they are used. The regulation in Annex I-V sets up rules on definitions, conditions of use, labelling and procedures. Authorisation procedures are based on the principle that it is for the applicant or the notifier to prove that the subject matter complies with Union requirements.

In Denmark, the Danish Food Agency plays a role in the authorization procedure of additives and has established a one-stop-shop to help innovators.

Novel food: This is an interesting area, where specific regulations were issued in the EU, based on a fear that novel food might be dangerous. Novel food regulation covers food not used before 1997 in Europe[54].

Novel food must be risk assessed and approved, before being marketed in the EU. Novel food includes microorganisms, fungi or algae.

The current regulation is *Regulation 2015/2283* and *Commission Implementing regulation* (EU) 2017/2469 dealing with administrative and scientific requirements. EFSA has also made detailed guidance. Compared to previous regulations the aim of the 2015-regulation was a.o. to improve conditions so that food businesses can easily bring new and innovative foods to the EU market, while maintaining a high level of food safety for European consumers. The main features and improvements include expanded categories of novel food (a.o. microorganisms, cell cultures, insects and food supplements); a generic authorization, which is not applicant-specific; and simplified, time-bound procedures. A simpler procedure has been established for certain products, but generally the criteria and requirements are rather strict.

In *Denmark* the Ministry of Food, Agriculture and Fisheries, The Danish Food Agency has issued "Guidance on Novel Food" (26 pages).

54 The definition is expanded in article 2: "Novel food means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, ...that falls under at least one of the following categories: food with a new or intentionally modified molecular structure, food consisting of, or isolated from microorganisms, fungi or algae; ...."
55

The regulation is complex, there are uncertainties, and the procedure is quite lengthy. The time-to-market can thus be rather long. It is normally 1½ years, but it may be prolonged if EFSA asks for more information. The simplified procedure takes 5 months. The approval process for novel food is somewhat different from that of bio-pesticides, but both EU, EFSA, Member States and the company are involved in the process.

An *applicant who* intends to place on the EU market a novel food can submit an application to the EU Commission. The company must determine whether the product is covered by the legislation. If they are unsure, they may consult the Danish Food Agency (Fødevarestyrelsen) by providing all the necessary information. The national authorities may consult colleagues in other EU countries and the European Commission. The application must include details, such as the name and description of the novel food, its detailed composition, production processes and scientific evidence, confirming that it does not pose any danger to human health. Technical data about nutrition, toxicity, risk assessment etc. are required.

A food is considered *novel* if it has not been used for consumption before 15th May 1997 and falls within 10 categories, consisting of, for instance, microorganisms, fungi or algae, animals or animal parts for instance insects, plants, etc. – unless long lasting safe use as food in the EU and produced by traditional propagation methods, etc. This covers a wide range of products.

The *EU Commission* – after having verified the validity of the application – makes it available to Member States and mandates EFSA to make a scientific assessment. The authority shall adopt its opinion within nine months of the date of receipt of an application. The EU Commission must establish a positive list of authorized novel foods and update it regularly.

EFSA performs risk assessment of a novel food application on the safety upon the request by the European Commission. The assessment is based on dossiers provided by the applicant. The risk assessment may ask for more data and scientific tests, which may prolong the time of assessing the risk. A deadline of 9 months has been issued to secure a smooth process, but some experience from companies suggest that the process often takes 1½ years.

The *EU Commission* sends a draft approval to a vote among the Member States. The Commission presents its final opinion on whether to authorize a novel food to the Standing Committee on Plants, Animals, Food and Feed. Its endorsement is necessary before the new product can be added to the positive list. The EU- Commission should normally make the process within seven months. In special circumstances the case processing time may be prolonged – in which case reasons must be given.

A simpler procedure has been established for certain products, for instance nuts, fruits and seed, where the data requirements are lighter, and they do not include toxicology. The criteria and documentation are, however, rather strict: long-term use of the novel food is required and that it has been consumed for at least 25 years as part of the usual diet in at least one country outside the EU. In addition, the novel food must have been consumed by a significant number of people. Normal case processing time must not exceed 5 months if there are no objections and 10 months if there are security-related objections.

The Novel Food regulation does not apply to genetically modified foods covered by special regulations, or foods used as enzymes, additives and flavoring covered by specific *regulations*.

GMO food: Genetically modified food must not "have adverse effects on human health, animal health or the environment, mislead the consumer or differ from the food which it is intended to replace to such an extent that its consumption would be nutritionally disadvantageous for the consumer." It must not be placed on the market unless it is covered by an authorisation granted and the relevant conditions of the authorisation are satisfied (article 4).

The *scope* is "foods which are to be delivered as such to the final consumer or mass caterers in the Community, and which:

a contain or consists of GMOs; or

b are produced from or contain ingredients produced from GMOs".

Special *exceptions* are made for instance regarding foods containing less than 0.9 % of the food's ingredients considered individually, and appropriate lower thresholds may be established a.o. in order to take into account advances in science and technology.

Application for authorization involves a rather complicated procedure, where the national competent authority, risk assessment, opinion of the authority, the EU Commission, the Member States etc. After an authorization has been issued, supervision will take place – post-marketing monitoring – and the EU Commission shall be informed of any new scientific or technical information which might influence the evaluation of the safety in use of the food (article 5–9).

Barriers according to the IRISGROUP

According to the report from the IRISGroup, the barriers regarding novel food are primarily:

1 To make a novel food application is both time-consuming, complex and costly, and it may take several years to obtain an approval. Some businesses also find it difficult to have an overview of the approval procedure in practice.

2 The fact that you cannot start the approval process until you are deep inside the development of a novel food/ingredients, and that there are no formal possibilities to get counselling from the authorities at the EU-level before and during the assessment of the application.

3 Some algae strains are novel-food-approved, while others are not. The unclear novel-food status for some algae strains hinders the development of new alternative proteins (because you deliberately limit yourself to approved algae strains) and thus creates unequal competition conditions.

4 It is allowed to use (selected) whole insects in food, but not allowed to secrete proteins from insects and use them in food, such as oil or flour. This limits the possibilities for producers of insects to develop new types of products.

Moreover, Denmark has long abandoned rules about pre-approval of microorganisms in food production as superfluous and unnecessarily burdensome, prolonging time to market with at least 3 years and causing considerable administrative burden.

Proposal for a regulatory sandbox on novel food, precision fermentation

When considering making a regulatory sandbox on precision fermentation, it seems relevant to include 'what is the purpose of such a sandbox?', 'who should take the initiative?', 'what is the legal basis?', 'what conditions should be made for being included in the sandbox?' and 'what could be the content of such a potential sandbox?'.

Purpose and benefits of a regulatory sandbox on precision fermentation

The *purpose* of a regulatory sandbox on novel food could be to test precision fermentation and at the same time as part of the regulatory sandbox to simplify and speed up the approval process. The wider purpose could be to test how to unleash the full potential of precision fermentation, providing innovative, green solutions for the food value chain.

The *benefits* could be faster access to better and more sustainable food. The purpose also includes ensuring the safety issues, but disregarding processes, which are disproportionate to safety issues and EU fundamentals. A regulatory novel food sandbox seems to be in line with regulatory sandboxes in new technological areas, where it is crucial to test safety issues of different kinds. However, in the area of novel food, regulatory legacy is also a challenge, both regarding legal certainty as to which regulation is relevant and regarding complicated procedures about additives, novel food and GMO food. Simplification of regulation is in line with EU policies and strategies, and to make better use of precision fermentation is beneficial for innovation, sustainability and competitiveness. Legal clarity seems to be a theme that also needs focus, as different EU regulations could be relevant in the field of precision fermentation.

Initiative to make a regulatory sandbox on novel food, precision fermentation

The initiative could be taken politically as part of a political strategy – maybe as part of a National Action Plan for Biosolutions. If a national one-stop-shop/single point entry is made[56], it seems relevant to include this in the initiative. This could for example be the Danish Business Authority. Together with the Danish Food Agency (Fødevarestyrelsen) they could collaborate as "competent authorities" on this sandbox project. They could discuss the novel food regulatory sandbox in the proposed Biosolution Forum with other agencies and use the experiences obtained from the Danish Financial, Supervisory Authority (Finanstilsynet) and the Maritime Authority (Søfartsstyrelsen). Moreover, the project could be discussed in the proposed Biosolution Forum+ (see above, 13.3.) with relevant companies (big and SMEs), researchers (for example Biosolution center at the University of Copenhagen) and the Business Lighthouse Zealand. Maybe other Member States could be encouraged to join the sandbox.

The legal basis and framework for a regulatory sandbox on novel food

The *legal basis* creates the framework for the regulatory sandbox, but it is not straightforward. The Net-Zero Industry Act article 33-34 will constitute the legal basis. However, as the Net-Zero act does *not* enable derogations from EU law, the outdated regulation on food still creates the framework, and the challenge is to find ways to allow constructive solutions within the current EU regulations. This is not an easy task. It seems necessary to use purpose-driven interpretation of current Danish and EU regulations. Maybe other options could also be explored.

The *Danish* part of the process, described above, can in principle be changed, to the extent derogations will be allowed in the legal framework. The process could thus be made faster and less cumbersome in a number of ways. A fast track could be made (see below). It could be explored if the Danish Novel Food manual could be simplified. It could also be explored whether the risk analysis could include a more holistic approach, taking for example effects on the green transition, the effect compared to traditional food etc. into account. The possibility of introducing the GRAS (Generally Recognised as Safe) principle from the US FDA could also be explored. Finally, it could be explored how to ensure more staff skilled in Biosolutions, including the potential in the new Kalundborg education.

The *EU part* of the process described above, can not include changes to EU regulations, but it could be explored to which extent "openings" in the current regulation could enable a more purpose-driven interpretation.

Conditions for being part in a regulatory sandbox on novel food/precision fermentation

Conditions for a regulatory sandbox may be found in the Net-Zero Industry Act, implementing regulation, when they are made. Inspiration can also be found in the current Danish regulatory sandboxes in the Finanstilsynet and Søfartsstyrelsen or sandboxes in other countries, for instance the UK FSA on fintech or other of the examples, mentioned in Part II above. Conditions would primarily include that an innovative technology is included, that the applicant is willing to undergo supervised testing, and that the application to be part of a regulatory sandbox is approved.

Content in a regulatory sandbox on novel food – legal certainty, testing, fast track, etc.

The regulatory sandbox could explore if fermentation could be tested in order to generate evidence about safety without the stricter regulations

56 Article 6 in the (proposed) Net-Zero Industry act.

adding stumbling blocks. A sandbox may include plant-beef, milk protein etc., but other areas could be discussed. It could, however, also be fruitful to address the legal certainty, speed, the complex procedure and the outdated provisions as part of the sandbox.

Testing themes: The innovator is responsible for proposing the testing themes. This may include the benefits of precision fermentation compared to traditional food. The innovator must address the risks and safety for human health, animal health and the environment, and this must be supervised by the supervisory authority – The Danish Food Agency (Fødevarestyrelsen).

Legal certainty: As different Regulations could be relevant it could be useful for the innovator, if a sandbox classic was established as a one-stop shop/ Single Entry Point, where guidance could be given to provide the innovator with legal certainty. This is relevant as different regulations with different conditions may play a role. Experiences from the Danish Supervisory Authority (Finanstilsynet) could be fruitful.

Fast track: An important barrier is that case handling times are very long, which is underlined by companies, the IRISGroup and others. A fast-track procedure would be helpful. As part of the regulatory sandbox, the Danish Food Agency (Fødevarestyrelsen) can establish a fast-track procedure. A Danish fast-track solution may help the approval of precision fermentation. Contact could be made with the EU Commission and/or other relevant EU authorities regarding fast track in the EU procedure.

Simplification and holistic risk analysis: It could be explored if the Danish guidance for novel food could be simplified. It could also be explored whether the risk analysis could include a more holistic approach, taking for example the effect on the green transition into account. Regarding the EU Regulations it could be explored whether the approval procedure could be shortened and simplified.

The Danish Food Agency could take the initiative to include this in a regulatory sandbox of novel food, exploring the possibilities of limiting the procedure to other regulatory provisions, for example novel food. Including innovators in the sandbox could enable mutual learning and a possibility of more smooth regulation, still ensuring safety and consumer interests. In the longer perspective, better regulation could be the result.

Further considerations: To unleash its full potential, providing innovative, green solutions for the food value chain, and to bring the EU in better line with international tendencies it would be fruitful to consider how to make a broader regulatory sandbox on food. Ideally this would be a regulatory sandbox, where classic fermentation as a test case is not regulated as additives but remains part of the responsibilities of the food business operator under the General Food Law. This would be in line with the practice in many other parts of the world and thus be beneficial for EU competitiveness. It could even be considered to propose to the EU that a 'class sandbox' on traditional fermentation be established and/or to make a GRAS principle like the US has regarding additives. A regulatory sandbox might also include microorganisms treated as "normal food". It would be good for competitiveness, as it could bring us nearer international regulations, without compromising safety.

The Netherlands used so-called Green Deals to obtain approvals and licenses within the area of novel food through changed procedures, for example in relation to insects for feed, food and medicines, and the regulation of Novel Food was part of the changed procedures. Cooperation with local, regional and European authorities responsible for implementing or changing specific regulations was established. It could be explored to which extent this can be an inspiration that can be used in the search for a legal basis to enable a novel food regulatory sandbox.

The aim could be a sandbox which shifts focus from the process to the product to test if safety issues are taken care of in a proportionate way. It could focus on specific areas, where the *process* includes the GMO, but the *product* does not. In this case the very strict GMO regulation seems unnecessary, and it may also be challenged if the regulations on novel food and on additives are relevant. This would be in line with the regulations in many places in the world and thus benefit EU competitiveness as well as sustainable food.

To sum up: Food and food safety are, of course, of great importance to EU citizens – and people in other parts of the world. There is a demand for *novel food* to support the green transition and competitiveness and to produce sustainable, healthier food to the benefit of society and consumers. *Precision fermentation* could be a relevant candidate for a regulatory sandbox. It is a stronghold for Europe and Denmark. A regulatory sandbox on novel food may include plant-beef, milk protein etc., but other areas could be discussed. The current *problems and barriers* are manifold with regards to getting approval from the authorities, which is necessary in order to go to market. It may be difficult to find out which regulations apply, and the approval procedure is complex, time-consuming and costly, and it may take several years to obtain approval.

A *regulatory sandbox on precision fermentation* could be prepared now with the purpose of making evidence about safety without stumbling blocks in relation to the documentation (dossier), and the approval procedure with the bureaucracy it entails.

The Danish Business Authority (Erhvervsstyrelsen) and the Danish Food Agency (Fødevarestyrelsen) could collaborate on this sandbox project. The purpose and content could be elaborated in the proposed Biosolution Forum and Biosolution Forum+. Contact might also be made to the relevant EU Commission authorities and EFSA to enable closer collaboration. A regulatory sandbox could include comprehensive *counselling*, in order to obtain *legal clarity*. The aim could also include simplifying and easing the cumbersome *approval procedures* and making a simpler procedure with a focus on securing safety. It would be helpful if EFSA could make the *risk assessment* more holistic, including a risk benefit analysis in relation to the

needs of the green transitions, food security etc. It would be extremely helpful if a precision fermentation sandbox could also include *testing* the safety aspects of approving the *food product* instead of the process, which might bring us nearer to the US regulations without jeopardizing safety aspect. However, this can only take place if the EU-Commission is willing to cooperate with Denmark (and other member states?) on the sandbox project.

13.7 GMO/NGT – CONSIDERATIONS ON PREPARING A REGULATORY SANDBOX

Genetically Modified Organisms (GMO) have been a controversial topic and an ethical battlefield in the EU for many years. A heated ethical debate resulted in very restrictive regulation in 1991 – a different approach to other parts of the world, for example the US. Many countries market GMO-based food and export many GMO-based products to other countries – including EU Member States. Outside the EU, several NGT plant products are already on the market or in the process of becoming available on the market.

Now science, the ethical debate and the political opinion seem to be changing, and new regulation has been proposed. However, there are still ongoing controversies regarding GMO.

In the following, a very brief outline is made of some developments in the current regulations on GMO and NGT, and barriers are described. Based on this, some interesting areas for potential future regulatory sandboxes are mentioned.

Development and examples of current regulations and purposes on GMO/NGT

Current regulations: The current EU regulations are numerous and complex. Just to mention a few: an EU directive on deliberate release into the environment of GMOs (2001/18); an EU directive on contained use of genetically modified microorganisms (GMM 2009/41/EF); regulation of GMO food (1829/2003) (outlined above, 14.2). Danish regulations mostly implement EU directives. A basic law is law on environment and genetic technology; other regulations are administrative orders on approval of release into the environment of GMOs; and law and administrative orders on cultivation of GMO crops.[57]

Purposes: The general purposes of the GMO regulations are the protection of human health and the environment, but a broader spectrum of considerations is also present.

According to the preamble to the current directive 2001/18/EF, the directive is based on considerations that living organisms that are the subject of commercial release can reproduce in the environment and cross-national borders and thus have irreversible consequences for other Member States. It is emphasized that protection of human health and the environment requires special attention to the control of risks. It is stated that the directive takes into account the prevention principle and the precautionary principle regarding release into the environment of GMOs. The preamble also refers to ethical principles.

The Danish Law on environment and genetic technology has a very broad purpose: Article 1 stresses that the law shall contribute to protecting the environment and nature so that social development can take place on a sustainable basis in accordance with ethical values and in respect for people's living conditions and for the preservation of wildlife and plant life. Protection of human health in connection with genetic technology is also mentioned.

NGT: In the last decade, a variety of New Genomic Techniques (NGTs) have been developed based on advances in biotechnology.

A proposal on NGT is pending[58]. This should a.o. be seen in the context of a judgment from the Court of Justice of the European Union. In its ruling in Case C-528/16, the Court of Justice held that Directive 2001/18 on release into the environment of GMOs cannot be interpreted as excluding from its scope GMO techniques/methods of mutagenesis which have been mostly developed since that Directive was adopted.

The EU Council requested the EU Commission to provide a study on NGTs, which concluded that the existing GMO legislation lags behind scientific and technological progress and do not sufficiently facilitate the development and placing on the market of innovative NGT products. Plants obtained by NGTs are still subject to the same rules as GMOs.

The EU proposal for new regulation on NGTs is focusing on plants which are not transgenic (mutagenesis and cisgenesis). The proposal creates two distinct pathways for NGT plants to be placed on the market. If they could also occur naturally or by conventional breeding, they are exempted from the requirements in the GMO legislation and no risk assessment must be made. For all other NGT plants, the current GMO rules would apply. They will be subject to risk assessment, an authorization procedure and adapted detection methods and tailored monitoring requirements. According to the proposal[59], it intends to reduce red tape:

> "The proposal intends to reduce red tape for companies and SMEs. In practice the proposed legislation will reduce the complexity, duration, and costs of authorization applications. It also eliminates nearly all costs for NGTs subject to the verification procedure. This is very beneficial for SMEs. Support measures will also be available, especially for SMEs. For instance, they will receive scientific advice before submission of an application. The risk assessment procedures will be simplified as well".

In the *explanatory memorandum* it is underlined: "Safety data are mainly available for plants obtained by targeted mutagenesis and cisgenesis, whereas it is at this stage difficult to draw relevant conclusions on other NGTs and applications in animals and microorganisms." There is significant demand for NGT plants because of their potential to contribute to addressing current challenges in the agri-food system.

57 Lovbkg. nr. 528 af 27.3.2021 om miljø og genteknologi, bekendtgørelser om godkendelse af udsætning i miljøet af genetisk modificerede organismer, lovbkg. rr. 28 af 4.1.2017 og tilhørende bekendtgørelse nr. 745 af 30.5.2022 om .

58 Proposal on plants obtained by certain new genomic techniques and their food and feed, 5.7.2023.

59 Proposal 2023/0226 (COD) 5.7.2023 - on plants obtained by certain genomic

The NGT proposal is still pending, and a decision is expected soon. The proposal does not deal with microorganisms as the EU finds that more knowledge is needed in this area.

Approval procedures: The general picture is that GMOs are to be approved before they can be used in the EU. In the current GMO regulation, the EU uses the precautionary principle, demanding a pre-market authorization for any GMO to enter the market and environmental monitoring. Both the EFSA and the member states conduct a risk assessment, which includes a.o. potential toxicity and potential environmental impact. They report to the EU Commission, which then drafts proposals for granting or refusing authorization.

Microorganisms: Where microorganisms are modified genetically, special rules apply. According to the genetically modified microorganisms (GMM) directive – Contained Use of GMM – users of GMMs must assess the contained uses regarding the risk to human health and the environment. The assessment results in one of four 'classes' ranging from activities with no or negligible risk, to low risk, moderate risk and high risk.

Danish regulations distinguish between different uses of GMOs and different Danish authorities are involved. There is a distinction between experimental releases (Forsøgsudsætninger) and contained use.

The *Danish Agricultural Agency* monitors the compliance with regulations on cultivation of genetically modified crops. As the first EU member state, Denmark has adopted a legislation on co-existence of conventional, organic, and GM crops. The aim of this legislation is to limit the spread of GM material to conventional and organic fields and crops if a GM crop is cultivated commercially.

Barriers according to the IRISGROUP, Fit4Future Platform etc.
According to the IRISGROUP, the experienced barriers from the big Biosolution companies especially are significant in relation to their product development and competitiveness.

The regulatory challenges are:

- The EU regulations on GMO are generally stricter than in the US and China (and expected soon in the UK), where gene technology also moves fast.
- Regulations in EU are process-focused rather than product-focused, which inhibits the development and marketing of products with properties that correspond to existing products, but which are manufactured cheaper or more sustainably on the basis of genetic technology.
- A revision on the current law is under way, but only includes plants, but not animals and microorganisms.

The Fit-for-FUTURE platform also have comments on the GMO Directive:

> "The problem is that the EU GMO Directive sets up the same requirements for 'traditional' genetic modification as newer genetic technologies, which lowers the incentive to innovate using modern gene-editing. The directive relies on the technology used to develop an organism for safety evaluation procedures. This approach was developed in the 1980s before biotechnological innovation accelerated in more recent years. Today, the regulations still focus on product technology rather than product characteristics in the safety evaluation, which has led to research investment being pulled out of the EU and a stalling of innovation there. In addition, sustainability criteria are not considered in the evaluation."

Remarks on potential future regulatory sandboxes on GMO
The following remarks are not specific proposals, as it is not explored to which extent it will be realistic to make sandboxes in this area. It is, however, wise ("rettidig omhu" [due diligence]) to try to foresee which areas could be important in the future and make some efforts to enable regulatory sandboxes on them in the not-so-far future.

Microorganisms: The scope of the new NGT regulation excludes NGT applications in microorganisms with the argument that it "at this stage" is difficult to draw conclusions on safety because of the lack of data. This seems to make a valid argument for making a sandbox on microorganism and this way obtain some of the data, that is lacking in order to be able to risk assess microorganisms. It is important to conduct testing both in contained environments and in the open land in order to generate the necessary data. Relevant safeguards are, of course, crucial in this respect. Outside the EU, new forms of regulation are emerging regarding NGT. The EU risks being excluded from this market. A regulatory sandbox seems to be relevant to prepare for new regulations.

It may be fruitful to consider whether a sandbox regarding microorganisms in NGT-based food could be created. The Fit-for-Future Platform argues for extending the NGT proposal to microorganisms in food, but instead of awaiting this, a sandbox could be proposed to gather new insights. As developments in other parts of the world are expected to continue rapidly, the EU should step up efforts to gather additional scientific knowledge on microorganisms obtained by new genomic techniques. Parallel policy initiative, based on EFSA (scientific) opinion on new developments in biotechnology applied to microorganisms. A sandbox might document if specific NGT products based on microorganisms are as safe as the two types mentioned in the legislative proposal.

GMO plants: There could be a need for tests in the open land of GMO plants, for example plants that may be immune to pests, which could make pesticides unnecessary. In such a case, a number of specific safeguards would be needed. Maybe a competition could be established, with a Biosolution Prize to the person or institution finding relevant ways to make

safeguards that could enable NGT plants to be tested in the open land, with close monitoring. Otherwise, it is hard to see how we can obtain the knowledge and testing necessary to develop NGT plants with the advantages this implies.

Ethical debate: GMO is still a controversial issue. The Danish Council of Ethics underlines that it is ethically problematic to reject GMO sorts of plants, if they can contribute to solve essential problems. They call for new ethical debates. It might be wise to start these debates in order to pave the way for acceptance of new genomic techniques.

From process to product: One of the areas where new approaches could be explored is a move towards approval of products instead of processes this would ease the approval procedure considerably. It could be interesting to obtain nuanced experiences from the US on their approval procedures, as they are more product-oriented than the EU. The Fit-for-Future Platform made a proposal, which speaks in favor of a sandbox: "The opportunities to focus on the potential risk pertaining to the product itself rather than the production process, while still upholding safety requirements for the environment and consumers should be analyzed."

To sum up: GMO/NGT (Genetically Modified Organisms/New Genomic Techniques) could be a relevant candidate for a regulatory sandbox. However, GMO has been a controversial topic in the EU for many years, and a heated ethical debate resulted in a very restrictive regulation in 1991 – which differs from other parts of the world, including the US. While science, the ethical debate and the political opinion seem to be changing, GMOs are still seen as controversial in some member states. The EU has made a proposal to change the GMO regulation, now emphasizing new genomic techniques (NGT). The new NGT proposal focuses on plants (but not transgenic plants) and does not deal with microorganisms. It is stressed by the EU that more knowledge is needed.

Probably *new knowledge* could be provided in connection with a regulatory sandbox. Relevant *testing* is needed to obtain the *evidence* that the EU is asking for before making the new NGT regulations cover wider aspects. A regulatory sandbox could explore some of the possibilities and results research is working with, including GMOs in the *open land*. In such a case, a number of specific safeguards would be needed and could be part of a regulatory sandbox under supervision of the competent authority.

Maybe a competition could be established, with a Biosolution Prize to the person or institution finding relevant ways to make safeguards – for example 'suicide-plants' and other methods – that could enable new valuable knowledge and evidence in the area of GMO/NGT. This could enable knowledge and testing necessary to develop new products with the benefits such innovations are expected to provide to help the green transition, competitiveness, food security, etc.

However, as the GMO topic is still controversial in some member states, this has to be taken into account. It might be relevant to start an *ethical debate* on the topic, and maybe on broader topics such as risk assessment seen in light of the climate challenges we face. The Danish Council of Ethics has in their recent report on GMO pointed to the possibility to contribute to such a debate, and the EGE (European Group on Ethics in Science and New Technologies) could also be part of establishing such a debate.

14 WHO COULD DO WHAT

Elements in the journey from red tape to red carpet – with responsible safeguards as companions – could include a number of initiatives. As always, it is important to point to relevant actors and ask, 'who should be active and responsible for taking initiatives?', and 'what should they do?'.

The EU acts on AI, DLT, Net-Zero Industry and proposal on medicinal products reflect a very clear sign from the EU that many more sandboxes should be established. In this respect, it is important to be aware of the fact that many barriers are due to the implementation of regulations, not necessarily the regulation itself. Civil servants in the EU Commission and relevant agencies may very well be future-oriented, wanting to help break down barriers and should be encouraged to do so. The new EU approach may be used as a 'door-opener' to make EU authorities more eager to help break down the barriers and to encourage and enable the transition to regulatory sandboxes as a traditional tool in areas where the three visions on sustainability, innovation and competitiveness are present.

The UK has established a fund: "Engineering Biology Sandbox Fund", which will support innovative engineering biology sandboxes which aim to accelerate pro-innovation regulatory reform and encourage business innovation and investment. UK regulators can apply to the fund (EBSF) with sandbox projects that accelerate regulatory reforms for engineering biology-derived products and improve the quality of decision-making when assessing these products. The fund will invest 5 million £. To be eligible for funding you need to exercise a "regulatory function".

In Denmark the Danish government in June 2024 presented an innovation package "World Class entrepreneurship country" (Et iværksætterland i verdensklasse"), where regulatory sandboxes within for example Biosolutions are mentioned and supported. The total funding for the scheme will be 2.1 billion DKK from 2024-2026. It would be fruitful as part of the scheme to copy the UK position and create funding for such sandboxes, including regulators.

14.1 RELEVANT ACTORS AND THEIR ROLES

Denmark can take initiatives and collaborate with EU institutions and other Member States to make regulatory sandboxes become a powerful tool. As the regulatory sandboxes are a relatively new phenomenon in the EU context, Denmark has a sublime opportunity to be *"first mover"* to make proposals for relevant regulatory sandboxes in the area of Biosolutions.

Relevant actors to unfold the potential of Biosolutions regulatory sandboxes are manifold.

Ministers and politicians already play a major role in encouraging Biosolutions sandboxes and helping break down barriers. The *political will* to propose and promote some measures, enhancing the companies' ability to take their Biosolutions into the market – and take them there faster – seems present. It is recognized that Biosolutions are important areas for Denmark and the EU. Their influence on EU politicians and EU authorities is decisive. Moreover, they can enable collaboration between ministries and agencies and make sure that their policy wishes are implemented. A National Action Plan would be a potent tool. It may be fruitful for relevant politicians to make a research visit to The Netherlands, Belgium, France, the US and maybe Brazil.

Authorities (ministries, supervisory authorities, agencies etc.) are also crucial actors. It is important that they implement policies and strategies, but also make proposals themselves, which seems to be on the agenda in some ministries and agencies. A debate on the need for change of culture regarding flexible interpretation and administration could be fruitful. They can also ensure efficient collaboration with colleagues in other ministries, agencies, companies and researchers. The impression from conversations seems to be that this is already on its way in some of the ministries and authorities. The Danish Financial Supervisory Authority (Finanstilsynet) and the Danish Maritime Authority (Søfartsstyrelsen) have paved the way and now have experiences operating regulatory sandboxes generation 1. Politicians and authorities could take sandbox enabling initiatives, to deal with capacity shortage in Denmark and secure sufficient skilled staff, education etc., where Business Lighthouses can play a major role (Knowledge Hub Zealand etc. is a good beginning.)

Innovators, for example companies, play a crucial role to make innovative processes and products, to point to barriers in the current regulation and practice and to be part of new regulatory sandboxes and influence their purpose, the testing themes. etc. They are generally very helpful in this respect.

The primary task of *researchers* is to use their research expertise to find new methods and basic research, but some collaboration with authorities and companies may also be fruitful. To a certain extent, this is also taking place already. It is paramount to include both science and law research in order to encourage and foster new regulatory models, to encourage purpose-driven interpretation and to be creative regarding regulatory experimentation.

14.2 PARTNERSHIPS AND CO-CREATION

Partnerships could be established to join forces. The experience from existing regulatory sandboxes in other member states has shown that cooperation with EU authorities and partnerships with other member states may foster regulatory sandboxes. Politicians and authorities could make joint efforts to enhance cooperation with relevant Member States, for example The Netherlands and France. They could also jointly work for close cooperation with relevant EU institutions. This implies dialogue on regulations and sandboxes, both in general terms and specific proposals, shortage of capacity and potential obligations for Member States to appoint experts.

Authorities and researchers should start a conversation with EFSA about the possibilities of making a holistic approach to risk assessments, including risk–benefit analysis, where sustainability aspects are taken into account. This may be inspired by the medical area with their efficiency check and multidisciplinary approach – and maybe in collaboration with relevant Member States.

Politicians and the Danish Council of Ethics could start an ethical debate about GMOs and more general risk assessment and the precautionary principle balanced against the climate challenges.

Authorities, innovators and researchers can use the Biosolutions Forum+, if established, to make proposals for sandboxes in relevant areas – agrifood could be a focus point with bio-pesticides, food and GMO/NGT, but other areas could also be relevant.

> Proposal from the Fit4Future Platform:
> "Enhance the cooperation within EU the group of biological experts from Member States and EFSA that, in close collaboration with the Commission, will be responsible for development of new guidance for substances falling under the definition of biological control. This would guarantee a consistent and scientifically sound approach that would at the same time considerably speed up procedures".

14.3 EU BIOTECH ACT

It is an important *step forward* here and now, that the Net-zero Industry Act (NZIA) includes possibility to establish regulatory sandboxes on Biosolutions. This enables sandboxes, as the legal basis will then be clear. Such regulatory sandboxes in the area of Biosolutions can foster innovation at some scale, if used to their full potential. Regulatory sandboxes based on the Net-Zero Industry Act can, however, only grant derogations or exemptions to a limited extent – national law but not Union law - which will scale down the potential for their use. In the Biosolutions area, where most of the law is comprehensive and detailed EU Regulations, this may create serious limitations for the regulatory sandboxes. The legal basis is taken care of, but not necessarily the need for exemptions. Flexibility in interpretation, implementation and enforcement may pave the way to a certain extent, but a clear legal basis would be much better.

Thus, the need for a *Biotech Act* is still present, as the room for derogation does not necessarily present flexibility enough. Especially, regulatory sandboxes in areas where regulatory legacy presents outdated, complex and detailed regulation could be encouraged, including ways to accept purpose-driven interpretation of administrative procedures. An EU Biotech Act could enable regulatory sandboxes with exemptions in a number of specific regulations within the area of Biotech, including Biosolutions, un-

der certain conditions and including safety measures. It could be explored to which extent the national 'France Experimentation' - and other countries making such general provisions enabling exemptions - could serve as inspiration.

With a longer perspective, the current complex, detailed EU regulatory landscape might be changed to an *EU framework regulation*, with much more flexibility and agility than the current patchwork. Inspiration may be achieved from the area of products, where such a transformation has taken place. Such a framework regulation could cover the whole Biosolution area and make regulations less fragmented and silo based. It could focus on the more principled questions, primarily dealing with safety issues, and not have the variety of complex approval procedures we see now.

In the meantime, it would be useful to create an *overview* of the specific Biosolutions regulations. A comparison on the different safety issues, scopes, approval processes with dossiers, involvement of other EU countries and EFSA, and risk assessments, could make it easier for the innovators, the regulators, the researchers and others to grasp, what the regulation embraces and demands. An AI tool could probably pave the way to such an overview.

In the Communication on Building the Future with Nature, mentioned above (1.2) the EU Commission plans on mapping key current bio-based value chains, analyzing the regulatory framework and the impact of relevant legislation, and thereby lay the foundations for a possible EU Biotech Act.

An EU Biotech Act could be modelled over the Net-Zero Industry Act and may also be inspired by the act on medicinal products mentioned above (10.1–10.4). The Biotech act could focus more on the areas where regulatory legacy with old-fashioned, complex and detailed regulation creates massive regulatory barriers. More openings to derogations from both national and Union law could be part of the Biotech law. The relevant conditions in the Biotech Act can include the essence of safety measures, including human health, animal health, environmental considerations and EU fundamentals. It would be helpful to widen the risk assessment, including a more holistic view, taking the green transition and the "better than" aspect into consideration. Delegated acts could elaborate on specific conditions, tasks and outcomes.

For inspiration, some crucial elements of such regulation could be:

> To unleash the huge potential of biotech solutions regarding food, health, the environment and the green transition, Member States may establish regulatory sandboxes in the following Biotech areas:
>
> a Plant protection products
> b Food, including novel food
> c Food using new genomic techniques
> d ...
>
> The regulatory sandbox shall provide for a controlled environment that fosters innovation and facilitates the development, training, testing and validation of innovative Biotech for a limited time before their being placed on the market, or putting into service. The process shall happen pursuant to a specific sandbox plan agreed between the providers or prospective providers and the competent authority. Such sandboxes may include testing in real world conditions supervised therein.
>
> Biotech regulatory sandboxes shall be made in close collaboration with industry and with relevant research institutes, local and regional authorities, social partners and civil society. The sandbox shall also foster regulatory learning and may include testing new administrative procedures, documentation etc.
>
> Competent authorities shall provide, as appropriate, guidance, supervision and support within the Biotech sandbox with a view to identifying risks, in particular to health and safety, the environment and fundamental rights.
>
> The Biotech sandboxes' effectiveness, advantages compared to traditional products and methods and potential in relation to health, the environment and the green transition, should be taken into account when deciding whether to grant a permit to a Biotech regulatory sandbox.
>
> Depending on the characteristics of the Biotech product, derogation from both national law and EU law should be permitted. In this respect it should be taken into account, if the product is low risk, more effective than traditional products and beneficial for the green transition.
>
> The competent authorities, both national and EU, shall exercise their supervisory powers in a flexible manner using their discretionary powers when implementing and enforcing legal provisions to a specific Biotech regulatory sandbox project, with the objective of removing barriers, alleviating regulatory burden, reducing regulatory uncertainty, and supporting innovation in Biotech.
>
> Competent authorities shall provide guidance on regulatory expectations and how to fulfil obligations regarding safety, health and the environment. National and EU competent authorities and other relevant fora shall cooperate in order to fulfil the objectives of this act.
>
> Special attention shall be paid to SMEs and start-ups.
>
> Contact points shall be designated by Member States in order to facilitate the establishment of Biotech regulatory sandboxes.
>
> Implementing acts may make more detailed arrangements for the Biotech regulatory sandboxes.

14.4 DENMARK AS A CENTER OF EXCELLENCE FOR BIOSOLUTIONS

Proposals have been made to make Denmark a 'Center of excellence' for Biosolutions, which seems innovative and future oriented. Denmark could initiate any dialogues with other member states and EU institutions. Testing in regulatory sandboxes could happen in Denmark. This would benefit sustainability, competitiveness and innovation.

It seems fruitful for Denmark to take initiative, as we have strongholds and can be seen as a frontrunner in the Biosolution area. We have excellent research, many big and small companies, making Biosolution products and bio-innovation. We focus on education and a skilled workforce. Being a small country, we are used to dialogue between different actors, nationally, and we can continue relevant dialogues with the EU Parliament, the EU Commission, different relevant EU authorities, EFSA etc.

It would be essential to make sure that learnings from Biosolutions and from Biosolution regulatory sandboxes are communicated broadly to the benefit also for other countries in the EU. In this way it could be seen as more beneficial to keep the development within the EU instead of exporting it to other places in the world, such as the US, China, the UK etc.

This golden opportunity necessitates a very active effort to be cooperative, creative and co-creative to play a crucial role in reaping the fruits of the bio-evolution and remain a frontrunner on Biosolutions.

14.5 THE WAY FORWARD

Initiatives can be taken in Denmark to clarify the political will and relevant fora etc. can be set in motion. This is relevant for the proposals on establishing a one-stop-shop, a Biosolutions Forum and a Biosolutions Forum+.

Parallel with the Danish initiatives, it could prove fruitful to contact potential partnership countries, for example The Netherlands and France, to start a dialogue on making 'joint ventures' or a Memorandum of Understanding regarding regulatory sandboxes on bio-pesticides, and Novel food/fermentation, etc.

Contacts can also be made to ESMA and the EU Commission, the relevant DG, to introduce the idea of a risk assessment, including also benefits to sustainability and competitiveness. Such a risk–benefit assessment could ensure that sustainability, etc., is taken into account, when it is decided whether to accept a (low-risk) Biosolution process or product as a sandbox or even as an approval to go-to-market.

Dialogue with the EC Commission could also include the principles of regulatory sandboxes in the area of Biosolutions. With reference to the EU's Net-Zero Industry Act, the EU's own visions and strategies regarding sustainability end competitiveness, and the urgent need for flexibility, speed etc., the way may be paved for regulatory sandboxes in the area of Biosolutions. These could explore and test safety issues in new areas, but also engage in modernization of the complex and cumbersome approval procedures. It is obviously in the interest of the EU to start this journey towards more flexible regulation to stop red tape and start a journey towards regulation more fit4innovation, fit4purpose and fit4future. Relevant DG's, ESMA etc., could be contacted.

This way - and with the help of Danish and EU politicians etc. - the idea of accepting flexibility also in the EU system, when interpreting and enforcing regulations in the Biosolution area, could be presented and debated in light of the very clear policy visions. Debates may for example be on the question of which safeguards are essential, whether changed administrative processes in the tests of regulator sandboxes could be accepted, and whether a holistic risk assessment taking into account the need for a green transition can be introduced, see part III.

It could be fruitful to go deeper into the regulatory approaches in the *US* – not to adopt their solutions as such, but to see if some of their findings could be an inspiration for the EU. One example could be the GRAS (Generally Regarded as Safe) approach, taking into account if products are considered generally safe. Another example could be the approach on products instead of processes – in a way adopting the new tendency to technology-neutrality into the area of Biosolutions.

Denmark could play a role to the benefit of Danish and EU companies and thus help speed up the EU and enable innovation, the green transition and competitiveness in relation to other countries. This way Denmark can be a stronger player and a green frontrunner helping innovators and societies to speed up the transition from red tape to red carpet.