OECD Regulatory Policy Working Papers No. 18

Case studies on agile regulatory governance to harness innovation: Civilian drones and bio-solutions

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https://dx.doi.org/10.1787/0fa5e0e6-en

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Authorised for publication by Elsa Pilichowski, Director, Public Governance Directorate.

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Case studies on Agile Regulatory Governance to Harness Innovation: Civilian Drones and Bio-solutions

Guillermo Hernández*, Miguel Amaral*

Abstract

This paper aims to enhance the evidence base underlying the implementation of the OECD Recommendation for Agile Regulatory Governance to Harness Innovation by means of two case studies focusing, respectively, on civilian drones and bio-solutions. Each of the case studies focuses on the key transformative impacts of the innovations at hand as well as the associated regulatory challenges and responses. In addition, they provide a number of relevant concrete examples.

Acknowledgements

This paper was prepared by the Regulatory Policy Division, headed by Nick Malyshev, under the direction of Elsa Pilichowski, Director of the Public Governance Directorate. It has benefited from the support and co-operation of the Danish Business Authority, as well as from valuable inputs from David Winickoff, Rex Deighton-Smith and Elisabeth Windisch (all from the OECD), Angela Lynch and Rory Hedman (both from the UK Civil Aviation Authority). It was prepared for publication by the OECD Secretariat.

JEL Classification: D7, H11, K00, K2, L5, O1, O33, O38

Key words: Regulatory policy, Better Regulation, regulatory governance, agile regulation, innovation

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Introduction

This working paper encompasses two case studies on regulatory governance focusing on civilian drones and on bio-solutions - the use of renewable bio-resources for industrial scale production, for example with a view to creating alternatives to petro-based and chemical products.

The case studies complement the series of Case Studies on the Regulatory Challenges Raised by Innovation and the Regulatory Responses developed jointly between the OECD and the Korean Development Institute (OECD/KDI, 2021[1]). They explore a range of issues pertaining to agile regulatory governance beyond "purely digital" innovations (e.g. smart contracts, *fintech*) focusing on the main transformative impacts of the innovations studied and their associated regulatory challenges and responses providing concrete examples.

Both case studies present a similar structure. First, they outline key elements of background and context. They then summarise the main transformative impacts of the innovation at hand. They subsequently discuss the main associated regulatory challenges as well as the regulatory responses that may help address those challenges, and present a short number of forward-looking conclusions.

The case studies illustrate the need for fit-for-the-future and innovation-friendly regulation, especially given the uncertainty surrounding decision-making processes in innovation-dominated policy areas. They also highlight the need for a whole-of-government approach to regulation and the crucial importance of testing, piloting and experimentation. As such, they are expected to further enhance the evidence base underlying the implementation of the OECD Recommendation for Agile Regulatory Governance to Harness Innovation.[1]

Note

[1] OECD/LEGAL/0464; available at https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0464#supportDocuments.

References

OECD/KDI (2021), *Case Studies on the Regulatory Challenges Raised by Innovation and the Regulatory Responses*, OECD Publishing, Paris, https://doi.org/10.1787/8fa190b5-en. [1]

1 Case study 1: Drones

Introduction

This case study explores a range of regulatory governance issues with regard to drones, which have the potential to become a reliable technology for civil, commercial and leisure use. However, existing drone regulations often lag behind technological advances, causing reluctance among potential adopters or hampering new developments (ITF, 2021[1]). Indeed, while drones have significant market potential, they raise multiple regulatory challenges, such as the need for data from real-life occurrences for informed, evidence-based decision making. In particular, this case study illustrates the need for future-proof and innovation-friendly regulation, especially given the uncertainty surrounding decision-making processes in innovation-dominated policy areas (of which drones are a prime example). This uncertainty can be a barrier to innovative start-ups and businesses who are developing new solutions while trying to navigate existing regulation. It also illustrates how regulatory policy can allow innovative solutions to be tested, developed and brought onto the market while upholding crucial regulatory protections for citizens and the environment.

Background and context

The International Transport Forum (ITF) defines drone as "all flying vehicles without a human operator on board" (ITF, 2018[2]), regardless of automation levels; drones can be manually piloted, remotely piloted or fully autonomous. Many drones are capable of vertical take-off and landing (VTOL) and thus do not require a runway to launch. This case study adopts the ITF's definition of drone. It should be noted, however, that a number of passenger transport services using drones will initially have a human pilot on board.

Drones can be used to transport passengers as well as freight. They also have the potential to support the performance of the transport system or carry out surveillance activities. This case study focuses on passenger drones as well as drones used for freight and delivery services, and many of its findings and conclusions will apply to drones in general. The terms drone, unmanned aircraft systems (UAS) and urban air mobility (UAM) vehicles will in some cases be used interchangeably in this case study.

In urban environments, passenger drones have the potential to be used for three main applications: intra-city flights, airport shuttles and intercity flights (see Table 1.1 for more details). Manufacturers are currently specialising in the production of three different types of aircraft catering to those needs: City Taxis with a range of 15 to 50 km, which would cover inner-city needs (e.g. during rush hour, when even short distances can be time consuming); Airport Shuttles with a similar range, which would bring travellers to airports, and Intercity Jets, which could cover distances of up to 250 km and would connect major cities (Roland Berger, 2020[3]). In addition, some projections suggest that long-distance passenger transportation without pilots on board could be introduced from 2030 onwards (ITF, 2018[2]). Passenger drones may be used to improve accident and disaster response, both by significantly reducing response times and enabling quick transport of injured persons to hospitals (e.g. blocked, congested or damaged roads). This can improve the number

of lives saved as well as the quality of the saved life in cases of life-threatening conditions such as cardiac arrest. Some analysts expect the sector to be initially dominated by hybrid, piloted vehicles, with electric air taxis making their debut after 2025, followed by autonomous aerial vehicles from 2030 (Frost & Sullivan, 2020[4]). However, experts consulted in the context of this case study indicated that there is considerable uncertainty regarding the timelines for adoption.

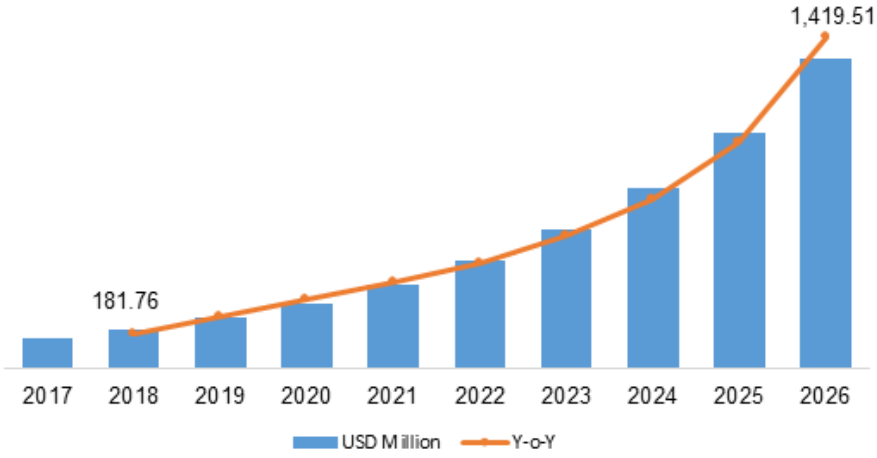
Table 1.1. Use of passenger drones across urban environments

Factors	Intracity	Airport shuttles	Intercity
Typical distance	Up to 50 km	Up to 100 km	Up to 200 km
Route type	Not fixed	Fixed	Fixed
Number of passengers	1-2 passengers	2-4 passengers	2-4 passengers
Luggage	20-30 kg	50-80 kg	30-50 kg

Source: (FutureBridge, 2020[5])

Estimates for passenger drones sold anticipate exponential growth, from about 450 units in 2025 to 18 000 units by 2035, or a compound annual growth rate (CAGR) of 45% (FutureBridge, 2020[5]). According to research firm Polaris Market Research, the size of the global passenger drones market (including hardware, software and services) reached USD 181.76 million in 2018 and is projected to reach USD 1.4 billion (CAGR of 29.5%) during the period to 2026. See Figure 1.1, which shows market size projections (bars) and annual variation (curve).

Figure 1.1. Passenger drone market, in USD million and annual growth



Source: (Polaris Market Research, 2018[6]).

Polaris identifies the following companies as the leading players in the passenger drones industry: Ehang, Volocopter GmbH, AeroMobil, Joby Aviation, Uber Technologies Inc., Boeing, Airbus S.A.S., Astro Aerospace, Cartivator, Lilium, and Terrafugia. It also identifies the decline in drone costs and technological advancement as main drivers of the passenger drone market. Additional drivers are the growing urban population and calls for fighting traffic congestion and emissions.

According to a recent study, around 110 cities and regions around the world are working on solutions in this area (Roland Berger, 2020[3]). Polaris' analysis also states that technological innovation enabling the progressive miniaturisation and improvement of components has encouraged investment in passenger drones. However, it points out that safety and privacy concerns are factors restricting market growth

(Polaris Market Research, 2018[6]). According to the ITF, a broader set of issues need to be overcome. Public acceptance will also hinge on environmental, employment and competition impacts, equity considerations, and impacts on real estate and land value.

The market potential of delivery drones is also noteworthy. By one estimate, the drone package delivery market is projected to grow from USD 528 million in 2020 to USD 39.01 billion by 2030, or a CAGR of 53.8% over the period (MarketsandMarkets, 2021[7]). By means of comparison, the global parcel delivery market in 2020 was estimated at approximately USD 500 billion (Apex Insight, 2021[8]). Mordor Intelligence, a research firm, note that"the retail and logistics segment currently dominates the market, and it is expected to continue its dominance during the forecast period due to the increased demand for drones to deliver parcels and packages from retailers, e-commerce providers, last-mile delivery companies, shore-to-ship drone operations, and postal companies". When examining the drivers of market growth, they also point out that, "due to the lack of delivery personnel and the impact of the global pandemic, the necessity to respond to changes in the logistics industry has become more urgent than ever before, and the use of drones may help realise automatic, contactless delivery services on remote islands, mountainous areas, and even within the cities" (Mordor Intelligence, 2021[9]). The transformative impact of delivery drones are further discussed in the next section of this case study.

In addition to the discussion about the drone market presented earlier in this section, it is important to consider the full drone ecosystem, which also encompasses services such as flight operations, ticket brokering, repairs and infrastructure. Roland Berger distinguish five main building blocks within the passenger drone ecosystem, each of which "must be compliant with overarching specifications and integrated with the others to function successfully" (Roland Berger, 2020[3]). Box 1.1 outlines these building blocks in more detail. While they are presented primarily in connection with passenger transport, a number of them are also relevant beyond that context.

Box 1.1. Building blocks of the urban drone ecosystem

eVTOL vehicles: drones must be specifically designed and built for a target market, whether inter- or intra-city travel.

MRO services: VTOL vehicles require *maintenance, repair and overhaul* (MRO) work, both on demand and at scheduled service intervals.

Flight operations: these involve all ticket distribution and passenger operations, piloting of manned/unmanned drone flights and ground handling activities, such as charging and storage.

Physical infrastructure: flight infrastructure (take-off/landing sites and passenger hubs), MRO infrastructure (such as hangars) and connected infrastructure, or nodes of transportation that bring passengers to UAM sites.

Digital infrastructure involving three main components: the Drone Control Centre (systems for remote surveillance); Air Traffic Management and Unmanned Aircraft System Traffic Management; and navigation aids, such as 5G networks.

Source: (Roland Berger, 2020[3]).

Among the above-mentioned ecosystem components (for drones in general), unmanned traffic management (UTM) systems will be of particular importance, not only in terms of efficient functioning but

also to manage environmental impacts and ensure equitable access to take-off and landing areas in areas of high demand (ITF, 2021[1]).

According to Frost & Sullivan, thanks to strong government support and ongoing pilot programs, the United Arab Emirates (UAE), New Zealand and Singapore are expected to be among the early adopters of UAM systems. According to a 2020 note, "Dubai is already on track to be the first city, globally, to commercialise air taxis. With the aim of launching these services within the next two years, companies like Volocopter and Ehang in collaboration with the UAE's Roads and Transport Authority (RTA) have carried out advanced tests. New Zealand's focus on the future of mobility is also evident; since 2017, Kitty Hawk Cora has conducted almost 1000 test flights in the Canterbury region. Singapore is also looking set to enjoy first mover advantage. Volocopter is working closely with a slew of government agencies to assess the feasibility of introducing commercial air taxi services in the city-state. Also in line to be early adopters are Brazil and Mexico who are set to leverage their expertise in helicopter taxis. Meanwhile, the U.S. has been the nerve centre of UAM development, with almost 70% market participants based in the country" (Frost & Sullivan, 2020[4]).

Key transformative impacts

Drones are already transforming economic activities such as delivery services (including essential supplies), farming and agriculture as well as security and surveillance (e.g. monitoring/inspection of infrastructure or industrial works). Mordor Intelligence note, for example, that e-commerce companies are increasingly partnering with local postal authorities, in collaboration with local governments, to launch drone delivery services that help reduce the cost of delivering packages and parcels to remote islands, mountainous areas and cities (Mordor Intelligence, 2021[9]). Drones' potential for improving first aid response times and effectiveness substantially has also been highlighted. Moreover, an ITF note concludes that "drones are proving to be versatile and effective tools in the Coronavirus epidemic" even if, "with drone regulation still in its infancy, their potential is not fully exploited" (ITF, 2020[10]).

Proponents of passenger drones stress their potential for helping to reduce congestion and increase transport safety in urban environments. However, some studies suggest that the mode share of drones is unlikely to be high enough to have significant impact on road congestion, and it has also been argued that drones may put additional pressure on urban space and hence traffic, as (public) space for the build of physical drone infrastructure (i.e. droneports) will be required (ITF, 2021[1]). Drones also have potential for facilitating rescue and emergency assistance services. In addition, passenger drones can provide enhanced connectivity and resilience to remote regions, render scheduling and routing more flexible, reduce infrastructure investment costs and address the potential shortage of pilots.

The OECD Observatory of Public Sector innovation has documented various use case examples of drones for public service delivery, including the following:

- Aerial mapping system for agricultural areas in the United Arab Emirates (OECD, 2019[11])
- Land and building management in Singapore (OECD, 2019[12])
- Incident management and public safety emergency response (combined with gunshot detection technology) at the local government level in the United States (OECD, 2019[13]) (OECD, 2018[14])

Although there are no comprehensive studies on the matter yet and substantial uncertainty levels remain, anecdotal evidence points to potential net economic gains from drone uptake. For example, PWC have estimated the potential impact of drones on the UK's economy. Their analysis suggests that drones could add a net GBP 42 billion (or about 1.9% of GDP) to the country's output by 2030. According to PWC estimates, cost reductions from drone usage will lead to an increase of 3.2% in multi-factor productivity across the UK economy, and spur growth in a range of sectors. In relative terms, the largest positive impact is expected to be on wholesale and retail trade given their intensive use of inputs from the transport and

logistics industry, which will see major efficiency gains thanks to drones (see Box 1.2 for an overview of selected examples of how drones can transform commercial delivery). The public sector is also expected to experience significant gains thanks to reductions in the cost of inputs from other services directly impacted by drones (PWC, 2018[15]). Figure 1.2 shows the projected contribution of drones, in relative terms, to output in key sectors of the UK economy compared to PWC's baseline forecast.

Box 1.2. Use of drones for commercial delivery: selected examples

Delivery using drones can be classified into two categories: i) direct delivery by drones and ii) collaboration of drones with trucks. In areas with sufficient logistics centres, drones can be used to ship directly from warehouses to consumers. If the delivery distance is long, carrying a drone on a truck may be suggested. When co-operating with trucks, drones are transported to a flight-able distance, from where they operate delivery and return to the truck.

Drone-only Delivery

The advantage of using drones for delivery is that it can reduce costs and delivery time, is more environmentally friendly, and is free from road conditions. However, drone delivery involves the issues of safety, noise and accessibility because the delivery takes place by air. Accordingly, commercialisation has been limited due to various regulations regarding aviation.

Starting with Google's affiliated company Wing, companies such as Amazon and Uber are trying to obtain permissions from their Aviation Administrations. The service has been started or tested mainly in small cities or suburban areas. Due to the limitation of battery capacity, the delivery packages weigh mostly less than 5kg and the flight range is mostly within 10km radius. While drones are currently mainly used to deliver small items, as technology evolves, they will be equipped to accommodate more weight and will become the new future version of last-mile delivery.

Drone Delivery by Google Wing

In April 2019, Google's affiliate Wing started operation, which was recognised as the first commercial application of drones in the United States by the Federal Aviation Administration. It launched its drone delivery service in Christiansburg, Virginia, USA on October 18, 2019. The US aviation authorities did not insist on regulating drone delivery, but opened the way for the "drone delivery" business with a regulatory solution that applied an existing charter license.

So far, long-distance commercial delivery using drones has not been permitted in the United States. The U.S. drone regulations, created in 2016, prevent commercial drones from flying out of the pilot's sight. Long-range drone flights were allowed only for testing purposes. Because of this, Wing was authorised to ship commercial drones in Australia, instead of the United States.

The Wing drone, with a wingspan of 1.5m and a weight of 4.5kg, is capable of carrying objects weighing up to 1.5kg, flying at a speed of up to 113km per hour. It is equipped with an additional motor to prevent fall and all flights are supervised remotely by the pilot. There are plans to expand the flight radius from 4 miles (about 6.4 km) to more than 12 miles (about 19.3 km).

Amazon's Experiment on Drone Delivery

In July of 2016, Amazon launched a drone delivery service called Amazon Prime Air. Amazon attracted attention by completing delivery via drone to customers living near Cambridge, UK. All of the delivered goods weighed more than 2kg, including TV set-top boxes and popcorn. At that time, the delivery took only about 13 minutes.

Given that the delivery time of the existing “Amazon Prime” delivery service is about 2 hours, delivery service through drones is expected to significantly shorten the time. The industry expects that delivery via drones will account for more than 80% of all deliveries in the next five years, especially since fast delivery services are gaining popularity.

Drone-Truck Co-operation for Delivery

Long-distance delivery with drones is made possible by loading drones on trucks. This complements the drawbacks of drones regarding long distance delivery. It can also overcome the inefficiency of truck deliveries owing to geographical conditions that restrict ground transportation.

Drones are loaded with cargo in autonomous trucks, then dispatched to deliver goods to their final destinations as they move around the shipping area. After delivery, they return to the autonomous truck and their battery starts recharging. Drones check addresses and deliver to the final destinations automatically.

UPS’s Drone Truck Co-operation

On 20 February 2017, UPS tested a hybrid electric autonomous truck and a drone to transport cargo. The test was conducted in Tampa, Florida, where the population is low, reflecting the characteristics of drones that are unsuitable to fly over long distances. UPS explained that drone delivery would provide faster and cheaper shipping. Unmanned aerial vehicles also save fuel and time because there are fewer stops. They can enhance the efficiency of delivery and reduce the costs of redundant operations. UPS claims that savings of up to 1.6 km per day per delivery could save up to $ 50 million a year.

However, regulations are holding back development of this technology. Under the Federal Aviation Administration (FAA) regulations, it is difficult for UPS drivers to monitor the drone's flight status at all times, which reduces the mileage and delivery time of drone-truck co-operation.

Amazon’s Patent on Drone Truck Co-operation

On December 24, 2019, Amazon registered a unique drone-related patent (US10514690) with the United States Patent and Trademark Office (USPTO). The patent describes how to build a system to support co-ordination between unmanned autonomous vehicles and drones.

Both ground vehicles and drones are managed by a central system. The ground vehicle is dispatched to deliver after completing the loading and unloading in the warehouse, and starts delivery in order. When the ground vehicle arrives near the customer's address, the drone takes over and finalises delivery.

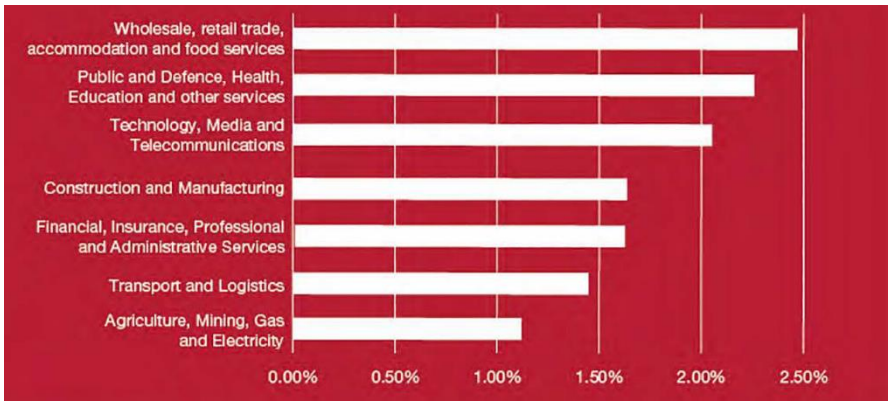
In this system, drones do not need to travel long distances, as the ground vehicle approaches a point that is at least three meters away from the destination, and the drone does not fly far from the warehouse to the destination,. The risk of accidents is reduced and the probability of noise problems is low, as it does not fly over people or private property.

The ground vehicle also serves to charge the drone. This is a great advantage for drones with limited flight times. Ground vehicles do not have to be cars. They can be anything from small mobile robots to large trucks.

While it is not certain yet, it is highly likely that the patented technology will be implemented as it is in the near future. Amazon has started investing in electric vehicle startup Rivian and autonomous startup Aurora, which is expected to accelerate the acquisition of autonomous driving technology.

Source: (OECD/KDI, 2021[16]).

Figure 1.2. Sector GDP impact by drones in the UK in 2030 (%)



Source: (PWC, 2018[15]).

PWC also foresee a "substantial" impact of drone development on UK jobs: "the combination of drones and automation may initially lead to some posts becoming redundant, but over time the gains in cost savings, productivity and consumer demand generated by drones will create new jobs (including about 630 000 jobs in the drone economy by 2030) and have a transformational impact on how we work and live". However, as pointed out by the ITF, given the remaining uncertainties regarding deployment, drones' potential impact on the job market remains difficult to assess (ITF, 2021[1]).[1]

From an economic and industrial perspective, transformative impacts induced by the development of drone-based transport will also come from cross-industry partnerships and acquisitions and investments, such as those having occurred in recent years; e.g. the USD 30 million investment in German start-up Volocopter by Daimler and its consortium partners, and U.S. based Terrafugia's acquisition by Geely, the Chinese parent company of Volvo. Nearly all major automotive firms are likely to enter the UAM vehicles market in the near future. In addition, "companies will need to work closely with real estate firms to acquire land to construct and maintain air taxi terminals and incorporate landing pads in residential buildings", and the UAM market is also likely to lead to "novel business models and services including pay per ride models, leased corporate fleets, and applications like first responder, critical care delivery and security in urban areas", thus creating an entire new ecosystem (Frost & Sullivan, 2020[4]).

The potential benefits of drone development should be carefully weighed against its potential negative effects. These include noise, vibrations and light pollution and their impact both on humans and wildlife; energy consumption, emissions and overall sustainability of drone transport (see Box 1.3 for more details); accountability and liability issues; workforce impacts; social equity; visual amenity (both during flight and for air/ground interfaces) and integrity of the environment, and impact on real estate values and infrastructure financing cost (ITF, 2018[2]). Impact distribution across stakeholder groups will also need to be carefully assessed. If drone services are not affordable to a majority of citizens (who will however suffer their negative externalities), social acceptance will be low, and large-scale drone innovation and deployment may be impeded from the outset (ITF, 2021[1]).

Box 1.3. Impact of delivery drones on climate and the environment: further evidence is still required

In a brief published in 2020, the European Environment Agency examined the environmental implications of delivery drone development. Many of the conclusions in this brief may to some extent be applicable to drones at large.

According to the brief, research results suggest that the main expected benefit for the environment is that, "compared with many traditional methods of delivery (motorcycles, cars, vans, lorries and planes using fossil fuel), drones could reduce CO2 emissions as well as other air pollutants for that sector". However, it warns that these results should be "viewed with caution" given the absence of comprehensive assessments, the relatively narrow focus of some studies, and uncertainty concerning potential development scenarios. For example, it points out that it is still unclear whether drone delivery will simply replace alternative delivery methods or lead to additional delivery trips, and that broader systemic effects along the entire logistics chain as well as with regard to the life cycle of batteries are not systematically taken into account. The brief concludes that available evidence does not allow for robust conclusions about the implications of delivery drones in terms of emissions of GHGs and air pollutants. This conclusion is generally in line with a recent ITF report, which stresses that net emissions will depend on the specific use case and local context. This report, which can be consulted for further reference on the environmental impact of drones, adds that large variations in both the size and physical characteristics of drones, as well as in the environments in which they operate, "mean that the mitigations that have been developed for traditional forms of aviation are unlikely to be sufficient to manage the environmental impacts of drones, and new approaches will be required".

The European Environment Agency also points to other potential environmental impacts, such as threats to wildlife, especially birds (since drones tend to operate at low altitude): "Beyond the obvious risk of collision, birds could be affected by the noise and stress caused by the frequent presence of drones in their habitat" (with consequences for reproduction and survival). Its brief mentions growing evidence of bird-drone interaction and mentions that, "in some areas, such as parks in London, authorities have banned drones from operating because of concerns over their negative influence on wildlife".

Source: (European Environment Agency, 2020[17]) (ITF, 2021[1]).

As discussed in the next section, meaningful, evidence-based analysis regarding the costs and benefits associated with the development of drones is likely to require a wealth of data from real-life occurrences, which can only be collected through testing and piloting.

Regulatory challenges

This section examines the main regulatory challenges associated with facilitating the timely development and commercialisation of drones without unduly compromising regulatory protections. In particular, it focuses on challenges to the design of fit-for-purpose regulatory frameworks in a context characterised by increased technological convergence and erosion of the traditional delineation of sectors, markets and policy areas. Crucially, it assesses the ability of existing regulatory frameworks (both national and supranational) and rulemaking approaches to promote and enable beneficial innovations and accommodate technology-driven disruption while ensuring a sufficient level of regulatory protection for people, businesses and the public interest at large.

According to the ITF, as far as drones are concerned, “the twin challenge for regulators is to ensure that innovation can flourish while at the same time mitigating potentially adverse economic and societal impacts that arise from disruptions” (ITF, 2018[2]). Drone regulation will also need to address the standard public concerns of efficiency, competition and sustainability. A research article published the same year also examines a number of regulatory challenges associated with drone developments (Du and Heldeweg, 2018[18]). What follows is a literature review summary of drone-related regulatory challenges. This summary draws primarily on the aforementioned publications and includes additional insights from complementary sources.

Rapid innovation and technological change leading to regulatory uncertainty

Drones, the technologies that enable them and their potential applications within the transport sector are diverse and rapidly evolving. Advances in engineering and manufacturing technologies are pushing the pace of change and future drone capabilities and costs. These developments include sophisticated simulation models, new materials, dispersed battery storage, 3-D printing of large (metal) parts, and biomimetic 4D printing methods for optimised elastic surfaces. They also include novel software tools and ICT technologies such as artificial intelligence, wireless 5G communication and the miniaturisation of electronics. These create opportunities for drones to expand into the civil aviation sector with new use cases that cannot be fully anticipated. Given the potential capacity constraints of public servants to even ask “the right questions” vis-à-vis highly specialised technology developers and providers, policy makers involved with creating new regulations need to consider how best to address this mismatch in skills. As discussed later in this section, the pace of innovation in this area also raises questions about the ability of existing legal frameworks to protect certain human and fundamental rights in that context (ITF, 2018[2]).

A concomitant challenge to rapid innovation (which develops at a faster pace than policies and regulations) is regulatory uncertainty, which can *ex ante* affect innovation insofar as the incentive for stakeholders to develop new unmanned aircraft systems technology may decrease if it remains unclear whether the operations of a novel type of aircraft will be authorised. Moreover, “subjective judgements about particular dangers and ethical concerns” (e.g. due to the lack or the delay of proper information delivered to the public or because of biases arising from value differences between individuals) may result in increased uncertainty and render regulatory action even more challenging (Du and Heldeweg, 2018[18]).

Limitations of existing regulatory frameworks

Many national regulations predominantly currently focus on controlling and minimizing *safety risks*, thus overlooking some of the broader impacts of unmanned aircraft systems on society and individuals. The cameras, sensors and other gadgets with which some small aircraft are equipped warrant, according to the authors, a distinct regulatory approach. Additional risks and threats relating to the use of drones that scholars and authorities have pinpointed over the years include a “chilling effect; dehumanisation of the surveilled; transparency and visibility, accountability and voyeurism; function creep; bodily privacy; privacy of location and space; and privacy of association” [(Finn, 2016[19]), quoted in (Pagallo and Bassi, 2020[20])]. In addition, it is unclear whether existing legal frameworks upholding human and fundamental rights can address the normative challenges brought about by the use of drones in the civil sector including further technology advancements, such as the use of highly sophisticated AI-enabled drones.

Du and Heldeweg attribute the unbalanced treatment of different potential risks and concerns to the limited remit of the regulatory and administrative bodies that produce, implement and enforce rules regarding the design, manufacturing and operation of unmanned aircraft systems. Under the current regulatory framework, civil aviation authorities (CAAs) are the main regulatory and administrative bodies involved in the regulatory process. The traditional scope of mandate of CAAs, they argue, tends to limit their ability to address other relevant concerns, such as privacy, data protection and security. According to some CAAs, however, the solution may not be to expand their remit, which they consider broad, but rather to strengthen

co-operation across relevant government agencies and regulators. They also point to existing tensions between, on the one hand, regulators, who are mainly resorting to traditional, *top-down* approaches, and, on the other hand, developers, manufacturers and operators, who call for flexible and *bottom-up* regulatory approaches in order to create an enabling environment for the rapid development of the UAS market. According to the authors, many market players perceive existing regulations as being "insufficiently technology neutral" and consider that they are likely to become "a barrier to the early to middle stages of the development of unmanned aircraft systems".

Moreover, many existing regulatory frameworks may be unable deal with the challenges raised by commercial drones; further technological developments such as collision avoidance systems could soon render them obsolete. There are parallels here with the need to update regulatory frameworks ahead of the introduction of automated vehicles such as driverless trucks on public roads (ITF, 2018[2]). According to the World Economic Forum (WEF), "most governments are subjecting drones to legacy approaches of aviation regulation, focused on specific equipment requirements. Regulators lack approval mechanisms for innovative new types of flight, including drones flying autonomously, as well as multiple drones flown by one operator, or beyond the operator's line of sight. These outdated approaches are hampering socially and economically beneficial uses of drone technology" (World Economic Forum, 2019[21]).

Lack of empirical evidence to inform decision-making

The potential impacts of large commercial drone fleets are not fully understood yet. Assessment of the potential impact on aviation has begun, but appraisal rarely adopts a cross-sectoral perspective. Indeed, the potential for disruption by drones extends beyond the aviation industry. The large-scale deployment of commercial drone fleets will challenge the transport system as a whole, for instance due to the potentially unlimited proliferation of "drone ports" for take-off and landing. To build trust and public support, questions of safety will require answers together with a wide range of concerns traditionally associated with transport, including noise, emissions, energy consumption and social equity, but also to novel challenges such as privacy and considerations about the visual amenity of cities and landscapes (ITF, 2018[2]). There remain substantial knowledge gaps about how to respond to public concerns public concerns about the large-scale deployment of drones, as there is only limited research on the potential impacts of drones that goes beyond assessing safety, security and privacy concerns (ITF, 2021[1]).

Moreover, restrictive regulations limit the possibilities of observing and collecting the outcome of real-life occurrences and creating more evidence-based approaches to safety. Several drone operators have been reported to stop developing their business cases for urban settings because of restrictive rules. A case study on Korea's approach also identifies the shortage of appropriate spaces and opportunities for conducting pilot/test flights: in this country, prior permission is required to fly a drone within a 9.3 km radius of major facilities such as an aerodrome. According to the authors, it takes more than a week to check the flight area for each test flight and obtain approval from local aviation agencies and the Ministry of Defence (OECD/KDI, 2021[16]).

Erosion of traditional sectoral and administrative boundaries and need for adapted regulatory frameworks for international operations

The growth of commercial drones leads to a blurring of the traditional administrative and sectoral boundaries. Furthermore, there are potentially overlapping regulatory responsibilities between national regulations or local authority rules in the case of urban drone operations. A corollary of this trend relates to the need for relevant public authorities to ensure co-ordinated approaches. It also warrants appropriate investment by relevant agencies to develop interdisciplinary competencies that may far exceed expertise in aviation and transport (ITF, 2021[1]).

Du and Heldeweg argue that "inter- or supranational rules on designing and operating unmanned aircraft systems or the mutual recognition of national regulations are still largely absent"[2], and that this can generate problems, for example, when an unmanned aircraft is designed in accordance with one state's regulations and cannot be operated in another state because of the inconsistencies with that state's regulations (Du and Heldeweg, 2018[18]). Other authors have pointed to the existence of relevant international instruments such as the Chicago Convention from 1944 with its Annexes (and subsequent amendments), as well as standards and recommended practices developed by the international civil aviation Organisation (ICAO). They note, however, that according to certain scholars, the unique challenges stemming from UAS and the need to develop and implement appropriate standards in a timely fashion warrant complementing this form of international co-operation through the development of a dedicated international legal framework (Pagallo and Bassi, 2020[20]). As reported by the ITF, "any unmanned international operations will still require special authorisation under Article 8 of the Chicago Convention". In addition, it states that "Article 7 of the Chicago Convention authorises limitations on "cabotage" (services between two points within the territory of the same State) and many States rely upon that provision to prohibit cabotage (though this is not required by the convention). These regulations were designed many decades ago for manned aviation and do not take into account potential differences in the structure of the drone industry versus the traditional airline industry". The growth of scheduled drone services could thus potentially be "constrained by geopolitical considerations that have in many cases constrained the growth and development of the manned aviation industry" (ITF, 2021[1]).

New legal and security-related challenges

The nature of drone operations makes it difficult to allocate liability amongst manufacturers, operators, the (remote) pilot, software providers or any other entity involved in drone operations. In case of mid-air collisions, drones may be involved in crashes either with other drones or with manned aircraft. The definition of damage may also prove contentious. When it comes to operators, the lack of an internationally harmonised liability regime (see discussion on international rules earlier in this section) can result in more complex and more costly legal proceedings for operators active in more than one country. In the case of potential victims, issues may arise with respect to identifying the source of damage and reporting it to the competent authorities. Protecting drones from cybersecurity risks is another important challenge since they can be targets for a cyber-attack themselves just as they risk being used as potential attack vectors. When it comes to cybersecurity and privacy standards for passenger drones, existing laws may have to be adapted and new security and privacy protocols will likely need to be negotiated and implemented (ITF, 2018[2]).

The next section outlines a number of relevant approaches through which jurisdictions are attempting to address many of the regulatory challenges described thus far.

Regulatory responses

This section provides an overview of selected regulatory approaches that either have been adopted or are being contemplated with regard to drones. The following main features are discussed: regulatory instruments at play (e.g. prescriptive vs. performance-oriented approaches), including tools used in the regulatory cycle (e.g. drafting new regulation or evaluating existing regulation); rationale behind the selected policy mix/choice of instruments (i.e. how they are meant to address regulatory challenges); instances of co-operation between public and private actors (e.g. development of self- or co-regulation arrangements), and use of regulatory testing and experimentation, including regulatory exemptions. The section will also present an example of how regulatory oversight can contribute to improving regulatory impact assessment (RIA), and thus regulatory quality, in innovation-dominated areas such as drones.

According to a study focusing on drone regulation and drone delivery services, although approaches to drone regulation differ substantially across countries, the core elements of regulations themselves are largely the same from country to country, "with wide ranges on the level of restrictiveness of each element that are often dictated by whether a country favors the promotion of new technology or a safety-first approach". Typical national regulations refer to a pilot's license, aircraft registration, restricted zones, and insurance. Requirements with regard to each of these elements vary depending on drone mass, flight altitude, drone use, and pilot license level. As to the regulatory methodologies for incorporating drones into legal systems, according to the study these range "from outright bans on the use of commercial drones, to permissive legislation, to a strategy of waiting to observe the efficacy of other nations' policies before acting". The study, which dates from 2017, also noted that "even for countries with existing drone legislation, laws are constantly being reevaluated", and pointed out that nearly all the laws it considered had been written or amended within the previous two years (Jones, 2017[22]).

Another research paper focusing on the EU context (Du and Heldeweg, 2018[18]) confirms the existence of a variety of approaches and examines three main models of governance for civil UAS in EU law. These models are the following:

- The *top-down model* of civil aviation law, supplemented by both soft law and the legal safeguards for the protection of human and fundamental rights. This model showed both convergences between legal systems (e.g. the EU and US general laws on civil aviation), and differences between technologies (e.g. the decentralised regulation of self-driving cars in the EU vis-à-vis the centralised EU governance of UAS);
- The *co-regulatory model* of data protection with the accountability principle enshrined in Art. 5 of the EU General Data Protection Regulation (GDPR), which applies to all processing of personal data in the EU, regardless of the technology concerned.
- The "middle-out" model of co-ordination mechanisms for legal experimentation (i.e. alternatives to fully bottom-up and fully top-down governance approaches, such as monitored self-regulation), which is being adopted by many legal systems to address innovation-related challenges.

The authors refer to these three models as part of a legal spectrum: "At one end of the spectrum, there are the strict top-down regulatory approaches that aim to govern both social and individual behaviour through the threat of physical or pecuniary sanctions, whereas, at the other end of the spectrum, we find pure self-regulatory solutions with limited accountability and legal framing. In light of the three models of UAS governance in civil aviation, data protection, and legal experimentation, we can thus say that the bar of legal regulation is progressively lowered as we move from the first to the second model, i.e. from civil aviation to data protection" (Du and Heldeweg, 2018[18]).

Indeed, regulation of the aviation sector highly risk averse because of the low level of public risk tolerance. An important question will therefore be whether drone regulations will or should adopt a similarly risk-averse approach, how this can be addressed and determined, and what implications it may have for the development of the sector. As pointed out by the ITF, "drone transport services may be subject to the same market access restrictions as manned aviation under the 1944 Chicago Convention and associated aviation licensing and traffic rules. Restrictions on operations could especially constrain the development of drone companies that engage in the carriage of goods or people". Exempting drone operations from certain restrictive rules involves determining how to distinguish drone services from manned aviation and whether to distinguish transport drones from those performing other commercial services such as aerial surveillance (ITF, 2021[1]).

While not comprehensive in nature, the present section outlines a selection of regulatory approaches that are of particular interest from the standpoint of agile and innovation-friendly regulatory governance. The section focuses on aircraft categories and use cases involving higher levels of risk and/or potential benefits.

The EU's common regulatory framework for the safe operation of drones

EU Regulations 2019/947 and 2019/945 set the framework for the safe operation of drones in European skies (EU and EASA Member States). They follow a risk-based approach and thus do not distinguish between leisure or commercial activities. Instead, they focus on the weight and specifications of the drone and the operation it is intended to undertake. EU Regulation 2019/947, which is in force since the end of 2020 defines three categories of operations by risk level: "open", "specific" and "certified" categories. The "certified" category involves the highest safety risk. Therefore, certification of the drone operator and the aircraft and licensing of the remote pilot(s) is required. Also part of the drones' regulatory framework in the EU is *U-space*, which was adopted in April 2021. According to the European Commission, U-space "creates and harmonises the conditions needed for manned and unmanned aircraft to operate safely, to prevent collisions between drones and other aircraft, and to mitigate the risks of drone traffic on the ground" (European Commission, 2021[23]).

In response to the increase in the volume and scope of drone operations in Europe, EASA has also recently published guidance for drone operators, manufacturers and national authorities explaining the process for the design verification of drones falling under the 'specific' category. This process is presented as following "a proportionate approach which will foster innovation and growth in this promising sector".[3]

In a 2021 study, EASA has also examined the attitudes, expectations and concerns of EU citizens with respect to UAM. It concludes that "EU citizens are calling for active and pre-emptive measures from competent authorities. In addition to mitigating risks related to safety, security, noise and environmental impact, these measures are expected to ensure that UAM will be a common benefit to all of society by offering affordable, integrated and complementary mobility". According to the study, "the notion of general/public interest is a determining factor for acceptance: use cases for the benefit of the community, such as medical or emergency transport or those connecting remote areas, are better supported than use cases satisfying individual/private needs" (EASA, 2021[24]). In a similar vein, a recent ITF report points out that authorities can enhance acceptance by ensuring that the public is informed about key issues of concern, such as accident and incident rates, methods of reporting and addressing grievances, rules that govern the flight and take-off and landing procedures of drones, and the benefits provided by drone operations (ITF, 2021[1]).The importance of social acceptance is further discussed later in this section (see "social licence to operate" in the UK).

Sweden's example of experimentation-friendly approaches to regulation

In 2018, prior to the implementation of the EASA-based regulatory framework, the ITF (ITF, 2018[2]) had identified Sweden as having adopted one of the most permissive approach to drone regulation worldwide, including by designing licensing regimes to accompany the use of experimental flights beyond the visual line of sight (BVLOS). Sweden's experimentation-friendly approach may have helped the country to be among the early adopters of drones in sectors such as healthcare and emergency response; e.g. delivery of automated defibrillators in the Gothenburg area. Everdrone, a Swedish company involved in the deployment of civil drone operations in this context highlighted the importance of long-standing dialogue and co-operation with authorities such as the national emergency call centre as having been "crucial for the realisation of the concept in terms of being able to perform a swift alarm response, and to manage the medical and ethical issues involved."[4] Other relevant areas include drone use for law enforcement and aerial reconnaissance activities during incidents such as fires, oil spills, and natural disasters.[5]

Drone taxi service trials in Dubai as part of the national "Smart Dubai" strategy

Dubai seeks to integrate air taxis (Volocopter 2X) into existing transportation systems and provide additional mobility for up to 10 000 passengers per day with a single point-to-point connection (FutureBridge, 2020[5]). As part of the "Smart Dubai" strategy that also includes a driverless metro, Dubai

has been inviting several passenger drone companies to help achieve the target of 25% of "autonomous journeys" of all trips by 2030. In September 2017, the first actual test flight with a passenger on board a drone took place in Dubai. The national Road and Transport Authority also announced that it would co-operate with the UAE General Civil Aviation Authority and the Dubai Civil Aviation Authority in order to develop requirements for regulations, standards, and certification requirements (ITF, 2018[2]).

In 2020 Dubai passed a new law "to help flying taxis and drone deliveries to take off" alongside a network of mini airports. The law is expected to facilitate the development of an integrated framework for licensing and issuing certificates, permits, and inspection services for the drone industry, as well as a legal system for investigating accidents and incidents. Dubai's strategy also involves creating a master plan for the use of infrastructure on the ground, classifying the main urban areas for the distribution of ground and air service sites. The project will rely on an integrated digital platform for providing regulatory services for UAVs to use domestic airspace and other related government services. This platform will grant instant permits and no-objection certificates for drone operations. It will also facilitate efficient governance of the sector to ensure security and safety and prevent any disruption to the civil aviation airspace. Another important component is a system to address safety and security risks of drone activities. The "Dubai Shield" system will "detect and track drones and take necessary counter measures in co-operation with relevant government and security authorities" (Urban Air Mobility News, 2020[25]).

China's First National Standard for Express Delivery Service by Unmanned Aircraft

In 2020, drone industry players including EHang, JD.com and ZTO Express jointly formulated China's first national standard for Express Delivery Service by Unmanned Aircraft.[6] This standard was issued by the State Post Bureau and became effective in January 2021. According to Ehang, implementation of the standard is particularly important for improving the last-mile delivery service, ensuring the safety of operations, and promoting the development of intelligent aerial logistics in the UAM industry. It applies to express delivery services by unmanned aircrafts with a maximum empty aircraft weight of 116 kg, a maximum takeoff weight of 150kg, and a maximum airspeed of 100km/h. The standard also specifies the service entities, conditions, procedures, assessments, safety issues and compensation of express delivery by unmanned aircraft, thus providing a clear reference for postal express companies and drone operators that envision engaging in drone delivery services (EHang, 2020[26]).

Rwanda's performance-based framework for drones

Rwanda's revamped regulatory framework for drones was designed with a view to allowing for more use cases and expanding the number of drone companies in the country. The new, performance-based framework was approved in January 2018. It set a new standard for open, accountable, and risk-based access to airspace that can enable any type of drone operation in any location while maintaining safety; "a first for drone regulations" according to the WEF. This framework is reported to have enabled new businesses to establish themselves for infrastructure inspections, agricultural and pest spraying, and surveying of crops and land tilling (World Economic Forum, 2019[21]). Rwanda's approach is mentioned as an example by the ITF, which recommends adopting performance-based standards that restrict noise levels, flight patterns, operation times and fuel sources "instead of overregulating drone use based on technological specifications that restrict innovation". The ITF notes that performance-based drone regulation may be the best way to prevent intrusive uses while permitting innovation. Regulation that specifies the volume, size, flight altitude and parameters, and use of drones can ensure that citizens' concerns are respected while still allowing companies adequate freedom to experiment without restrictions on technology or equipment". It also states that "regulators and policy makers around the world will need to work closely with industry and other stakeholders to establish performance-based standards for UTMs that are interoperable and interact with existing air traffic control systems" (ITF, 2021[1]).

Advocacy and engagement (also) matter: the example of France's Civil Drones Council

France's Civil Drones Council has launched a number of structuring actions to involve French manufacturers and operators in European regulatory and normative processes and has worked to facilitate the implementation of current regulations for professional operators. It has notably advocated an evolution of the French regulations from operational restrictions, which have allowed the emergence of the sector, towards a more aeronautical logic (airworthiness, demonstration of safety) which is essential to authorise those new uses (ITF, 2018[2]).

Regulation Reform Roadmap in Korea

According to a case study developed by national experts, Korea's current aviation law severely restricts drone flights. The Korean regulatory agency is mainly concerned with safety issues. Although there are various pilot projects in the country's island and mountain regions, strict regulations prohibit drone delivery in densely populated areas. Furthermore, since most of the residential units in Korea are apartments, it is difficult to secure spaces for the takeoff and landing of drones. Due to high population density, dense radio waves around the residential areas can disturb the signals controlling the drone and cause accidents.

According to the case study authors, Korea's current regulatory framework does not fully support commercial drone-based projects. The tryouts on modulating regulations such as allowing flights without prior approval and expanding the altitude range more favourably turned out to be not of much help for commercialisation. To address this situation, the Ministry of Land, Infrastructure and Transport in Korea has put forward the *Drone Regulation Breakthrough Roadmap* with the goal of establishing commercialised drone delivery by 2025. Table 1.2 shows a benchmarking analysis carried out in the context of Korea's reform efforts in this area.

Table 1.2. Key Parameters of Drone Regulations in selected countries

	Korea	United States	People's Republic of China	Japan
Report & Register	For business or over 12kg	For business or over 250g	Over 7kg	Over 200g
Qualification	Over 12kg For business* * 14 years old and older	For business* * 16 years old and older	Over 7kg	Over 200g
Altitude Limits	Lower than 150m* * From ground, water surface or structure	Lower than 120m* * From ground, water surface or structure	Lower than 120m* * From observer or pilot	Lower than 150m* * From ground or water surface
Flight Zone Restriction (radius)	Seoul (9.3km) Airport (9.3km) Nuclear Plant (19km) DMZ Area	Washington (24km) Airport (9.3km) Nuclear Plant (5.6km) Stadium (5.6km)	Beijing, Airport, Nuclear Plant Area	Tokyo (All) Airport (9km) Nuclear Plant Area
Flight Speed Limits	Unrestricted	Lower than 161km/h	Lower than 100km/h	Unrestricted
Out of sight, Night flight	Principle not allowed, but exceptions allowed * * Test flight, flight in pilot project area	Principle not allowed, but exceptions allowed * * Per case through Waivable Regulations	Principle not allowed, but exceptions allowed* * Cloud system access or separate report required	Principle not allowed, but exceptions allowed
Flight Above Crowd	Principle not allowed, but exceptions allowed* * Dangerous flight prohibited	Principle not allowed, but exceptions allowed	Principle not allowed, but exceptions allowed* * Cloud system access or separate report required	Principle not allowed, but exceptions allowed* * Keep over 30m away from people, vehicles, buildings, etc.
Drone Usable Range	Unrestricted* * Exclude projects that threaten the safety and security of the people	Unrestricted	Unrestricted	Unrestricted

Source: Regulatory Reform Roadmap of Drones, Ministry of Land, Infrastructure and Transport, Korea, quoted in (OECD/KDI, 2021[16]).

The Ministry of Land, Infrastructure and Transport of Korea has planned various projects to identify and improve regulatory issues related to commercialisation of drone delivery. By 2022, the Ministry is planning to commercialise drone delivery in non-urban areas. Furthermore, the Ministry expects to expand drone-based delivery to urban densely populated areas by 2025.

Such milestones are ambitious and a number of conditions will need to be met. Certain regulatory improvements, such as those shown in Table 1.3, will be necessary to that end. In order to address safety concerns, noise issues, and radio frequency problems, government agencies such as the Ministry of Land, Infrastructure and Transport and the Communications Commission are preparing specific regulations designed mostly in terms of qualifications and responsibilities. They also deal with issues of flight availability in specific regions based on the nature of the flight area. According to case study authors, meeting the Roadmap's objectives will require, as discussed in the section on regulatory challenges, conducting numerous test flights. However, in the current context, flight spaces are strictly limited: there are only ten pilot airspaces without flight restrictions in the country at the time of writing.

Table 1.3. Korean Government Agencies' Regulation-related Projects

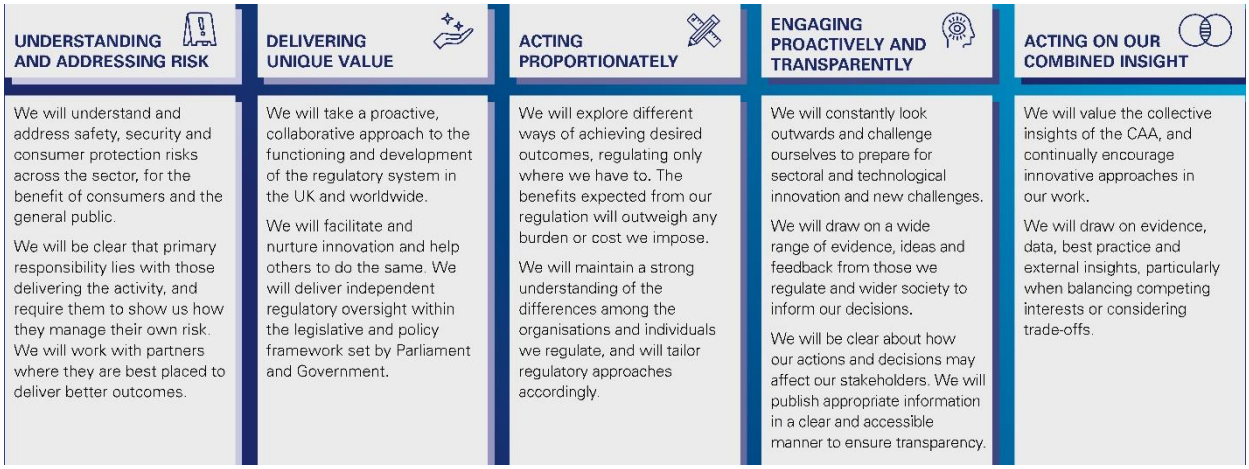
Regulation Issues	Project Name	Due
Safety	Advancement in drone insurance system	2021
Flight region	Establishment of standards for drones to fly to major national facilities and control areas	2021
Safety	Establishment of drone accident report management system	2021
Safety	Drone flight record and pilot qualification management system	2021
Radio frequency	Frequency discovery to support long-distance driving	2021

Source: Regulatory Reform Roadmap of Drones, Ministry of Land, Infrastructure and Transport, Korea.

The UK Civil Aviation Authority's innovation-friendly approach

The UK Civil Aviation Authority (CAA)[7] constitutes a good practice example in that it has defined a set of regulatory principles that seek to improve safety, security and consumer protection outcomes and, crucially, integrate the innovation dimension in a cross-cutting fashion. These principles are to guide the design, prioritisation and implementation of regulatory activities.

Figure 1.3. Regulatory principles of the UK's Civil Aviation Authority



Source: UK Civil Aviation Authority.

In addition, in April 2019, the UK Civil Aviation Authority (CAA) launched its Innovation Hub with the following objectives in mind:

- Making it easier for innovators to access CAA expertise, guidance, and viewpoints on regulations and providing a focal point of contact and information;
- Helping innovators maximise regulatory readiness for the demonstration of their aviation systems by testing them in safe environments and learning how they address regulatory challenges; and
- Accelerating the development of new policies and regulations by anticipating regulatory challenges in areas of innovation, then defining the requirements for new policies and regulations.[8]

The cornerstone of this scheme is the Innovation Sandbox, which notably focuses on future innovation in aviation, including air mobility, and relies on an iterative, co-operative approach (through workshops, live trials and simulations). In this context, the CAA's website states that, "whilst existing aviation regulations can enable the exploration and trialling of innovative future air mobility solutions, they do not yet enable commercial operations or fully provide a scalable, proven certification approach", and recognises that the CAA needs to play a role "in identifying and supporting answers to regulatory challenges and working alongside Government, industry and public stakeholders".[9] The Sandbox is conceived as a learning platform for policy and regulation as well as a means of accelerating the development of a robust evidence base that will support regulatory approvals for demonstration flights.

There are no restrictions to apply to the so-called Sandbox challenges. Some of the sandbox participants – including smaller firms with limited resources – receive UK Government funding, which allows them to access CAA support in this way (but the CAA does not provide funding for innovation related projects). Moreover, although it seeks to improve the regulatory readiness of participating companies, the CAA does not help them with the approval procedure itself as this could confer them an unfair advantage. In addition, it shares openly all relevant information generated by the Sandbox. The CAA has published two case studies based on its experience with this instrument: respectively, on the experience of Volocopter, one of the first companies to join the Innovation Sandbox,[10] and on operating Beyond Visual Line of Sight (unmanned aircraft – case study by Skyports[11]).

Another key feature of the CAA's innovation-friendly approach has to do with the dissemination via their website of information on how they are responding to novel technologies and business models through iterative testing and trials, including guidance papers, viewpoints on future regulations and information on regulatory approvals that companies may need to consider for conducting trials of their solutions. In the area of Advanced Air Mobility (AAM), the CAA has published a comprehensive document outlining its *use case* approach to exploring AAM and its implications for regulation and the aviation sector. According to this document, "the aim of the use case regulatory approach is not to enable all proposals unquestioningly, but to allow AAM concepts to be fully explored so that safe proposals can be developed iteratively in partnership with the Regulator".[12]

The CAA has also issued guidance on how innovators can build in social engagement as a key part of their development strategy. This guidance document revolves around the notion of social licence to operate. Social licence is defined as "the ongoing approval from stakeholders for an organisation's products, services, business practices and operations"; "underpinned by a 360° view of stakeholders, a social licence brings with it the tangible business benefits of being considered legitimate, credible and trustworthy". It is "particularly important where there is a high degree of change or disruptive and new services involved", as well as in situations in which "it is often not immediately evident to the public whether innovations will help or harm them" or with no existing regulatory framework or independent oversight authority.[13]

One of the challenges to implementing this innovation-oriented vision has to do with the limited availability of suitable spaces for pilot flights and related approval procedures, which can be lengthy and have a deterring effect. According to the CAA, it is also important to have a strong government policy ensuring

appropriate co-ordination of all relevant regulatory authorities. For example, the drone ecosystem has implications for areas including local space planning and national building requirements, as well as communications (delivery) and energy (electric aviation). International engagement is also essential even if, for the moment, drone services are less cross-border in nature compared to traditional aviation. This involves the exchange of views and experience on regulation (as the CAA does with its US counterpart among others) as well as multilateral co-operation through international organisations.

Drones in Regulatory Impact Analysis and the role of regulatory oversight: a statement from Norway's Better Regulation Council (NBRC)

In 2019, Norway's Better Regulation Council issued a statement on proposed regulations for unmanned aerial vehicles. It noted that "increasing use of drones provides new and exciting opportunities for the business sector, and it is important that clear rules are provided for their use to enable the technology to be further developed". Furthermore, it stressed the important potential for the use of drones in the business sector, and that regulation should therefore be designed to stimulate business development as well as R&D, and "ensure that society does not lose out on the hitherto undiscovered benefits of drone use".

The Council considered that the RIA accompanying the proposed regulatory changes was not adequate, and pointed out key areas for improvement. The Council's statement is an example of the important role that regulatory oversight bodies can play in ensuring that regulatory management tools effectively help improve regulatory quality in high-innovation areas such as drones. Since most of the points raised by the Council relate to aspects that should be addressed by RIA and related analyses on similar topics across countries, they are summarised next for ease of reference.

NBRC noted that there were almost 4 000 registered or approved drone operators piloting unmanned aerial vehicles for business or otherwise useful purposes in 2018, according to the consultation note. NBRC would have liked to see a description of the type of business or otherwise useful purposes for which drones are currently being used, and which businesses have adopted drones and for what purposes. Furthermore, it stated that the Civil Aviation Authority should have described in more detail which drones and drone tasks will be covered by the "open category", "specific category" and "certified category", as this would have provided a better basis for assessing the impacts of the proposals. It also called for "a full description of the applicable drone legislation, the type of commercial and useful activities that drones are used for today, and how current drone use will be impacted by the rules in the new Basic Regulation".

Furthermore, it underlined the importance of involving of other government agencies and stakeholders in the regulatory work. Moreover, it stated that an assessment of how corresponding problems are solved and how corresponding rules are formed in other countries would have been valuable, as "this is particularly important for the regulation of technology that may be cross-border in nature". The Council also emphasised that "the Civil Aviation Authority and the Ministry of Transport and Communications should, in connection with further work on the regulation of drones, collaborate with businesses that have adopted the technology", and that it is important "to facilitate clear and easily understandable rules for those concerned".

In addition, it pointed out that the competent authorities should have a strategy for evaluating the regulations. "Predictability is important for affected businesses. At the same time, the technology is developing fast, and rule changes may be necessary after a short time in order to ensure that the rules fulfil their intended purpose."

In its conclusion, the NBRC emphasised that, since regulation can promote or inhibit innovation and technological development, how the rules are formulated and which rules are introduced is essential. Moreover, it stressed that regulators should bear this in mind with regard to innovations that are under continuous development and are being adopted in increasingly new ways. The NBRC encouraged adopting this perspective in further work on the drone regulations (NBRC, 2019[27]).

Conclusion

As is often the case in innovation-dominated environments where disruption is at play, a major challenge in the context of drone regulation is the need to remove or update obsolete norms and/or put forward new ones that help promote socially beneficial innovation while minimising the associated risks. In the same vein, it is important to ensure that applicable regulations are as technology-neutral as possible and do not impair early stage development of potentially valuable drone technology application. Developing new, purpose-specific, regulation may, however, not involve the same considerations as modifying or repealing existing regulation. In some cases, it may be necessary to retain existing rules while modifying definitions to exclude (in full or in part) the innovative product or service at hand. In addition, constituencies benefiting from existing rules may oppose their modification or removal.

As illustrated by the examples presented in this case study, regulatory decision making entails clearly understanding both the costs and the benefits of intervening in a particular market and transparently achieving an appropriate balance between these. This assessment is guided by the expected net benefit but also informed by societal issues such as the acceptability of certain types of risk. Achieving this is particularly difficult in the context of emerging technologies, due to the lack of information on their performance and impacts. In this situation, countries are increasingly enabling structured experimentation in a collaborative environment between business and regulators, thus minimising risks, increasing the rate of knowledge acquisition and sharing and facilitating trust. Some experts have pointed out that a "learning by testing" approach, can indeed help create an enabling legal environment and facilitate innovation without causing "unacceptable negative results" (Du and Heldeweg, 2018[18]).

In this context, enabling and speeding up observation and collection of data and information on the outcomes of real-life occurrences would help develop more evidence-based approaches to safety and should therefore be considered a priority both in terms of the regulatory framework itself and the availability of appropriate spaces for testing and piloting. Dedicated innovation flight test corridors and efforts by regulators and market surveillance authorities to improve regulatory readiness of firms in the sector could both be instrumental in this respect. Testing and experimentation approaches identified should, however, be risk-based and as transparent and inclusive as possible. Proactively seeking stakeholder buy-in, providing appropriate guidance and allowing the iterative development of safe proposals by adopting a use case approach have all proven effective to that end. Where possible, early trials of drones should focus on use initial use cases that align with overall public policy goals and offer clear public benefits, such as transporting medical goods and improving access to remote communities (ITF, 2021[1]).

In addition to ongoing monitoring, timely evaluation of regulatory approaches is essential, as is the publication of results. Moreover, the complexity and far-reaching implications of drone development call, more than ever, for a whole-of-government, holistic approach to regulation. This requires extensive co-operation with a broad range of government agencies and stakeholders, including across borders – since regulatory coherence is essential to promote drone development and increase safety. This is all the more important given the rapid erosion of traditional administrative boundaries and the potentially overlapping regulatory responsibilities between national regulations or local authority rules in the case of urban drone operations. The development of a "communities of practice" approach to facilitate the sharing of knowledge and experience by regulators within as well as across national borders, both through overarching mechanisms and direct interaction, can be useful in that respect.

Notes

[1] In (ITF, 2021[1]) (p. 16ff), the ITF presents an analysis of the likely evolution of drone uses in transport together with their expected market potential across various categories.

[2] The next section briefly discusses, however, the recently enacted common EU regulatory framework.

[3] https://www.easa.europa.eu/newsroom-and-events/press-releases/easa-issues-guidelines-design-verification-drones-operated.

[4] https://news.cision.com/everdrone-ab/r/autonomous-drones-are-now-delivering-defibrillators-to-80-000-residents-in-sweden,c3112538.

[5] https://enterprise-insights.dji.com/user-stories/how-swedish-police-started-case-study.

[6] The standard's text is only available in Chinese: http://www.spb.gov.cn/zc/ghjbz_1/201508/w020201204542195544172.pdf.

[7] Source for this section: exchanges with CAA officials via phone and e-mail.

[8] https://www.caa.co.uk/our-work/innovation/about-the-innovation-team/.

[9] https://www.caa.co.uk/our-work/innovation/regulatory-challenges-for-innovation-in-aviation/.

[10] https://publicapps.caa.co.uk/docs/33/cap1949%20volocopter%20case%20study.pdf.

[11] https://publicapps.caa.co.uk/docs/33/bvloscasestudy.pdf.

[12] https://www.caa.co.uk/cap2122.

[13] https://www.caa.co.uk/cap1900.

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2 Case study 2: Bio-solutions

Introduction

This case study explores a range of agile regulatory governance issues with regard to bio-solutions. Bio-solutions use renewable bio-resources combined with elements such as enzymes, proteins and bacteria, for production on an industrial scale, and could make a decisive contribution to the green transition provided that an enabling policy and regulatory framework is in place.

In this context, the case study illustrates the need for future-proof and innovation-friendly regulation for bio-solutions. It also illustrates how regulatory policy can allow innovative solutions to be tested, developed and brought onto the market while upholding key regulatory protections for citizens and the environment.

Background and context

Biotechnology holds great promise for addressing some of the critical challenges of our time, from pandemics, through climate change, to transitioning to sustainable production systems. Potential applications include vaccines, green chemistry (e.g. biofuels) and bio-based materials. In addition, biotechnology firms represent an increasingly important segment of the economy. As shown in Box 2.1, the term biotechnology encompasses a very broad range of applications. This case study focuses to a significant extent on bio-solutions, which use micro-organisms such as cells, proteins, bacteria and enzymes to harness the potential of renewable biomass (e.g. side streams from food production or other sustainable sources), create alternatives to petro-based and chemical products, and plant and seed breeding (see Figure 2.1 for more details). It also discusses, however, other biotechnology applications. In addition, it will refer to related concepts such as the bioeconomy, bio-based materials, bio-innovation[1] and bio-based products,[2] which for simplicity will in some cases be used interchangeably.[3] Furthermore, certain aspects discussed in the sections dedicated to regulatory challenges and regulatory responses are more general in nature, given the need to integrate a comprehensive policy framework perspective as well as the existence of a number of systemic challenges.

Box 2.1. Proposed OECD single and list-based statistical definitions of biotechnology (2016 update)

Single statistical definition of biotechnology

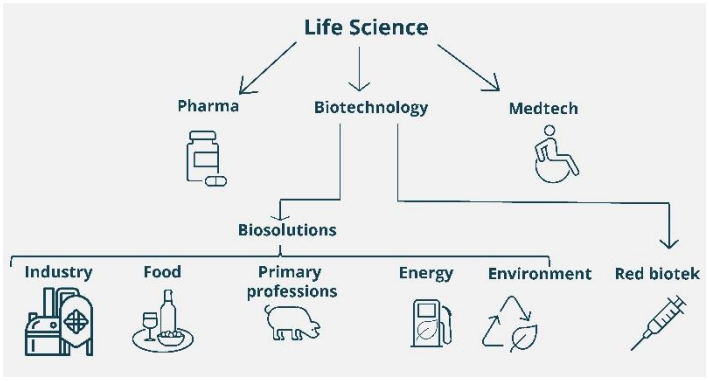
The application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services.

List-based statistical definition of biotechnology

- DNA/RNA: Genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling, and use of antisense technology, large-scale DNA synthesis, genome- and gene-editing, gene drive.
- Proteins and other molecules: Sequencing/synthesis/engineering of proteins and peptides (including large molecule hormones); improved delivery methods for large molecule drugs; proteomics, protein isolation and purification, signalling, identification of cell receptors.
- Cell and tissue culture and engineering: Cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation, marker assisted breeding technologies, metabolic engineering.
- Process biotechnology techniques: Fermentation using bioreactors, biorefining, bioprocessing, biopulping, biobleaching, biodesulphurisation, bioremediation, biosensing, biofiltration and phytoremediation, molecular aquaculture.
- Gene and RNA vectors: Gene therapy, viral vectors.
- Bioinformatics: Construction of databases on genomes, protein sequences; modelling complex biological processes, including systems biology.
- Nanobiotechnology: Applies the tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics, etc.

Source: (Friedrichs and van Beuzekom, 2018[1]).

Figure 2.1. Biotechnology and bio-solutions at a glance



Source: (Iris Group, 2021[2]).

New generation bio-solutions can provide durable materials which can attain different degrees of flexibility and strength, from soft materials such as fabric to hard objects such as chairs or even wind turbine blades. These materials can contribute to a transition to circular economy in a broad range of economic activities. Furthermore, reactions occur at low temperatures and ambient pressures, thus requiring low energy inputs. Indeed, the expansion of a bio-based economy "can help to bring economic growth and environmental policy goals closer together" and help achieve objectives such as rural industrial development. According to research examined by the OECD, at least 50 countries, including the G7 countries, have either national bio-economy strategies or policies steering towards a bioeconomy (OECD, 2017[3]).

In addition, bio-solutions may constitute a compelling alternative to fossil and chemically based products, whose production generates large greenhouse gas emissions. The use of bio-based materials within construction, for instance, has been identified as a potential means of improving sustainability within the built environment (Jones et al., 2017[4]). Bio-solutions may also offer alternatives to fossil-based plastic packaging in the food industry and synthetic textiles in the fashion industry, and may be used for producing new and more sustainable ingredients for food and feed, as well as for pest control in the agricultural sector.[4] It should however be borne in mind that bio-solutions' contribution to the increased sustainability of these and other economic activities will depend on the sustainability of the biomass which they process. Without attention to sustainability and carbon footprints, bio-based value chains will not be compatible with climate-change objectives (OECD, 2021[5]).

Key transformative impacts

The development of bio-solutions and bio-innovation more generally is expected to have a range of transformative effects, including creating employment and economy activity, accelerating the green transition and, by the same token, contributing to major changes in the chemical and petrochemical industries.

The contribution of the bioeconomy, bio-solutions and bio-innovation to economic activity

The OECD helped develop the notion of "bioeconomy" more than a decade ago. It has been argued that the bioeconomy in 2030 would likely involve three elements: advanced knowledge of genes and complex cell processes, renewable biomass and the integration of biotechnology applications across sectors (OECD, 2009[6]). OECD work has notably focused on three main areas of development: agriculture and livestock (OECD, 2009[6]); health (OECD, 2009[6]); and industry (OECD, 2009[6]). In addition to improving environmental sustainability (see next sub-section), the bioeconomy has the potential to yield efficiency gains in many productive processes.

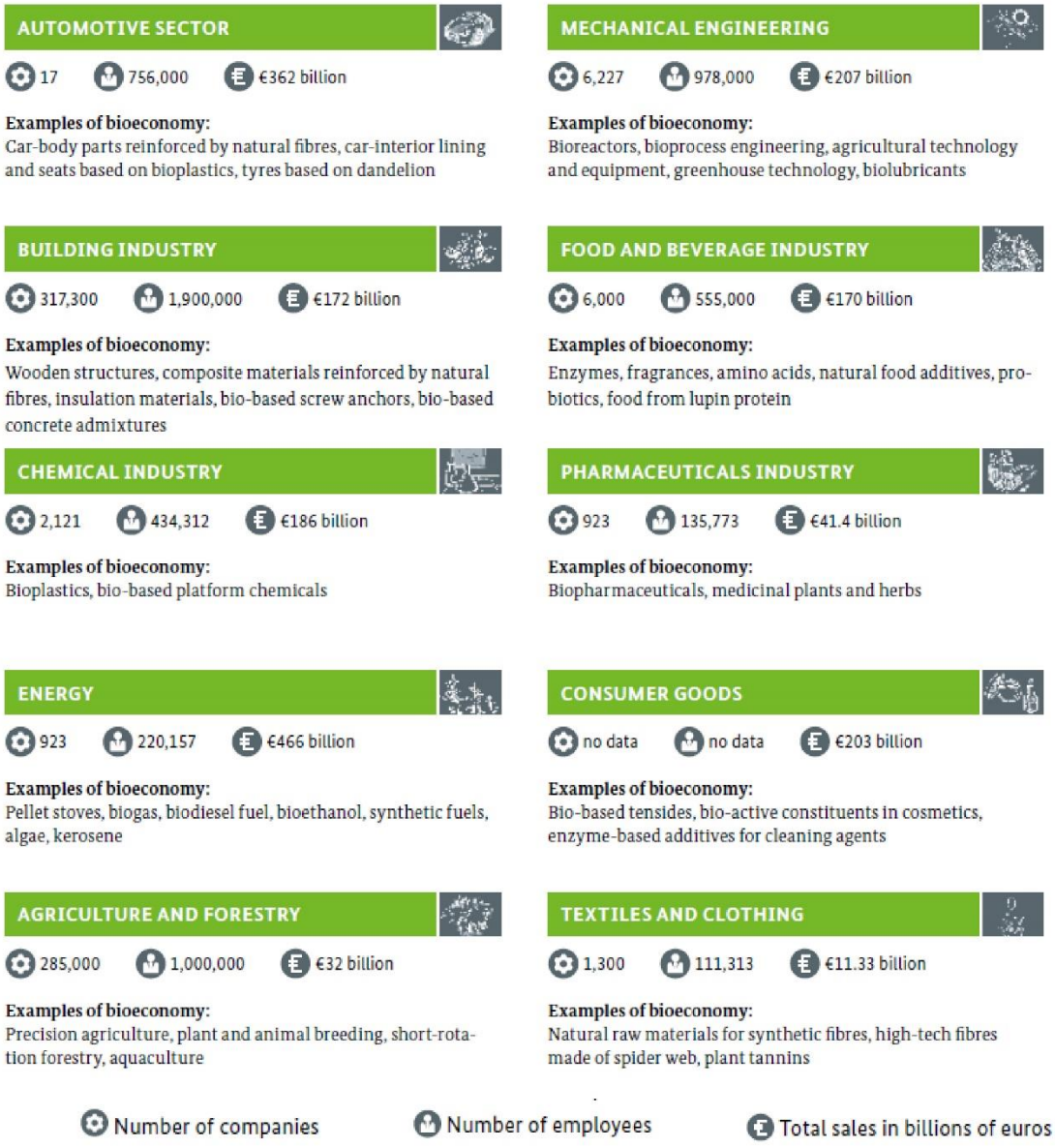
The European Commission, in turn, describes the bioeconomy as "encompassing the sustainable production of renewable resources from land, fisheries and aquaculture environments and their conversion into food, feed, fibre bio-based products and bio-energy as well as the related public goods", "including primary production, such as agriculture, forestry, fisheries and aquaculture, and industries using/processing biological resources, such as the food and pulp and paper industries and parts of the chemical, biotechnological and energy industries" (European Commission, n.d.[7]). According to a 2018 report, the bioeconomy created up to EUR 614 billion of value added in 2017 in the EU-27, or 4.7% of the region's GDP. Around 35% came from the food, beverages and tobacco industry, and 31% from agriculture. In 2017, the bioeconomy employed 17.5 million people in the EU-27, or 8.9% of the total labour force. Of these, 53% worked in agriculture and a quarter in the food, beverages and tobacco industry. EU Labour productivity gains were achieved in all bioeconomy sectors over the 2009-2017 period, except for the bioelectricity sector. The report also highlights that "the bioeconomy can act as a buffer against unemployment in times of economic crisis" (Ronzon et al., 2020[8]) (European Commission, 2020[9]). Furthermore, bio-based industries could create a million new jobs in the EU by 2030 according to recent estimates (JRC, 2021[10]).

According to a report quoting data from the US Department of Agriculture (FAO, 2018[11]), the bio-based industry in 2014 contributed a total of about USD 400 billion value added to the US economy; supported a total of 4.2 million jobs through direct, indirect and induced contributions; and generated 1.76 jobs in other sectors of the economy for every bio-based job. Additionally, the indirect jobs in satellite activities are estimated to be around 1.53 million jobs, while induced jobs (produced from the purchase of goods and services generated by the direct and indirect jobs directly supported the bio-based product industry)

resulted in 2.7 million spillover jobs. The report also estimates that the bio-based industry generated USD 127 billion in direct sales and USD 266 billion in spillover sales over the period.

Germany's bioeconomy strategy, in turn, defines bioeconomy as "the knowledge-based production and utilisation of renewable resources in order to provide products, processes and services in all economic sectors, within the context of a future-capable economic system" (BMBF & BMEL, 2015[12]). The concept of bioeconomy therefore encompasses all economic sectors and their associated commercial services involved in producing, working or processing, using or trading with renewable resources (FAO, 2018[11]). An analysis of bioeconomy's contribution to the German economy, including the mapping of relevant application examples, was carried out in 2015 based on this conceptual framework (see Figure 2.2).

Figure 2.2. Facts and figures of bioeconomy in Germany



Source: (BMBF & BMEL, 2015[12]), quoted in (FAO, 2018[11]).

Acceleration of the green transition in many economic sectors including energy, food and agriculture, construction and manufacturing

Recent OECD work has concluded that the development of the bioeconomy could play a critical role in supporting sustainable development (OECD, 2018[13]). The movement towards using wastes, co-products and residue sources resonates well with circular economy principles of making the most efficient of uses of natural resources, as does as transition in focus from virgin to secondary materials in production (Philp and Winickoff, 2018[14]). In addition, certain bioeconomy activities such as waste biorefining can help address several major policy goals (see Box 2.2 for more details).

Box 2.2. Potential contribution of waste biorefining to strategic policy objectives

Using wastes materials in biorefining can be highly instrumental in meeting several policy goals and challenges, particularly in that:

- It relieves pressure on land, thereby enhancing sustainability
- It avoids the issues around indirect land use change
- It avoids issues such as the food versus fuel debate
- It improves public opinion through the first three
- In the case of waste industrial gases, especially CO and CO2, as well as the above four advantages, this uses GHGs that would otherwise become emissions, i.e. it contributes to science and policy goals around reducing emissions in climate policy
- In the case of municipal solid waste all of the above apply (as it is converted to methane in landfill sites, and methane is a much more potent GHG than CO2), and an additional policy challenge is also addressed – the diminishing supply of suitable sites for new landfills, a problem for many countries.

Source: (Philp and Winickoff, 2018[14]).

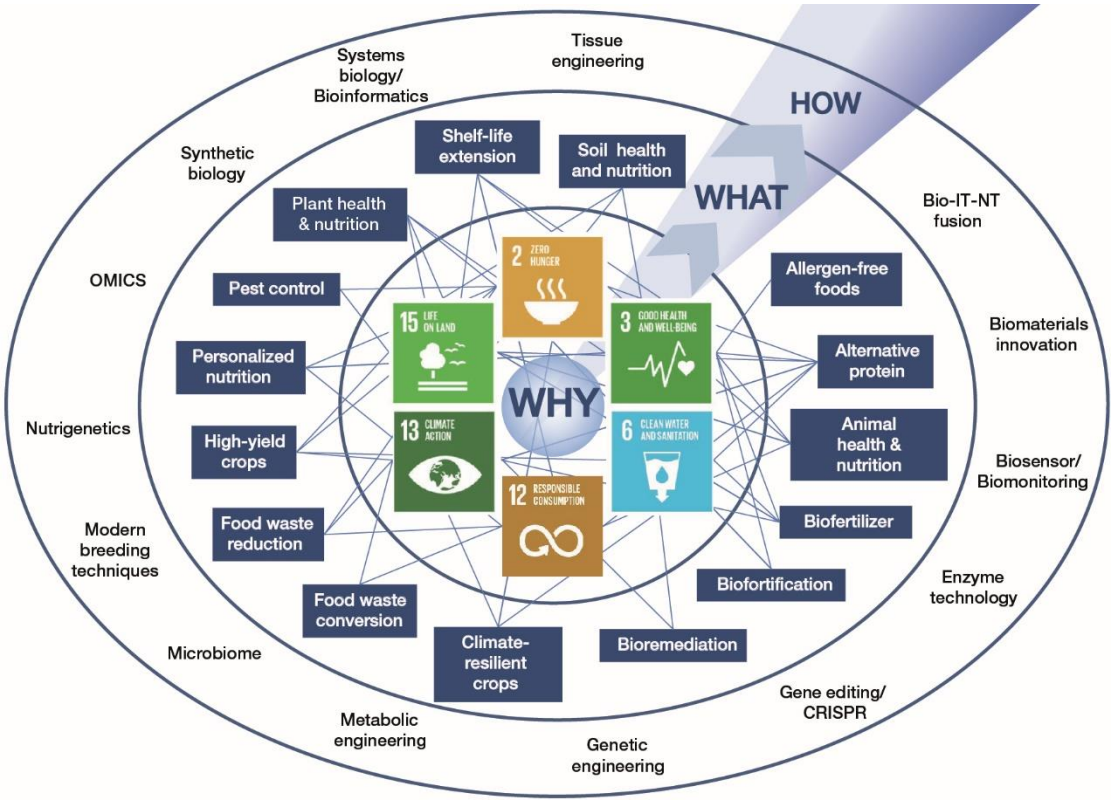
OECD analysis also highlights that “the need to reduce carbon emissions and fossil-fuel consumption represents an opportunity for engineering biology to emerge as a service and manufacturing sector”. Indeed, by 2100, more than 95% of chemicals and polymers may need to be derived from renewable resources. It is noted, for instance, that biotechnology “could be used to engineer microbes to produce targeted nutrients for human consumption, while bacteria could be manipulated to produce lightweight construction tools and materials” (OECD, 2021[5]).

In a similar vein, in the EU, support to a sustainable bioeconomy is viewed as a means of transforming the region’s agricultural and industrial base through the creation of new bio-based value chains and greener, more cost-effective industrial processes, as well as enhancing the overall status of natural resources and ecosystems (JRC, 2021[10]). In the US, bio-based products are estimated to displace about 6.8 million barrels of oil a year and have the potential to reduce GHG emissions by 10 million metric tons of CO2eq/year (FAO, 2018[11]).

The potential of bio-innovation in the food system for bringing about new production and consumption systems that use renewable biological resources to produce food and feed, materials and energy has been particularly highlighted. A report by the WEF stresses that “closing the biological cycle is a key pillar for circular or closed-loop models that are currently being developed and tested worldwide”. This report showcases the example of the city of Amsterdam, which is pioneering work at the municipal level to develop both biological and technical circular models. In line with the above-mentioned OECD analytical

work, it states that "addressing food waste and food loss at the farm and consumer levels offers particularly compelling opportunities for bio-innovation to contribute to more circular models; for example, the safe and efficient conversion of post-harvest losses and by-products from farming as a renewable energy source for fertilisation or other applications is a win-win situation for farmers and the environment" (World Economic Forum, 2018[15]). Figure 2.3 shows the range of areas within the food system where bio-innovation could play a transformative role. The figure also indicates their relationship with relevant UN sustainable development goals (SDGs).

Figure 2.3. Bio-innovation in the food system



Source: (World Economic Forum, 2018[15]).

Regulatory challenges

The development of bio-solutions may be hampered by significant regulatory gaps, uncertainties and overlaps, making it difficult for start-ups and innovative businesses to test, develop and introduce new bio-solutions on the market while at the same time ensuring they are compliant with existing regulation. In addition, certain bio-solutions may fall outside the definitions of products that can be regulated under existing regulations, and consequently may not be subject to pre- or post-market oversight and fail to undergo the necessary assessment. Moreover, in some countries, case handling times for approving new bio-solutions can be particularly long.

A study for the government of the Netherlands featured in an OECD report (OECD, 2017[3]) identified close to 80 regulatory barriers to the bioeconomy and grouped them around the following categories:

- **Fundamental constraints:** call for a political and policy approach (e.g. import duties, level playing field, certification, and financial feasibility).

- **Conflicting constraints:** cannot be removed, but governments can help companies to meet the regulations (e.g. REACH regulations).
- **Structural constraints:** require adjustments to regulations, but do not demand policy or political action.
- **Operational constraints:** the regulation itself is not the problem but its implementation. Especially for SMEs, these lead to substantial barriers to investment in the bioeconomy.

According to the same report, governments should seek to remove existing barriers by focusing on three main objectives as far as regulation is concerned: develop instruments, in particular standards, to reduce barriers to trade in bio-based products; promote institutional co-ordination and policy coherence; address regulatory hurdles that hinder investments; and establish a level playing field for bio-based products. Regulatory hurdles and institutional co-ordination and competition issues are briefly discussed next together with a set of considerations on emerging risks and vulnerabilities. Technical standards are in turn discussed in the next section, as part of the array of regulatory responses to the challenges presented earlier in this document.

Barriers to trade in bio-based products and regulatory hurdles hindering investments

The OECD has identified considerable variability in estimates of environmental impacts as a hindrance to bio-based production. This hindrance could be removed through international standardisation. In a similar vein, the OECD points out that, in a context where "the term "bioeconomy" itself means different things in different countries", a shared definition of 'bio-based product' is needed as a standard for public procurement and business development" (OECD, 2017[3]).

As an example, according to exchanges with government authorities, a Danish company specialised in bio-based substitutes for chemically based pesticides used in the agricultural sector is reported to have been unable to bring its products onto the EU market thus far due to lengthy market approval processes.

On a related note, a study on the needs and challenges of companies in the bioeconomy in north-western Europe notes the importance of regulatory barriers, especially those relating to lack of commonly agreed and global assessment tools as well as of internationally agreed sustainability criteria and certification systems (NNFCC Ltd, 2018[16]).

Need for institutional co-ordination and policy coherence

The development of commercially viable bio-solutions and bio-based products involves the creation of new value chains and innovation ecosystems. Doing so requires, in turn, appropriate institutional and policy co-ordination enabling the adoption of a holistic approach that also takes account of interlinkages across sectoral regulations. In particular, the evolution of waste regulation, which is still predominantly defined as something that must be discarded rather re-used (Philp, 2020[17]), is likely to affect the scope and pace of development for bio-solutions and the bioeconomy more generally. As highlighted in OECD work, national policy that overwhelmingly favours second-generation biorefining using waste materials as feedstocks directly contradicts national policy that aims to minimise waste. The creation of "virgin" value-added products from waste feedstocks makes second-generation biorefining difficult to categorise within the classical waste hierarchy. To address this policy contradiction, the OECD has suggested classifying these waste feedstocks as 'secondary raw materials' instead, in order to lower waste management regulatory barriers (Philp and Winickoff, 2018[14]). An OECD analysis of Thailand's bioeconomy highlighted the need for regulatory reform as a major barrier for the development of the industry. A key area in this regard relates to zoning/city planning regulations (which are often not risk-based when it comes to authorising bio-based industrial activity). According to this analysis, this seems to be "a regulatory barrier of high importance as it contradicts the ambition of rural biorefining and increasing bioeconomy in general" (OECD, 2021[18]).

A related regulatory challenge will result from the potentially conflicting needs of agriculture and industry. As underscored by the FAO, "in the post-fossil-fuel world, an increasing proportion of chemicals, plastics, textiles, fuels and electricity will inevitably have to come from biomass, and this will increase competition for land" (FAO, 2018[11]).

As highlighted by the World Economic Forum, balancing diverse levels of governance, from local to global, is another important consideration from a co-ordination standpoint:

> *At one end of the spectrum, a rapidly growing number of local actors and applications will require locally developed and owned governance solutions. Governance solutions would then be aligned with local needs and culture, and local communities would be empowered to make their own benefit and risk assessments. At the other end of the spectrum, the global implications, even of local activities, on shared natural resources and biodiversity, cross-border ecosystems and trade, and our shared culture of ethics call for more general principles and guideposts. In addition, the trend towards more open and distributed bio-innovation is underpinned by large-scale data and technology platforms, whose ownership and influence raise global governance questions in their own right. Last but not least, national governments will continue to play a crucial role in setting framework conditions for bio-innovation, for example by providing research funding, defining rules for competition and intellectual property, ensuring food safety and providing information to the wider public. (World Economic Forum, 2018[15])*

Prevalence of an uneven playing field

An uneven playing field may be created, for example, if bio-based products must conform to standards and rules tailored to limit risks related to fossil-based processes and products. When aiming to ensure a level playing field, regulators should also bear in mind that complex and time-consuming regulation is far more damaging to small bio-based companies than to their larger counterparts (OECD, 2017[3]). Similarly, barriers to entry can stem from the difficulties new, relatively smaller entrants face in scaling up, whereas centralised, large-scale manufacturers in the chemical industry may have already achieved efficiencies.

Emerging risks and vulnerabilities

Regulators will also need to take into account the new risks and vulnerabilities (e.g. cyber-attacks) resulting from the increasing convergence and integration in bio-based production of robotics, microfluidics, cell-free systems design, synthetic metabolic engineering and other technologies, as well as from the involvement of many different types of organisations (OECD, 2021[5]). A related challenge has to do with the increasingly data-driven nature of bio-innovation. With more data being collected, stored and analysed, data privacy and ownership issues become more acute. Like in other sectors, the rise of larger platform players owning data or dominating data analytics capabilities raises new questions around who controls information and how it is used.

On a related note, it has been stated that "the proliferation of biotechnology research and development raises questions of control and safety. The more players have access to next-generation tools, the more challenging it will become for any single player, for example a regulator, to have visibility into who does what". In addition, lower technology cost and ease of access "can lead to do-it-yourself garage-type biology beyond government sanctioned or otherwise certified laboratories" (OECD, 2021[19]). Appropriate oversight is thus essential in this context.

Regulatory responses

This section presents selected relevant regulatory approaches that either have been adopted or are being contemplated with regard to the innovations under consideration in this case study. The following main features are focused upon: regulatory instruments at play (e.g. prescriptive vs. performance-oriented approaches), development of self- or co-regulation arrangements, and use of regulatory testing and experimentation, including regulatory exemptions.

Technical standards and certification for bio-based products

Technical standards are voluntary instruments developed "in response to a need in a particular area expressed by stakeholders through a bottom up approach" (OECD, 2016[20]). They can be developed domestically, by national standards bodies, or internationally (or regionally), by international (or regional) bodies. They can also be developed by private bodies. Technical standards may then be referenced or incorporated by States within their domestic legislation (OECD, 2021[21]).

Standards have strategic importance and provide a solid basis for introducing new products and technologies onto the market and a basis upon which further R&D can be built (They also help to remove the uncertainties that companies face. Developing standards in close co-operation between industry, research and policy makers is essential to create the right environment for full-scale deployment of new products and technologies. Crucially, standards provide the necessary scientific basis for implementing legislation by demonstrating compliance with legal requirements.

Previous OECD work has highlighted the importance of clear sustainability standards and certification, which provide credibility to claims of performance and sustainability, such as "bio-based", "renewable raw material", "biodegradable", "recyclable", or "reduced greenhouse gas impact". Standards and certification help verify claims such as biodegradability and bio-based content that will promote market uptake. Claims should be verifiable by consumers, waste management authorities and legislators. They can also be used to verify that policy goals and targets are being met. In this context, product labels should give clear and reliable information about the environmental performance of bio-based materials. This applies especially to bioplastics as these are the most likely to be contentious in society as a result of negative outcomes and perceptions coming from the use of petro-plastics. Today, many different "eco-labels" are used globally, and definitions and certification procedures differ widely. Significant efficiency gains may result from harmonising eco-labels in the medium term. (OECD, 2017[3]).

In a similar vein, OECD analytical work has notably underscored the importance of developing international standards in sustainable fuels, as "the globalisation of supply chains, industry actors, and travel routes means that instruments with international coverage are required to promote sustainability without compromising business models" (OECD, 2021[21]).

To help to develop the market for bioplastics, the Japan BioPlastics Association (JBPA) started a certification programme for products containing biomass-based plastic. The association has established standards as well as a methodology for the analysis and the evaluation of these plastics. The programme includes a logo that consumers can recognise easily. The JBPA certification, *BiomassPla*,[5] specifies that products with the logo must contain 25% of bio-based plastic (as measured by weight). In addition, the JBPA claims to co-operate with counterparts in the US (BPI), EU (European Bioplastics), China (BMG) and Korea, notably with regard to analytical methods to evaluate biodegradability, product specifications and recognition and labelling systems.[6]

Creation of regulatory incentives: the case of Italy

In the bioeconomy, a frequently mentioned example of successful regulation to stimulate innovation is the single-use plastic bag ban in Italy. In January 2011, Italy promoted a first-of-kind regulation aimed at replacing traditional plastic carrier bags with biodegradable and compostable bags (compliant with the harmonised CEN Standard 13432) and reusable long-life bags. This is considered to have triggered various desired effects in Italy including new investments in bioplastics production, with positive cascade effects along the value chain. The regulation created improvements in waste management, while Italian citizens adopted a behaviour with a positive impact on environmental sustainability (OECD, 2017[3]).

Anticipatory approach developed by the Swedish Committee for Technological Innovation and Ethics (Komet)

The Swedish Committee for Technological Innovation and Ethics (Komet) aims promotes "a more future oriented way to work with regulation", and "rules that are clear, future-proof and developed with legally safe methods, but encourage and facilitate ethical and sustainable innovation". To do so, it helps the Swedish government to proactively address improvements that technology could create for citizens, business and society, but also to highlight the conflicting goals that may arise. As stated on its website:

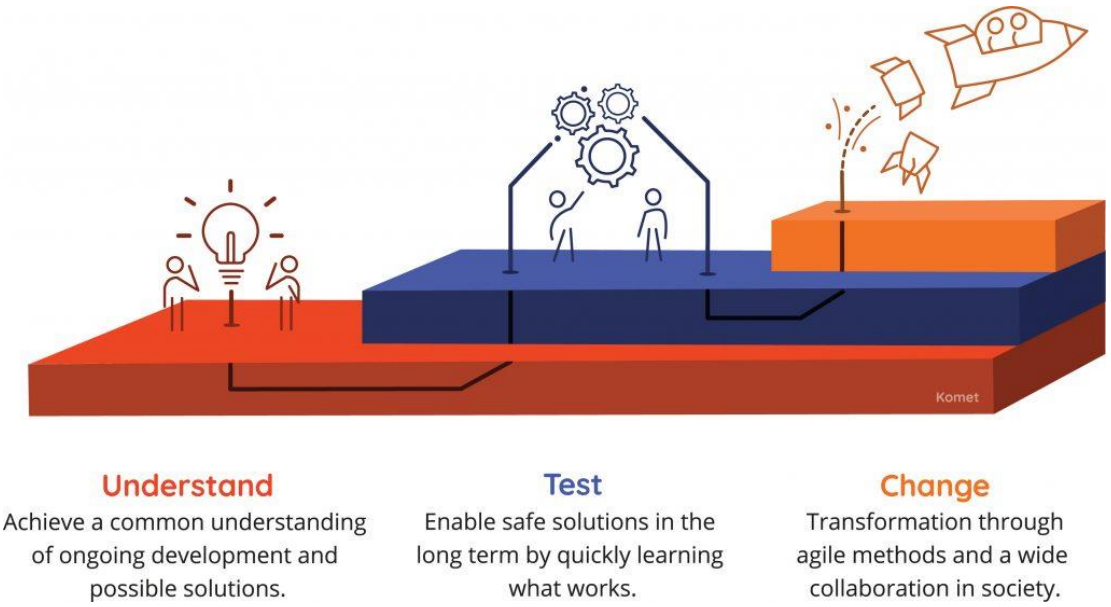
> *An important objective of the Komet work is to instil courage in the public sector. Although innovators are often private, at the end of the day, it is the public sector that must enable, be willing to and dare to meet the demands of both business and society. It is the public sector's role to ensure that the proper regulations are on the table. (Committee for Technological Innovation and Ethics, 2020[22])*

The Committee has developed a model to support the increased need for broad collaboration, testing and experimentation "as a fast and more secure way to learn about new technical solutions" (see Figure 2.4). To do so, it has examined various initiatives promoting experimental activities for technological innovation internationally. In addition, "a proposal to Government regarding controlled experiments where outcomes for both innovation and regulation can be achieved" is under development.

Stakeholder engagement also features prominently among the Committee's activities; e.g. by developing surveys, organising seminars on technological innovation, ethics and integrity, and creating an open mailbox to capture problems with rules and regulation.

Beyond the Swedish example, it should be noted that anticipatory and upstream approaches have emerged in a range of relevant areas that may help explore, deliberate and steer the consequences of innovation at an early stage. They allow for responding to public concerns or changing circumstances along the development trajectory. From an industry perspective, upstream approaches can incorporate public values and concerns, potentially mitigating potential public backlash against technology. In OECD countries, frameworks for upstream governance have entered policy debates, e.g. in the context of the "Anticipatory Governance" pillar within the US Nanotechnology Initiative. Likewise, under the major EU research-funding programme, Horizon 2020, the Responsible Research and Innovation (RRI) pillar has attempted to mainstream this approach across all research activities, echoed by recent developments in the United States. Anticipatory governance also mitigates hubristic tendencies in risk management that one can estimate complex risks and guard against failure with authoritative certainty (OECD, 2020[23]) (OECD, 2021[5]).

Figure 2.4. Swedish Committee for Technological Innovation and Ethics: model for collaboration, testing and experimentation



Source: (Committee for Technological Innovation and Ethics, 2020[22]).

OECD's Working Party on the Harmonisation of Regulatory Oversight in Biotechnology

The OECD's Working Party on the Harmonisation of Regulatory Oversight in Biotechnology (WP-HROB) deals with the environmental safety of genetically-engineered organisms (plants, animals, micro-organisms). Its work constitutes a relevant example of regulatory co-operation to enhance consistency in technical regulations across jurisdictions, facilitate exchanges and help achieve public policy objectives. This Working Party aims to ensure that the types of elements used in biosafety assessment, as well as the methods to collect such information, are as similar as possible amongst countries. This improves mutual understanding and harmonised practice, which, in turn, increases the efficiency of the biosafety assessment process, limits duplication of effort and reduces barriers to trade. The WP-HROB participants are mainly officials from OECD countries responsible for the environmental risk/safety assessment of products derived from modern biotechnology. There are also representatives from key partners (Brazil, P.R. China, India, Indonesia, South Africa), other interested countries (e.g. Argentina, Kenya, Paraguay, Philippines, Russian Federation, Thailand, Uruguay, Viet Nam); Business at OECD (BIAC); FAO; UNEP; the Convention on Biological Diversity Secretariat; the African Biosafety Network of Expertise (AUDA NEPAD-ABNE) and the Agriculture and Food Systems Institute. Participation from non-OECD countries is supported by the Global Forum on Biotechnology.

The publication of Consensus/Guidance Documents is a major output of the programme. These constitute a set of practical tools for regulators and biosafety assessors dealing with new transgenic plant varieties and organisms, with respect to environmental safety. The 60 Consensus Documents issued to date address a range of subjects including the biology of crops, trees and microorganisms, as well as selected traits that have been introduced in plants. All documents are made available through the OECD BioTrack website[7] (OECD, 2021[19]).

Policy co-ordination and public-private co-operation

Avoiding value-chain weaknesses and other policy problems requires a whole-of-government, co-ordinated approach. To this end, it can be useful to establish an independent advisory body, such as the German Bioeconomy Council, which advises Germany's Federal Government on the implementation of the country's National Research Strategy Bioeconomy 2030 and National Policy Strategy on Bioeconomy. The Bioeconomy Council aims to support research and development in the knowledge-based bioeconomy, set up positive framework conditions for a biobased economy, improve training and professional development in the bioeconomy, and conduct an open dialogue with different societal stakeholder groups (European Commission, 2021[24]). Other countries having established dedicated bio-economy advisory councils or stakeholder panels include Finland, France and Italy, whereas Costa Rica has committed to forming one (International Advisory Council on Global Bioeconomy, 2020[25]).

Such advisory bodies can help align the objectives and strategies of the different ministries and agencies, and facilitate the interaction between government and industry. Roadmaps can be used as policy co-ordination tools in this context, in which case advisory bodies can help ensure that roadmaps are implemented timely and successfully (OECD, 2021[5]). An interesting example in this respect is the UK's Synthetic Biology Leadership Council, which is chaired jointly by a minister and a representative from industry or academia and has developed a Synthetic Biology Strategic Plan that focuses on the research and commercialisation of Synthetic Biology.

Another example of policy co-ordination comes from the US, whose 2012 National Bioeconomy Strategy emphasised the benefits of co-ordinating federal efforts, especially with regard to R&D and regulation. In recent years, the country has taken steps to modernise the regulatory system relating to the bioeconomy. In 2017, the US Department of Agriculture released an interagency task force report outlining the need to increase public acceptance of biotechnology products, modernise and streamline the federal regulatory system for biotechnology products, and expedite the commercialisation of biotechnology products. The White House also released an "Update to the Coordinated Framework for the Regulation of Biotechnology" (EPA, 2017[26]), which aimed at streamlining regulatory processes and accelerating the translation of bio-innovations to market (International Advisory Council on Global Bioeconomy, 2020[25]).

Regulatory sandbox launched by the Korean Ministry of Commerce, Industry and Energy

In 2020 it was announced that the government of South Korea would designate ten industrial sectors, including the biotechnology industry, that would benefit from the country's regulatory sandbox.[8] Within 30 days, the government will inform companies if their intended business projects breach existing regulations. If the government does not respond within the deadline, the firms can assume there are no existing rules covering the enterprise. If regulations do exist, the government can give companies exemptions with provisions added; e.g. to carry out tests. After such tests, companies may obtain either a temporary or an official approval to commercialise the goods or services in the country.[9]

Conclusions

Bio-solutions, and the bioeconomy more generally, can be instrumental in addressing many sustainability-related challenges. It is thus very important to ensure that applicable regulatory frameworks do not stifle useful innovations and are technology neutral so as to guarantee a level playing field for bio-based products. In addition, these frameworks' design and enforcement provisions will need to be risk-proportionate to avoid unduly hampering innovation. This involves allowing the testing and piloting of innovative bio-based products in suitable contexts, as these experimental approaches can enhance the evidence base for decision making and thus improve regulatory quality and outcomes.

Well-co-ordinated and holistic approaches are also needed to ensure alignment and consistency of applicable regulations across sectors and policy areas (e.g. waste management and use, zoning regulations), thus avoiding potential contradictions. Dedicated advisory councils or stakeholder panels can facilitate institutional co-ordination and help ensure that there is sufficient understanding and social acceptance of the implications of developing the bioeconomy, including bio-solutions.

Moreover, a whole-of-government, co-ordinated approach, together with appropriate international regulatory co-operation and robust oversight, are essential to remove regulatory hurdles such as the lack of commonly agreed and trusted assessment tools, sustainability criteria and certification systems. International standards for bio-based products (e.g. on bio-based content, biodegradability, sustainability and functionalities) can help ensure consistency across sectors while enabling the development of labels for these products. Clear and credible labelling systems can in turn stimulate innovation and uptake; e.g. by providing consumers with clear information on the environmental performance of the products and guiding their purchasing behaviour towards sustainable choices. In addition, given the proliferation of national and international labelling schemes, it would be beneficial to associate bio-based products with "a successful existing scheme that has a harmonised and standardised approach" (Philp and Winickoff, 2018[14]). In some cases, labelling and certification schemes may be strengthened through public-private co-operation.

Going forward, and given the increasing technological convergence (i.e. integration of multiple technologies, in particular bio-, nano- and digital technologies) and associated uncertainty, policy and regulatory assessment will require anticipatory approaches that can assess innovations and technologies more holistically, while foreseeing possible ethical, social and governance challenges (OECD, 2020[23]) (García and Winickoff, 2022[27]).

Notes

[1] The World Economic Forum defines bio-innovation as “a set of advances in biotechnology, coupled with evolving economic and governance models”, thereby recognising “that innovation is shaped by both technological and social factors and that the role and impact of technology cannot be dissociated from the interests and norms in society that shape it, and are shaped by it” (World Economic Forum, 2018[15]).

[2] In its legal documents, the OECD Council has defined “Bio-based Products” as “commercial or industrial goods (other than food or feed) composed in whole or in significant part of biological products, forestry materials, or renewable domestic agricultural materials, including plant, animal, or marine materials. These are products developed from biological materials, with the intent of replacing or enhancing products derived from non-renewable resources. The term bio-based product encompasses bio-based chemicals, bio-based plastics, enzymes, bio-based materials, and bio-fuels. Food and feed are excluded.” (OECD, 2012[28]).

[3] While these concepts are broader in scope, much of the analytical work carried out on these topics is relevant for the purposes of this case study.

[4] On a related note, the OECD Observatory of Public Sector innovation has documented an interesting example from Ljubljana, Slovenia, of processing of invasive alien plant species into new, useful products (instead of composting or incinerating them), including paper and wood products, dyes and hybrid coatings, extracts for controlling of plant harmful organisms, food source, input materials for the industries of the future and 3D composites (OECD, 2016[29]) (OECD, 2019[30]).

[5] http://www.jbpaweb.net/english/e-bp/.

[6] http://www.jbpaweb.net/english/.

[7] www.oecd.org/science/biotrack.

[8] https://en.yna.co.kr/view/aen20200116007451320.

[9] http://www.koreaherald.com/view.php?ud=20190110000327.

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