REGULATORY HORIZONS COUNCIL

Regulatory Horizons Council

Briefing Note: Potential Priority Areas for the Council

23 December 2020

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Introduction

Background

The Regulatory Horizons Council (RHC) is an independent expert committee that identifies the implications of technological innovation, and provides Government with impartial, expert advice on the regulatory reform required to support its rapid and safe introduction. To inform the selection of its first, circa six-month, tranche of work, a summary of potential priority areas was created for the first Council meeting in August 2020. From this longlist, the Council decided to focus on the following four areas; genetic technologies, fusion energy, unmanned aircraft and medical devices.

The purpose of this document is to share summaries of potential priority areas, to inform Governmental and wider consideration, as well as to act in the interests of transparency and openness.

The primary information gathering period for what is contained herein was Summer 2020. As such, there will have been numerous developments, not least the completion of the Spending Review, the Ten Point Plan for a Green Industrial Revolution and the Energy White Paper, that are not reflected in this Briefing Note.

Priority areas for the RHC are defined as technological innovations and/or business models with high potential economic, social and environmental benefit, and where regulatory reform is – or could be – needed to facilitate the rapid and safe introduction of these products, services and business models.

Three vectors generated potential priority areas. Firstly, and primarily, an extensive horizon scanning and prioritisation exercise was undertaken. This was used as the basis for creating a long-list of 31 potential priority areas which was then tested via engagement with internal and external stakeholders and built out via desk-based research.

Secondly, through the course of this engagement with Government departments and external stakeholders - including a series of roundtables and interviews with experts in various fields - we sought to test and appropriately supplement our list of potential priority areas with wildcards.

Thirdly, the Council has an open consultancy offer to Whitehall Departments and appropriate bodies, to commission the RHC. The Council accepted a commission from a cross-government group to include genetic technologies as a priority area.

Content and Structure

This note sets out brief and consciously uncomprehensive introductions to a collection of technologies, sometimes applied in a specific sectoral context. It seeks to highlight the potential economic, social and environmental benefits, or disbenefits, to the UK if an appropriate regulatory approach is, or is not, put in place. It sets out the existing regulatory landscape and, at a high level, outlines how regulatory reform in its broadest sense could potentially unlock benefits or mitigate risks.

The summaries are not intended to provide recommendations or proposals and instead could act as a springboard for further in-depth work or consultation, taken on either by the Council or by other stakeholders within government, academia, or industry.

This document includes high level summaries of:

- The four priority areas in tranche one;
- Two possible priority areas for tranche two;
- Four other possible future areas; and
- The wildcards.

Tranche one: Genetic Technologies (Commissioned Area)

Introduction – Agri-food applications and industrial biotechnology

Genetic technologies are ways of understanding, making, or adapting genetic material. The genetic technologies being considered here include genetic modification and synthetic biology/engineering biology and one in particular, genome editing, that is attracting attention as it enables faster, easier, cheaper, and more precise changes to DNA. A possible focus area is the application of these technologies in plant and animal breeding and in modification of micro-organisms, being employed in agriculture and food production and in industrial biotechnology. This broad spectrum of applications is relevant to a variety of Government Departments.

The products of these platform genetic technologies have the potential to contribute to a circular economy in the production of food, materials, energy and chemicals; to help meet the UN Sustainable Development Goals; and to deliver the UK Government's Net Zero and circular economy policy commitments. The agri-food sectors contributed £121.7 bn to the UK economy in 2017, employing over 4 million people, and UK food and drink exports reached £22.6 bn in 2018[1]. However, in the context of climate change contributions, the agri-food sector is considered, along with aviation, to be 'hard to treat'. In the UK, the sector currently contributes ~9% of CO_2-equivalent (CO_2e) emissions but, by 2050 its percentage contribution to UK total emissions is expected to be ~25%, given the extent to which emissions have been reduced in other sectors.[2]

As far as we are aware, none of the policy scenarios in this area have yet taken account of the potential contributions of genetic technologies to delivering the Net Zero commitment for agri-food. However, they have the potential, given a proportionate and adaptive regulatory environment, to bring the UK percentage CO_2e contribution of the agri-food sector by 2050 much closer to zero, and perhaps even into negative figures. For example, this could include low carbon farming practices aimed at reducing soil, livestock and manure emissions through the use of genetics.[3]

[1] https://www.fdf.org.uk/exports-2018-q4.aspx#:~:text=Headline%20data%20indicates%20a%20modest,share%20of%20exports%20to%2061.4%25

[2] https://www.theccc.org.uk/publication/net-zero-the-uks-contribution-to-stopping-global-warming/

[3] https://www.theccc.org.uk/wp-content/uploads/2019/05/Net-Zero-Technical-report-CCC.pdf

The industrial biotechnology sector is also expected to make major contributions to the production of food, pharmaceuticals, new materials, energy, and chemicals, using modified micro-organisms in large scale bio-culture. It has the potential to disrupt UK markets worth more than $34 billion, where economic growth is either low or negative and likely to remain so, with a compound annual growth rate (CAGR) of 0.2% up till 2022. Future global markets addressed by industrial biotechnology promise, for example, a CAGR of 5.1% (bio-surfactants, 2017-22) and 28% (bioplastics, 2017-23[1]). The markets targeted will be key to the development of a circular economy and will also contribute to a reduction in CO_2e emissions and Net Zero targets.

These sectors have been subject to EU regulatory systems that are widely regarded as disincentivising the development of new products. This has seriously limited the extent of innovation in these areas, leading to pressure to reconsider how our regulatory systems, post-Transition Period, could be adapted to open our industries up to new international markets as well as contributing to domestic economic, environmental, and societal objectives.

Creating a more modernised and streamlined regulatory framework can foster innovation in the UK by facilitating the use of genetic technologies as tools for a wide range of sustainable practices. It is important that future developments in the regulation of genetic technologies should consider the benefits to all areas in which they are applied, and that they are carefully implemented, to maximise the potential of these technologies in meeting larger-scale sustainability goals.

How can the RHC add value in this area?

The RHC could add value by advising on the nature of future regulatory approaches, short term and medium to long term, with the aim of optimising the contributions of these industry sectors to the UK economy and to our environmental performance.

Current work (policy or regulation related)

In the short term, the RHC is undertaking workshops with stakeholders on post-Transition Period opportunities for the UK to diverge from the EU approach to regulation of crop plants developed using gene editing technology, to facilitate research and development in the UK.

Regulatory opportunities

There are also medium to long-term opportunities to advise on reform of current legislation as it applies to the products of all genetic technologies, leading to a UK regulatory system that enables the safe and competitive development of important

[1] https://www.bioindustry.org/uploads/assets/uploaded/d390c237-04b3-4f2d-be5e776124b3640e.pdf

industry sectors based on modified crops, animals and micro-organisms, working with any and all of the available genetic technology platforms. We want to learn from a range of stakeholders about specific initiatives that could contribute to future regulatory reform, and how our regulatory systems could be smarter in future.

What are the possible benefits for the UK if we get the regulation right?
Some of the potential benefits of getting the regulation right are outlined above. Also, the use of genetic technologies in agriculture could bring economic benefits in the form of increased crop yields and environmental benefits in terms of lower usage of chemical pesticides. It could also improve yield and increase disease resistance in crops and farmed animals. More transparent and efficient governance of genetic technologies will also encourage investment in research and development in the UK and create new, high-value jobs.

Getting the regulation right might involve, for example, moving from an EU-style 'process-based' regulatory approach that focuses on the technology used to develop the product, to a 'product-based' approach that is agnostic about the technology used and focuses on the properties, including both hazards and benefits, of the end product itself. It will also involve a broad array of adaptive instruments that could contribute to either a product - or a process - based regulatory approach, for example, using standards or guidelines to deliver regulatory equivalence with existing regulatory systems, or using innovative technology solutions to remove a current risk and avoid the need for a particular regulatory instrument.

Adopting an efficient approach to governance after the Transition Period has ended will be important in enabling innovation in agricultural biotechnology, capitalising on the UK's research strengths. Internationally, there are ever-increasing numbers of agricultural applications of genetic technologies (including genome editing) and non-EU countries have developed, or are in the process of developing, new policies and regulations in this area. There is evidence that new approaches to regulation (e.g. in Argentina) and the agile use of existing regulations (e.g. in the US) have enabled innovation in this area.

Genetic technologies have great potential in agri-food sectors, but for this to be realised, public trust and confidence in the applications of the technology and in its governance must be established and maintained. We cannot take it for granted that the existence of a solid scientific evidence base plus the appropriate oversight from government will inevitably translate to public trust and support and ultimately the social license required to maximise the potential of the technology.

Timescale
Outside of the EU, products arising from genetic technologies are already well established in many markets and these markets are growing rapidly. The most recent areas of innovation, synthetic biology, and genome editing are also rapidly building up their contributions to the economies of other nations and to societal

benefits in promoting biodiversity and mitigating climate change. Given its strong research base in these areas, there is an immediate opportunity for the UK to begin to open up and rapidly expand new areas of market activity. There are therefore immediate EU-Exit opportunities in which the RHC could play a role in the next 3-6 months.

Are there any cross-cutting opportunities?
Reform in this area will have implications for the interests of several major industry sectors and Government departments. Our approach to this initiative is designed to ensure that the regulatory reforms we propose will take account of the potentially competing interests of different sectors, e.g., plant breeding, animal breeding, crop production, industrial biotechnology, and food processing.

Who have we spoken to?
Relevant policy contacts at the Department for Environment, Food and Rural Affairs (DEFRA), the Department for Business, Energy and Industrial Strategy's Bioeconomy team, Office for Life Sciences, Home Office.

Healthcare applications
In light of COVID-19 and EU-Exit, how medical devices are regulated to maximise efficiency while ensuring safety and addressing ethical concerns is highly topical and reform is a Government priority.

How gene therapies are regulated within this reform is an area where the RHC could add value. The application of genetic technologies in healthcare is focused primarily in two areas: Genomics and Advanced Therapy Medicinal Products (ATMPs). Better regulation in these areas could improve the speed at which new medicinal products such as gene therapies come to market and the attractiveness of investing in these technologies in the UK, both of which have significant benefits in terms of economic value and health outcomes.

For example, ATMPs offer unprecedented promise for long-term health management. ATMPs comprise cell and gene therapies. They are a type of precision medicine that involves the use of cells or other materials, from donors or the patient, designed to provide a highly personalised therapy. Cell and gene therapies may offer longer-lasting effects than traditional medicines. They also have the potential to address complex diseases for which there are no effective treatments.

The Global Cell and Gene Therapy market is estimated to be worth between £9 to £14 billion ($14 to $21 billion) per year by 2025.[1] The UK took an early lead in capturing ATMP medical research. Furthermore, the innovation funding to date via Innovate UK, UK Research and Innovation and the Industrial Strategy Challenge Fund has created a national infrastructure including the Cell and Gene Therapy

[1] https://www.abpi.org.uk/media/1458/advanced-therapies-manufacturing-taskforce-report.pdf

Catapult and manufacturing centre and three Advanced Therapies Treatment Centres, to support the growth and international standing of ATMPs in the UK.

Timescale

In healthcare, there are already clinical trials underway for gene therapy products and so in the short to medium term these should reach the market and begin to have significant economic and health benefits as listed above.

Tranche one: Fusion Energy

Introduction

The broad category from our prioritisation process is energy generation, but the highest priority within this from our engagement was specifically on Fusion Energy. Fusion joins two light elements (with a low atomic mass number), forming a heavier element, whilst nuclear fission splits a heavy element (with a high atomic mass number) into fragments. In both cases, energy is freed because the mass of the remaining nucleus is smaller than the mass of the reacting nuclei.[1]

The UK is globally recognised as a world leader in fusion technology[2] and the STEP (Spherical Tokamak for Energy Production) programme will be important in commercialising the technology. STEP aims to develop and build the world's first commercially viable fusion power plant in the UK by 2040.[3]

Fusion is inherently safer than nuclear fission in terms of security risk. Fusion R&D is not regulated by the Office for Nuclear Regulation (ONR) but instead by the Environment Agency (EA) and the Health and Safety Executive (HSE). This current framework is widely seen as fit for purpose in an R&D context. However, it may need to adapt as fusion moves towards commercialisation in the coming years.

BEIS' objectives for a future fusion regulatory framework are that it should:

- Maintain human and environmental protections in a way that is proportionate to the risks and hazards involved in fusion;
- Provide assurances to the public; and
- Help to make the UK the best place in the world for commercialising fusion energy.

BEIS continues to investigate all options that would achieve these objectives and will set out views in due course.

How can the RHC add value in this area?

There are several ways in which the RHC could add value. This could include:

Current work (policy or regulation related)

The BEIS Fusion team has been working with UKAEA, ONR, EA, and HSE to conduct a gap analysis aimed at identifying the regulation areas which require

[1] https://www.iaea.org/topics/energy/fusion/faqs /

[2] https://epsrc.ukri.org/newsevents/pubs/indrevfissionfusion

[3] https://www.gov.uk/government/news/uk-to-take-a-big-step-to-fusion-electricity

amendment (if there are any) and those which are already fit for purpose. The main objectives for a fusion regulatory framework are those set out above.

Regulatory opportunities

- The RHC could add value by helping answer key questions necessary to achieve such a framework.
- There is also a global opportunity for the UK taking an anticipatory approach to the regulation of fusion. Shaping international standards from the outset to create a consistent approach to the regulation of innovation in the nuclear sector globally – can benefit UK research and businesses. A world leading regulatory framework on its own can help improve trade by giving industry confidence that products and services are safe. But the real benefits lie in internationalising this. Harmonising a regulatory approach with other countries which can help attract investment, generate export opportunities, and reduce burdens on business.

What are the possible benefits for the UK if we get the regulation right?
The world needs low-carbon, clean, reliable energy sources, to mitigate against climate change and the degradation to the environment associated with burning fossil fuels. Fusion energy would offer low carbon, continuous, and effectively unlimited power generation, with no high hazard waste or risk of nuclear meltdown. It would be particularly relevant for countries with limited scope for renewables such as wind, hydro-electric or solar and/or opposition to traditional nuclear power.

The basic science and engineering involved in the production of fusion energy is now well advanced, and the UK is a world leader in the most promising fusion technologies. In the near term, sustained investment in public R&D programmes remains essential to tackling the remaining technical challenges of fusion and ensuring that the UK can capitalise on the future economic benefits offered by this low carbon energy technology.

A dedicated fusion energy regulatory framework that is ‘pro-innovation’ could also play a critical ‘enabling’ role. This would increase market confidence and certainty, and so support private investment into promising fusion technologies as these technical challenges are overcome. There has already been over $1bn of investment globally to date into private sector fusion.[1] Any changes to the existing fusion regulatory framework would need to maintain human and environment protections, but – in view of the far smaller radiological risks of fusion – do so in a way that avoids replicating the costly regulatory processes that are applied to nuclear fission, both in the UK and around the world. Unlike fission, fusion involves no risk of nuclear meltdown nor any high-hazard, long-lived radioactive waste.

[1] https://www.sciencefocus.com/future-technology/meet-the-renegades-building-a-nuclear-fusion-reactor-in-your-neighbourhood/

Nuclear technologies are one of the most heavily traded sectors as it is highly international in nature (requiring flows of specialised skills, expertise, machinery and materials). It has the highest number of notifications of technical regulations being laid by member countries at the World Trade Organisation suggesting that a large part of this trade is driven by international standards, but also that there is a significant number of additional country specific regulations that might hinder trade. This issue will also need to be addressed in any future regulatory framework, to facilitate the global development of fusion energy technology.

Timescale/ urgency

A 'fusion energy regulatory framework' would need to be established in time to facilitate investment into UKAEA's STEP programme later in the 2020s. As well as STEP, private companies are also looking for regulatory clarity from Government to support market investment in their reactor development programmes – a small number of UK private companies aim to build and operate their own fusion demonstration reactors by the mid-2030s. To support this process, the Government may wish to set out at a high level what regulatory changes may be needed.

On Wednesday 2 December 2020, local communities across the UK were asked to step forward with proposals to house this prototype fusion power plant. The successful site will be home to the construction of the plant and will become a global hub for fusion energy and associated industries. To support this process, the Government may wish to set out at a high level what regulatory changes may be needed.

Are there any cross-cutting opportunities?

There are likely to be cross-cutting lessons learnt about addressing any public perception of risk with new innovations, as even though Fusion has far less risk than fission, the public and some stakeholders may not perceive it this way. There may also be useful cross-cutting lessons on how innovations can fall between different regulatory remits and the processes required to best manage this.

Who have we talked to?

We have engaged in numerous conversations with key stakeholders in the Fusion Energy sector such as the BEIS Fusion Policy Team, the Fusion Industry Association (FIA), Tokamak Energy, First Light Fusion, and the UKAEA. To build our knowledge further on the fusion regulation question we have engaged with the Environment Agency, the Health and Safety Executive, the Office for Nuclear Regulation and a wide range of other relevant stakeholders.

Tranche one: Unmanned Aircraft

Introduction

Our prioritisation highlighted multiple uses for unmanned aircraft (including drones and the broader category of unmanned vertical and/or short take-off and landing vehicles) in transport, aerospace, logistics, medical treatment, as well as food, water and agriculture. An unmanned aircraft is defined as an aircraft in which the "person responsible for piloting the aircraft is not onboard it"[1]. "Unmanned Aircraft may also be referred to as: Drones, Remotely Piloted Aircraft Systems (RPAS), Unmanned Aerial Vehicles (UAV), Model Aircraft, Radio Controlled Aircraft."[2]

Unmanned aircraft have the potential to significantly improve productivity, efficiency and accessibility across numerous sectors and applications, meaning that the potential impact is high if we get the regulation right. For example, "thermal sensors attached to drones hovering above pipelines can detect leaks and first-person, aerial-view video can scope structures after disasters when conditions on the ground are too risky for people."[3] Unmanned aircraft can also "deliver food aid and medical supplies to areas hit by disaster".[4] "The rapid delivery of vaccines, medications and supplies right to the source could quash outbreaks of life-threatening communicable diseases."[5]

In 2019, the European Commission adopted EU-wide safety standards for the manufacture and operation of Unmanned Aircraft. Those are found in the Delegated Regulation (EU) 2019/945 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems and Implementing Regulation (EC) 2019/947 on the rules and procedures for the operation of unmanned aircraft.[6] These regulations, which will form part of retained EU law and include a transitional period, set out design requirements for, among other things, mass, power, lights, and geolocation of unmanned aircraft. The regulations also impose national registration requirements for remote pilot training and unmanned aircraft in all EU member states.

[1] https://www.caa.co.uk/Consumers/Unmanned-aircraft/Our-role/An-introduction-to-unmanned-aircraft-systems/

[2] https://www.caa.co.uk/Consumers/Unmanned-aircraft/Our-role/An-introduction-to-unmanned-aircraft-systems/

[3] https://www.powermag.com/five-inspections-made-easier-with-drone-technology/

[4] https://www.dronesinhealthcare.com/

[5] https://www.dronesinhealthcare.com/

[6] https://eur-lex.europa.eu/eli/reg_del/2019/945/oj

How can the RHC add value in this area?

There are several ways in which the RHC could add value. This could include:

Current work (policy or regulation related)

There are already unmanned aircraft initiatives that the RHC could complement, such as the Future Flight Challenge (FFC) and the Government Drone Pathfinder. The FFC "is a 4 year, £125 million Industrial Strategy Challenge Fund (ISCF) programme." "The aim of the programme is to: demonstrate innovative ways to enable greener flight in a publicly acceptable manner leading to reduced carbon footprint for aviation; investigate and create new services and ways to travel; increase mobility; improve connectivity; alleviate congestion."[1] The Government Drone Pathfinder Programme is "part of a wider programme of work, both government led and across the UK's public and private sectors … aimed at enabling integration of drones into UK airspace."[2] "The programme aims to rapidly drive progress in drone technology and regulation over the next ten years, enabling industry and the public sector to fully exploit the market in areas such as geo-mapping, infrastructure inspections, surveying and logistics to both commercial and public-sector industries."[3] The Connected Places Catapult, funded by DfT, is supporting testing and trialling of drones beyond visual line of sight within the Pathfinder programme. The Civil Aviation Authority (CAA) is seeking to understand the risks and mitigations in these new use cases.

Regulatory opportunities

The standards regulating airspace are some of the most stringent and exacting in any industry; and the safety, security and feasibility of any new technology currently is thoroughly vetted before it is applied on a wide scale.

The EU Implementing Regulation, applicable in the UK from 31 December 2020, will create a new overarching regulatory framework for the operation of unmanned aircraft. Within this there will be discretion for national authorities to issue their own guidance and requirements. For the UK, the CAA have established some 'pre-defined risk assessments'[4], which operators may use for certain operations. However, blanket pre-approval for particular configurations is lacking, adding further cost and time-lags. Other national authorities and EASA are potentially moving more quickly.

[1] https://apply-for-innovation-funding.service.gov.uk/competition/471/overview

[2] https://cp.catapult.org.uk/pathfinder/

[3] https://cp.catapult.org.uk/pathfinder/

[4] See page 9 of CAA's CAP1789: https://publicapps.caa.co.uk/docs/33/CAP1789%20Edition3%20June2020%20cor.pdf

For some specific possible applications of unmanned aircraft, current regulations preclude utilisation. For example, prescriptive HSE regulation around how pesticides are applied to crops prevents innovation. Regulation of this form presents significant barriers to innovation, limiting the incentives for development of drones/unmanned aircraft using precision application of chemicals because there is no clear route to market for these products yet. Operators of unmanned aircraft struggle to gain permission to operate beyond visual line of sight (BVLOS), limiting their use in applications including surveying, crop inspection and monitoring of livestock on hill farms. Regulatory reform in this area could offer significant opportunities for innovation and productivity improvements. Rules limiting the number of drones operated by a single pilot at any one time also increase costs and inhibit innovation. Remote inspections could save businesses time and money in several sectors.

Separately, ensuring secure communications and improving download speeds with drones is essential to their safe operation so there may be an opportunity to look at spectrum allocation. The World Radio Forum says commercial entities cannot use 4G or any cellular device for Unmanned Aircraft due to a global agreement. There may be solutions for telecoms operators to release spectrum for these or similar purposes or work with rural communities on novel applications.

There is also an opportunity for government agencies to use unmanned aircraft to gather environmental data and evidence which can be used to shape policy, regulatory responses or enforcement action. Regulation could be made more efficient and effective, supporting business and economic growth.

There are privacy concerns and questions over the legal use of data gathered this way. The Regulation of Investigatory Powers Act 2000 covers evidence used in enforcement and prosecution. The legal and regulatory framework for regulator use of unmanned aircraft and the use of any evidence/data gathered therefore needs consideration.

The RHC may best add value by gathering a diversity of opinions and offering a strategic view of the social, economic, and environmental opportunities and trade-offs for various visions.

What are the possible benefits for the UK if we get the regulation right?
PwC estimated that the net cost savings to the UK from the advances of unmanned aircraft by 2030 would be £16 billion.[1]

The UK could attract inward investment and shape the development of unmanned aircraft, if its regulatory system enables safe innovation. The UK regulator, the CAA,

[1] PwC (2018), The impact of unmanned aircrafts on the UK economy - Skies without limits, https://www.pwc.co.uk/issues/intelligent-digital/the-impact-of-drones-on-the-uk-economy.html

is a key driver of global norms, so getting the balance right here will lead to export opportunities.

Unmanned aircraft may also have significant social benefits. They can deliver treatments and medicines to remote areas primarily in developing countries. This technology exists and is in practice and has huge application potential in warzones and for the military with the medical unmanned aircraft market set to grow from its current market value of more than $88 million to over $399 million by 2025.[1] In general, unmanned aircraft produce vast amounts of high-quality data, with benefits in agriculture, scientific research, weather forecasting and geographical applications such as mapping and monitoring.

Delivery by drone will be faster save money on fuel, fleet maintenance, and labour costs. This is particularly true for the last leg of a delivery journey between the warehouse and the customer's home or office. Unmanned aircraft generally fly using battery power and if batteries are recharged with low-carbon energy, CO_2 emissions could be reduced.

Precision technology promises to transform farming. Monitoring and managing crops from the sky using agricultural drones will enable agronomists and farmers to spray crops with pesticides, use novel techniques such as lasers to deal with weeds and pests, gather data on crop health and ripeness and monitor and manage the welfare of their livestock.

The aerospace industry now makes use of small, unmanned aircraft to provide inspections of commercial aircraft. With traditional technology, visual inspections can take up to six hours, but small unmanned aircraft could significantly reduce the amount of time and provide increased accuracy and ease of documentation.

Disaster management could be much improved by the speed and range of drones in reaching affected areas and returning high quality data to aid the response coordination. There are also safety benefits when avoiding humans undertaking hazardous work that can instead be done by a drone, such as surveying and inspections.[2] The Environment Agency has used unmanned aircraft in flooding events to check assets and the extent of flooding in recent years.

One significant benefit is around safety. Drones can replace the need for humans to operate at height, or in planes or helicopters, while inspecting rail lines, electricity and phone cables, roofs, buildings, wind turbines, oil or gas platforms.

[1] https://azbigmedia.com/business/health-care/medical-drones-market-expects-to-reach-almost-400m-by-2025/

[2] https://www.mydronelab.com/blog/drone-uses.html

Timescale/urgency

The UK is already seeing the uptake of unmanned aircraft across a wide range of applications and there are long term gains to be made in this sector. The main risks of not regulating unmanned aircraft effectively are:

- "Injury to people or damage to property arising from drones that fall from above or crash into buildings or other aircraft."[1] One of the biggest risks with unmanned aircraft operation comes from "radio frequency interference, resulting in loss of control, and, in the worst cases, fatalities.";[2]
- "Privacy, as virtually all drones are equipped with cameras";[3]
- "Cyber liability, as drones capture both data that is stored within the drone and what's beamed to the cloud";[4] and
- "Financial loss if usage of a drone causes business interruption."[5]

EU-exit offers the opportunity to consider diverging from some regulations which impact unmanned aircraft, such as the Health and Safety Executive (HSE) regulations around aerial spraying of chemicals for agriculture.

Are there any cross-cutting opportunities?

Unmanned Aircraft are an archetypal example of a technology that cuts across multiple sectors and applications, disrupting traditional vertical regulatory frameworks and institutions, and providing lucrative opportunities for regulatory reform. As a result, various government departments have a key interest in this area including, DfT, BEIS, Defra, UKRI, Centre for Connected and Autonomous Vehicles (CCAV), Home Office and the Police. The use of unmanned aircraft in a wider range of contexts and for a wider range of purposes requires reform to a diverse range of regulatory regimes not designed with unmanned aircraft in mind.

Who have we talked to?

We have engaged in numerous conversations with key stakeholders in the drones sector, including many private-sector firms as well as the CAA, DfT, CCAV, BEIS, Home Office, Police, Defra, Environment Agency, Natural England, Knowledge Transfer Network, Agri-EPI Centre. There is a strong consensus that regulatory reform in this sector is needed and more engagement is planned.

[1] https://www.argolimited.com/benefits-risks-using-drones-businesses-know/

[2] https://riskandinsurance.com/drones-offer-risks-underwriting-challenges/#:~:text=One%20of%20the%20biggest%20risks,aerial%20surveillance%20and%20data%20collection.

[3] https://www.argolimited.com/benefits-risks-using-drones-businesses-know/

[4] https://www.argolimited.com/benefits-risks-using-drones-businesses-know/

[5] https://www.argolimited.com/benefits-risks-using-drones-businesses-know/

Tranche one: Medical Devices

Introduction

As the UK approaches the end of the Transition Period with the EU, the opportunities for regulatory reform of medical devices need to be balanced against the risks of uncertainty through divergence. The Medicines and Medical Devices Bill seeks to empower the UK to amend regulations after the Transition Period. The Bill aims to ensure that the NHS and patients have faster access to the best innovative medicines, while supporting the growth of the UK life sciences sector; ensuring the UK remains at the forefront of the global life sciences sector once the transition period has ended. The Bill also responds to the recommendations made in the Cumberlege review.[1] This summary, at a high-level, covers the opportunities available within the medical devices sector that can be considered within the Regulatory Horizons Council's review of these regulations and non-regulatory opportunities. Ensuring the UK's regulatory approach to medical devices is as efficient as possible will significantly contribute to the country's growth: the UK life sciences industry employs 256,100 people and generates a turnover of £80.7bn (as of August 2020).[1]

'Medical devices' is a broad sector and encompasses any instrument, apparatus, appliance, material or other article (encompassing software including machine learning/artificial intelligence components) intended to be used for a range of medical purposes including diagnosis, prevention, monitoring, treatment of disease or injury or investigation, replacement or modification of anatomy or physiological process or control of conception. This document looks at the overarching medical devices sector; AI, Big Data and Machine Learning in Health are considered in more detail later in this Briefing Note.

There are currently several areas where existing regulations require updating to improve the regulatory framework for emerging technologies for medical devices. In addition, consideration needs to be made of the divergence that will occur as the rest of the EU moves from the current shared regulations (known as the 'Directives') to the EU Medical Devices Regulation (EU MDR) and EU in vitro Diagnostic Medical Devices Regulation (EU IVDR) from 26 May 2021 and 26 May 2022 respectively.

Concerns raised by stakeholders regarding the current system include:

- The system is complex and is made more difficult to navigate due to areas of ambiguity leading to requests from developers for greater assistance in finding their way through this framework;

[1]https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/910590/Bioscience_and_Health_Technology_Statistics_2019.pdf

- The way the regulatory pathway aligns to other 'gate-keepers' within the UK health sector, is not always clear or streamlined, as they may have different medical device evidence requirements;
- Notified bodies have decreased in number Europe-wide over the last ten years.
- The MHRA which will take on all regulatory responsibilities for the UK including that which was previously shared as part of the EU wide framework;
- There is considerable uncertainty amongst device developers and manufacturers regarding:
    - Which components of the existing regulatory framework will be retained long-term or whether there will be a transition to a new UK-specific regulatory framework; if the latter, the extent to which this will align to the new EU regulatory frameworks (EU MDR/EU IVDR); and
    - How the UK and other regulatory frameworks are going to be adapted to provide adequate cover to innovative areas such as the introduction of AI systems into health, and to the wider concerns from citizens and policy makers regarding the adequacy of regulation of devices compared to regulation of pharmaceutical therapies.

Additional factors that need to be considered arising from leaving the EU include:

- New relationships to international bodies such as the Medical Device Single Audit Program (MDSAP) and the opportunity to be a full member of such organisations;
- New barriers to accessing the EU including, in a non-negotiated outcome scenario, the EU will no longer recognise results of conformity assessments undertaken by UK Notified Bodies (NB); and
- New opportunities through alternative routes to accessing markets.

The safety of medical devices is at the forefront of developing regulations and regulatory alternatives in this area. Safety and encouraging innovation need to be the fundamental basics of regulation around medical devices. Baroness Cumberlege undertook a review entitled 'First Do No Harm', which examined how the healthcare system in England responds to reports about harmful side effects from medicines and medical devices and investigated what had happened in respect of two medications and one medical device (Primodos, sodium valproate, and pelvic mesh, respectively). The report made recommendations that seek to improve the healthcare system, including adverse event reporting and medical device regulation.[1]

[1] https://www.immdsreview.org.uk/Report.html

How can the RHC add value in this area?
There are several ways in which the RHC could add value. This could include:

Current work (policy or regulation related)

The Medicines and Medical Devices Bill had its second reading in the House of Lords on 2nd September 2020. The regulatory making powers in the Bill will allow existing Medical Device Regulations to be updated, including to facilitate innovation.

Regulatory opportunities

There are many regulatory opportunities within medical devices. The regulatory opportunities identified from initial sessions with stakeholders relate to the areas listed below. The initial stakeholders consulted included medical experts, colleagues at the Department for Health and Social Care (DHSC) and Office for Life Sciences, and the Medicines and Healthcare products Regulatory Agency (MHRA).

- Safety:
    - Ongoing safety monitoring;
    - Further testing and development of AI algorithms to assure effectiveness and safety in a UK population;
    - Appointing a Patient Safety Commissioner; and
    - Levels of adverse event reporting.

- Routes to market:
    - (MDSAP) – a different route to market;
    - Timescales in general; and
    - Targeted Assessment System (TAS) – targeted tests on top of accepting another country's certification mark where indicated.

- Dual use of data:
    - Alignment of approvals from UK bodies.

- Guidance (non-regulatory activities):
    - Training for device manufacturers on regulations;
    - Educational resources for developers on regulations; and
    - 'Way-finders' to support developers through regulatory framework.

- Diagnostics and digital innovations:
    - Targeted additions to regulations to encompass innovation in these areas.

What are the possible benefits for the UK if we get the regulation right?
There are a broad range of health benefits from better access to safe medical devices. For example, in the context of COVID-19, early approval of rapid, high accuracy diagnostic tests can lead to more people being able to get back to work

quicker and for the economy to re-open with greater confidence. Similarly, the earlier diagnosis and even prediction of serious conditions such as cancer, cardiovascular disease or dementia, can enable intervention at an earlier stage, personalised medicine and preventative healthcare. Software as a medical device (SaMD) including AI systems has the potential to improve the delivery of health care in terms of quality, efficiency and equity across the UK, but may be inadequately supported by existing regulatory frameworks.

Weaknesses within our UK diagnostic sector (manufacturing) were exposed by COVID-19. If investment grows and if it is supported by a solid regulatory system this will support health resilience. UK medical devices manufacturing firms could be able to explore easy access to devices produced in other markets. Investment can help the UK recover quicker from the effects of COVID-19. The UK could also be more able to respond quicker to future pandemics.

The UK is already seen as a global technology hub, this reputation could be improved further and provide more investment for the UK. Maintaining this will require continued international access and a strong regulatory voice in international forums. It will be hard to maintain this without review and investment in the UK regulatory system.

There is a significant opportunity for the UK to take on an international leadership role in the regulatory sector for medical devices. One such opportunity would be to become a full member of the Medical Device Single Audit Program (MDSAP), not just as an EU observer, and so directly shape medical device regulations on the global stage, for example in the regulation of AI systems in health. This would enable the UK to not only innovate in such areas but share this regulatory excellence internationally. In this context there may be an opportunity to achieve regulatory alignment through leading rather than following.

Timescale/ urgency

Royal Assent of the Medicines and Medical Devices Bill is due at the end of 2020. The MMD Bill is a delegated powers Bill which provides regulatory making powers. All changes to the regulations for medicines and medical device will be made via secondary legislation, not via the Bill itself. Deep dives on the medical devices sector are expected to conclude by mid-2021.

Are there any cross-cutting opportunities?

There are significant cross-cutting opportunities to the following two areas being considered by the RHC: Genetic technologies (Tranche 1); and Artificial Intelligence, Machine Learning, and Big Data (Tranche 2). Work in these areas will be aligned.

Who have we talked to?

Relevant colleagues at the DHSC, Office for Life Sciences, the RHC and the MHRA and independent device experts from both health and engineering sectors have been consulted at this initial stage.

Tranche two (tbc): Artificial Intelligence, Machine Learning and Big Data in Healthcare

Introduction

Artificial Intelligence, Machine Learning and Big Data provide a powerful opportunity to improve healthcare through enhanced insight and decision making. Artificial intelligence describes computer systems that can perform tasks normally requiring human intelligence, notably the analysis of data to model some aspect of the world to predict and also anticipate possible future events. Machine learning is a subfield within artificial intelligence, in which algorithms 'learn' i.e., they improve performance as they are exposed to more data over time. Big Data is high-volume data which may additionally be fast moving ('high velocity') and diverse ('high variety') information. The combination of both scale and complexity in such datasets mean that the information contained is difficult to extract through standard statistical techniques. But these could be amendable to machine learning approaches for which the scale of the data is an advantage.[1] Therefore, Big data may be an asset which artificial intelligence (specifically machine learning) enables us to exploit, identifying patterns, making predictions and recommending interventions.[2] Hereafter the term artificial intelligence (AI) will be used in this document to refer to these capabilities.

AI has potential applications within most business sectors, including healthcare which is the focus of this document. AI is seen as critical for improving efficiency within the healthcare system at all stages. This includes both operational ('back-end' systems) and patient-care systems (ranging from diagnosis to risk stratification of patient data, personalisation of healthcare, and prognosis/predicting outcome). AI is also increasingly used in biomedical research to accelerate the understanding of disease, the interaction of genetics and environmental factors on health and the development of new treatments.

Healthcare is facing significant challenges. Demand is increasing through the ageing population, increasing prevalence of obesity and diabetes, and treatments are becoming more expensive due to the creation of effective but costly new interventions (particularly pharmacological). Additionally, people have increasing expectations both from the health service and that their lives will be long and healthy.

[1] https://ico.org.uk/media/for-organisations/documents/2013559/big-data-ai-ml-and-data-protection.pdf
[2] https://www.gov.uk/government/publications/artificial-intelligence-an-overview-for-policy-makers

AI offers the potential to help to meet these significant challenges and to provide greater consistency, while reducing overheads and boosting efficiency.[1]

Getting regulation right for the use of AI in healthcare is critical to ensure that such innovations are safe, effective and equitable. Safety in this context includes both the performance of the innovation, and the appropriate use of the data in the development, validation and performance of these innovations. Effectiveness needs to be assured not just under ideal conditions, but for the diversity of the population and settings for which it is intended to be used. Linked to this, there needs to be confidence that certain groups are not disadvantaged by that technology. Confidence in this process can help support public trust, a key factor in the rate of uptake of these innovations.

Regulation is often perceived as being a barrier to the implementation and adoption of AI in healthcare. However, NHSX[2] found it is not the regulation *per se* but rather a combination of challenges that make this process difficult for innovators to navigate.[3] These include a perceived lack of coordination between regulators and statutory bodies, and legal and technical barriers for sharing information.

A key challenge is data protection, the UK's National Data Strategy commits to high data protection standards that are fit for purpose amidst rapid technological change to benefit both businesses and consumers. Regulations will need to consider accountability, human agency (allowing humans to make autonomous decisions) and human oversight (ensuring AI systems do not undermine human autonomy), transparency, technical robustness and safety.[4]

How can the RHC add value in this area?
There are several ways in which the RHC could add value. This could include:

Current work (policy or regulation related)

A key purpose of the Regulatory Horizons Council (RHC) is to support regulation that accelerates innovation and the implementation of emerging technologies, in this case the rapid and safe introduction of AI into healthcare. In regulatory terms, AI falls under 'Software as a Medical Device (SaMD)'. The Medicines and Medical Devices Bill had its second reading in the House of Lords on 2nd September 2020. The regulation creating powers in the Bill will allow existing Medical Device Regulations to be updated.

[1] https://digital.nhs.uk/data-and-information/data-insights-and-statistics/innovative-uses-of-data-and-data-science

[2] NHSX is the UK Government unit with responsibility for setting national policy and developing best practice for NHS technology, digital and data, including data sharing and transparency.

[3] https://www.nhsx.nhs.uk/media/documents/NHSX_AI_report.pdf

[4] https://ec.europa.eu/futurium/en/ai-alliance-consultation/guidelines/1

The MHRA is leading on a future regulatory framework for medical devices.[1] As the EU Medical Device Regulation (MDR) and EU In-vitro Diagnostics Regulation (IVDR) will not apply in GB, MHRA will use the powers currently being created through the Medicines and Medical Devices Bill to develop a robust, world-leading regulatory regime for medical devices that prioritises patient safety. MHRA will engage with stakeholders within the life sciences and healthcare sectors on this regime. As part of these discussions, it will identify and prioritise elements of international practice that promote public health and patient safety. This will be followed by a formal public consultation with the aim of delivering an attractive world-class regulatory system.

Regulatory opportunities

There is potential to explore the ability and readiness of regulation to underpin the safety, effectiveness and equitability of the employment of these technologies in the medical context.

What are the possible benefits for the UK if we get the regulation right?
AI offers significant opportunities for keeping people healthy, improving care, saving lives and saving money. It can also support clinicians to make the best use of their expertise, informing their decisions and saving them time.

"I think AI and autonomous systems will have a much wider role in diagnostics and diagnostic support – we will increasingly get to a point where patient data is automatically analysed via algorithms increasing efficiency and accuracy – in this context the role of a doctor is more in communication of conditions and exploring different risk pathways for treating conditions with the patient." (Alastair Denniston, Consultant Ophthalmologist at University of Birmingham Hospital, RHC member)

AI systems will not just match human performance, but exceed it, especially on tasks that benefit from processing high volume, high complexity data such as some aspects of diagnosis, prognosis, and prediction. The potential benefits of AI in Healthcare are far-reaching, and if supported by a solid regulatory system this will help advance public health and improve resilience.

AI can assist in making decisions, standardise approaches and enhance efficiency across the whole pathway of care. It can use image recognition technology to support medical experts make diagnoses e.g., symptom checkers, decision supporters and risk stratification. AI can also support digital epidemiology and National screening programmes to identify people at increased risk of contracting a disease or condition, enabling earlier treatment. AI can help predict illnesses and provide preventative advice, and it can support personalised treatments and participatory approaches.

[1] https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021

There is an opportunity for the UK to take on a leadership role e.g., through membership of the Medical Device Single Audit Program (MDSAP), not just as an EU observer, and so being a global leader in shaping medical device standards and forming AI requirements. The UK can develop its own procedures and concentrate on outcome-focused regulation. The UK could lead the development of global regulatory approaches to developing new technologies through MDSAP or similar. The UK could work to ensure the system becomes a global 'gold' standard, allowing products developed within it to access the rest of the world too. This would rely on supportive developments in AI international political economy and global standards.

Timescale/ urgency

COVID-19 has caused heightened interest in medical devices, including AI. AI in healthcare is in the early stages but significant progress has already been made, including the formation of the NHS AI Laboratory in August 2019.[1]

Deep dives on AI, Machine Learning and Big Data may be included as part of the Tranche 2 work identified by the RHC. Tranche 2 is due to commence in March 2021 with recommendations being produced in September 2021.
N.B. AI in Healthcare overlaps with Medical Devices, some topics in AI will be covered within the Medical Device deep dive, which are due to conclude in March 2021.

Are there any cross-cutting opportunities?

AI have applications across nearly every economic sector. Some examples include:

- Some AI algorithms could be replicated for other emerging technologies, e.g., self-driving vehicles, and therefore DfT would be key to engage on this work;
- The RHC are undertaking a deep dive on gene-editing which offers productive intersections with AI;
- DEFRA are another key stakeholder for developing regulation on safe decommissioning and recycling of any hardware and plastics; and
- The issue of 'explainability or 'AI black boxes' across applications is a key concern.

Who have we talked to?

So far, we have engaged with relevant colleagues at the MHRA, Care Quality Commission, DHSC, Office for Life Sciences (OLS), and the RHC, plus a handful of medical experts.

[1] https://healthtech.blog.gov.uk/2019/08/08/introducing-nhsxs-new-national-artificial-intelligence-laboratory/

Tranche two (tbc): Satellites, Space Travel and Aerospace

Introduction

This classification covers a wide area in terms of both the in-orbit economy and launch. For the purposes of this note, the in-orbit economy refers to satellites, space debris removal, satellite servicing and space robotics. Launch refers to launching vehicles into space from spaceports in the UK.

In 2017, the UK Space industry represented roughly 5.1% of the global space economy with exports accounting for 37.4% of the total income (a third higher than the export share of the UK economy as a whole).[1] It is currently estimated to be worth £15.5bn. A Morgan Stanley Space Report (2019) estimated that the global space industry could generate $1 trillion annual revenue by 2040, up from $350bn currently.[2]

The UK Space Agency (UKSA) and Ministry of Defence (MOD) are currently co-authoring a National Space Strategy (the first for the UK) which will set out the long-term aims for the sector and how it will support government objectives.

BEIS, UKSA and MOD have identified that the Space sector is increasingly a high priority for the UK with wider national security and defence equities taken into consideration.

The key pieces of legislation in the UK are the Outer Space Act 1986 and the Space Industry Act 2018. The Space Industry Act 2018 is a major step towards establishing the high-level legal framework to enable commercial launch to be carried out from the UK. It will also support and regulate activities carried out from the UK such as the operation of a satellite in orbit or the operation of a spaceport.[3] A consultation on draft regulations made under the Space Industry Act 2018 was launched on 29 July 2020.

Whilst the Space Industry Act 2018 is now law, the draft secondary legislation contained in the consultation is required to create the regulatory framework necessary for commercial launch operations to be licensed in the UK.

[1] London Economics. 2019. 'Size and Health of the UK Space Industry 2018: A Report to the UK Space Agency'

[2] Satellite Industry Association and Morgan Stanley Research. 2019. At https://www.morganstanley.com/Themes/global-space-economy

[3] https://www.gov.uk/government/consultations/spaceport-and-spaceflight-activities-regulations-and-guidance

How can the RHC add value in this area?
There are several ways in which the RHC could add value. This could include:

Current work (policy or regulation related)

- UKSA and MOD are currently co-authoring the UK's first *National Space Strategy*, informed by the Integrated Review. It will be the first holistic strategy where commercial and defence activities are aligned and coordinated across government.
- Cabinet Office, working with UKSA and MOD, are also establishing a Ministerial National Space Council to oversee the implementation of the Strategy.
- New legislation was introduced in 2018 (the Space Industry Act 2018), which created the high-level legal framework to enable commercial spaceflight and associated activities to be carried out from the UK.
- A consultation was launched on 29 July 2020 on draft regulations made under the Space Industry Act 2018 and associated guidance documents.

Regulatory reform opportunities

- Explore potential to increase transparency in our regulations, making clear requirements up front.
- Explore potential to reduce insurance requirements, which industry feels are uncompetitive.
- Reconsider unlimited indemnity: the UK is out of kilter with other nations, with our unlimited indemnity policy making it prohibitive for companies to raise capital to invest in the UK. A consultation on this could help.
- In-orbit economy. Though further clarity is needed, it appears there could well be opportunities to boost the in-orbit economy through further development of regulatory frameworks to better accommodate the safe and secure conduct of new and novel activities. This will be explored further with publishing of the Strategy.
- Manufacturing in space would require international regulatory groundwork to be enabled.

What are the possible benefits for the UK if we get the regulation right?
The space sector is growing globally, and the UK would benefit from growing its own industry and exporting technology abroad. It is a fast-changing sector with increasing commercialisation of spaceflight, as exemplified by the current NASA model and success of, e.g., SpaceX. The UK Space sector is fast growing, R&D intensive (six times more than UK average) with a small but highly educated workforce, so can benefit from this increased commercialisation.[1]

[1] London Economics 2019, p.1

Growth in space research has already delivered many societal benefits. It has enhanced scientific understanding of water cycles, air quality and the natural environment more broadly. Climate change concerns have led to a growth in the use of data derived from Earth observation satellites with combined public and private sector R&D funding. The information gathered through surveying and monitoring tools will be highly valuable in positive environmental action, such as sustainable resource management. Space technology will also be part of other technologies outlined e.g., 5G networks.

Technologies developed as part of space research, ranging from increasingly accurate GPS to semiconductor solar cells, have wide-ranging uses that increase efficiency, improve renewable energy options, and reduce emissions. GPS greatly improves journey accuracy and therefore reduces emissions between 15-21 %, more than improved engine or fuel efficiency have so far achieved.

The need for solar power in space has driven advancement in solar cell performance, with important benefits in renewable energy generation already realised. There are further opportunities in orbital solar power stations, which could always face the sun and therefore avoid common issues on Earth of clouds or night-time. It would also minimise the land-use of solar power on Earth. This technology is currently constrained by the cost of lifting materials into space, although many private companies are investigating space manufacture and even mining materials from space. If this continues, costs will fall dramatically.

The Space Industry Act 2018 and draft regulations made under it are drafted to be flexible enough to accommodate emerging technological advancements. In addition, for new and novel activities in the space environment, international engagement is key, with best practice in space discussed in forums such as the UN Committee for the Peaceful Uses of Outer Space. For the in-orbit economy, continuing engagement in these forums is important for the UK to demonstrate its leadership in space sustainability as a responsible space faring nation. In particular, UK leadership on establishing and championing best practice to meet the safety and security challenges posed by new and novel activities in space, such as proximity missions, will be key both for enabling such activities and for shaping their conduct.

Timescale/ urgency

The UKSA and MOD teams coordinating the Space Strategy have identified how further development of in-orbit policy and associated international engagement can help enable the vibrant UK in-orbit economy to continue to innovate.

BEIS, UKSA and MOD plan to establish an external group of experts to form a challenge group for the Ministerial National Space Council, to aid Government in implementing the National Space Strategy.

Are there any cross-cutting opportunities?

Space technologies are often cross-cutting in nature with aerospace more broadly seen as the instigator of technological change in many fundamental engineering disciplines. They deliver capabilities like Global Navigation Satellite Systems delivering positioning, telecoms infrastructure for communications and Earth observation apparatus. These are useful in a whole range of sectors, including communications, health, transport, security, agriculture and defence – with others being added all time. It is estimated that wider UK industrial activities in these sectors, representing over £300 billion, are supported by satellite services.[1]

Who have we talked to?

Currently our engagement on this subject has largely been restricted to Government entities including UKSA, MOD, DfT, BEIS and the Civil Aviation Authority (CAA).

[1] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/774450/LE-SHUKSI_2018-SUMMARY_REPORT-FINAL-Issue4-S2C250119.pdf

Possible future area: Mobility as a Service (Platforms and User Interfaces in Transport)

Introduction
Mobility-as-a-Service (MaaS), as part of the broader category of platforms and user interfaces, is the integration of various modes of transport along with payment and ticketing functions into a single mobility service. MaaS is about providing a seamless travel offering for the user. The journeys are optimised based on users' travel needs- whether they want to take the cheapest, fastest, or the most environmentally friendly route, they make a single payment under a single platform for an entire journey despite using multiple modes, making it extremely user-friendly and convenient.

How can the RHC add value in this area?
There are several ways in which the RHC could add value. This could include:

Current work (policy or regulation related)

The RHC could potentially assist the policy team with the regulatory responses to the Future of Transport Regulatory Review call for evidence.

Regulatory opportunities

DfT highlighted that there has not been a comprehensive review of transport for a significant period. A summary of points from the call for evidence where the RHC could potentially assist are as follows:

- What is the role of local authorities, central government, or other transport authorities?
- What is required for the standardisation and interoperability of data, for example the routing, ticketing and timetabling data, to deliver Mobility as a Service? Who should lead these further areas?
- Is the roll out of the integrated style of ticketing required to facilitate Mobility as a Service prevented by any regulatory or commercial barriers?
- What competition concerns could Mobility as a Service present that could be difficult to address through existing regulations?
- Does the current framework for consumer protection need to be expanded to include liability for multi-modal journeys?
- Could Mobility as a Service present any particular accessibility and/or inclusivity concerns which might be difficult to address through existing regulations?
- How can digital accessibility and data privacy be ensured?

- Is guidance or a code of practice a good next step for MaaS, and if so, what should be included?[1]

What are the possible benefits for the UK if we get the regulation right?
MaaS offers the opportunity to create a more optimised and efficient transport sector, reducing friction for passengers as well as reducing environmental impacts by encouraging ride-sharing, more active travel and/or sustainable transport, leading to a modal shift. Department for Transport's Future of Transport Regulatory Review provides additional detail and makes the following high level points regarding MaaS: *"MaaS platforms provide a layer between mobility providers and consumers, by integrating and analysing data from multiple modes of transport to offer a choice of journeys to consumers. This requires service timetabling and fares data to be interoperable and available to MaaS platform providers, along with the ability for consumers to purchase tickets digitally. There are often commercial or regulatory arrangements between MaaS platform providers and mobility providers underpinning access to this data that regulation needs to be aligned with. Over time, new modes and sharing models also have the potential to be integrated within MaaS platforms. Commercial MaaS platforms tend to operate on a subscription basis."*

MaaS is an infant industry but may be able to deliver wide-ranging potential benefits for society through the optimisation of the transport system. Detailed information is also set out in the Government's Future of Mobility Urban Strategy Paper, including on the following benefits: safer streets; a more inclusive transport system; smoother journeys; boosting active travel and public transport; reducing emissions; tackling noise pollution; unlocking spatial opportunities; tackling congestion; improving productivity; attracting investment and creating jobs.

All winners of the Government's Future Transport Zones are expected to trial MaaS platforms. An important impact of MaaS is that it may contribute to phasing out the private ownership of vehicles. Car-sharing enables more efficient use of vehicles, as it is estimated that most vehicles are not utilised 96% of the time (RAC Foundation, 2018). This is widely considered to promise many benefits including improved air quality from a reduction in emissions, less congestion and more parking spaces, reduced degradation of road infrastructure and improved accessibility of vehicles where the price may otherwise be prohibitive. They can also promote the use of electric vehicles. ZipCar, a car club with 250,000 members in London, partnered with Volkswagen in 2018 to introduce 325 electric vehicles into its fleet and aims for the fleet to be fully electric across all vehicle types by 2025.

There are also significant individual savings through car sharing. For those that had previously owned a vehicle, car club members generally reduce the number of vehicles owned and spend less on buying and maintaining their own vehicle,

[1] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file938347/FoT-Regulatory-Review-Summary-of-Responses-Accessible.pdf

meaning that their disposable income increases. In the UK, this has been estimated at £7,000 per car club vehicle (CoMo, 2017). However, a key barrier is awareness and uptake. DfT's Transport and Technology: Public Attitudes Tracker (Dec 2017) found that only 1% of people used a Car Club and only 26% are aware.[1]

Regulatory approaches will shape the benefits of MaaS as it becomes more widespread. An example is France, which has the most successful market for peer-to-peer car-sharing in Europe. Its strict regulations enforce all free-floating vehicles to be electric or hybrid, which enhances the environmental benefits of car-sharing schemes.

Timescale/urgency

DfT's regulatory review of the future of transport call for evidence for this closed on 3rd July 2020 and the RHC could potentially assist the policy team with the regulatory responses to this. Longer term opportunities could arise from assisting with more cross-cutting approaches to transport regulation.

Are there any cross-cutting opportunities?

A long-term opportunity could be the creation of something like a 'road transport regulator', with wider powers than the Office for Rail and Road, in much the same way that the Civil Aviation Authority (CAA) has a broad remit around all air traffic. This proposition would need to be tested. But the regulator could have the ability to pick up issues and opportunities that can be missed by our current regulatory system, and it could assist areas like MaaS by providing constant regulatory learning and expertise. It could lead to benefits such as dedicated regulatory experts with the resources to progress more areas of future transport innovation.

Who have we talked to?

At this early stage, our primary engagement has been with CCAV (Centre for Connected and Autonomous Vehicles) and policy officials in BEIS. We have had high level conversations with policy teams about MaaS but have engaged less with other types of stakeholders such as the commercial sector and academia.

[1] https://www.gov.uk/government/publications/transport-and-transport-technology-public-attitudes-tracker#history

Possible future area: Hydrogen Fuel Cells in Transport

Introduction

Hydrogen fuel cell technology is an area of the automotive industry that is becoming increasingly important as more manufacturers commit to developing this type of powertrain. In simple terms, hydrogen fuel cells operate a bit like a battery. Oxygen and hydrogen are fed into the cell. Under the action of catalysts, water (in the form of invisible superheated steam) and electricity are produced to provide energy to drive the wheels through electric motors.[1]

Some experts maintain that hydrogen fuel cell vehicles are less efficient overall when compared to a battery electric vehicle (BEV). This is true in the sense that electricity taken from the national grid and stored in a BEV battery involves fewer steps than using the electricity to first generate hydrogen, which is then used to generate electricity in a fuel cell. However, while fuel cell production costs remain high, current FCEVs (fuel cell electric vehicles) have significant performance advantages over BEVs: the range of most FCEVs is currently around three times that of the average BEV and refuelling times are significantly shorter.

How can the RHC add value in this area?

There are several ways in which the RHC could add value. This could include:

Current work (policy or regulation related)

There is currently work on hydrogen compressors, hydrogen in tunnels and subsidies for low carbon hydrogen.

Regulatory opportunities

In addition to the broader opportunities around clarifying leadership of the policy issues in government and assessing what the barriers are, the policy teams identified the specific issues below.

- **Tunnels:** Hydrogen vehicles contain compressed gas, and this means that, in theory, they cannot go through the euro tunnel. However, there is no concrete way of enforcing this at the moment. There is currently a study to check whether you can exclude hydrogen from that regulation and a joint funded programme with the EU. However, there would be a need for a broader view of who owns this and an overall review;

[1] https://www.gov.uk/government/publications/alternative-fuel-vehicles-guidance-for-mot-testers/hybrid-electric-and-hydrogen-fuel-cell-systems-guidance-for-mot-testers

- **Hydrogen compressors (noise issues):** Shell and other companies need to get approval for these but there can be complications with achieving this because of the noise levels of the compressors in built up areas. Local Authorities have rules about it being 'less than background noise' which is notably low and challenging to meet. There could there be some room for manoeuvre here and a role for the RHC to convene the necessary stakeholders to progress this;
- **Price:** The right regulatory framework could increase the number of refuelling stations, which would in turn increase the use of FCEVs and drive down the price of hydrogen for consumers; and
- **Coordination:** Energy intensive industries are exempt from grid charges designed to support renewables deployment but, if the DfT allow grid transmitted renewable electricity to qualify for the Renewable Transport Fuel Obligation (RTFO) support, it is likely that the renewable hydrogen suppliers would be liable for grid charges. Ensuring that hydrogen producers are not disadvantages against other EIIs (e.g., petrochemicals) would help deployment.

What are the possible benefits for the UK if we get the regulation right?
Like electric cars, FCEVs are classed as ultra-low emission vehicles (ULEVs) since the only substance to come out of the exhaust is water vapour. This environmental benefit often translates directly to user benefit: for example, FCEVs are exempt from the London Congestion Charging Zone and, with no carbon emissions, are exempt from paying Vehicle Excise Duty (VED or road tax).

The current thinking is that FCEVs can be used for long-distance or heavy-duty applications, working as a complement to BEVs that would primarily be used for shorter, lighter work. However, there are currently fewer than 20 operational refuelling stations in the UK, compared with around 5,000 (and rising) electric vehicle charging points. The right regulatory framework could increase the number of refuelling stations, which would in turn increase the use of FCEVs and drive down the price of hydrogen for consumers.

The UK has a good commercial industry for hydrogen (such as through hydrogen buses) and there are economic opportunities through export. For example, America commanded the largest share and surpassed a valuation of USD 753.1 million in 2016. Fuel cell deployments, especially in North America, has been influenced by federal R&D and demonstration programs and is supported by federal tax incentives for hydrogen infrastructure, FCVs, and fuel cell stationary power generation. Increased investment and support by the state government have augmented the use of fuel cell and hydrogen technologies in some parts of the nation. The market in America is predicted to expand at a CAGR of 24.72% by the end of 2025.

Timescale/urgency
Hydrogen fuel cells in transport already exist in the UK and it is likely to have short-term impacts within the next ten years. However, the extent of this impact will largely

depend on whether price can be driven down and improvements to the regulatory framework for hydrogen suggested below could have a role to play here.

Are there any cross-cutting opportunities?
As with MaaS, a road transport regulator could be a cross-cutting opportunity here (see MaaS section).

Who have we talked to?
At this early stage our primary engagement has been with the Office for Low Emission Vehicles and the Department for Transport more broadly.

Possible future area: Battery Technology in Transport

Introduction

With electrification of transport set to be one of the main pathways to decarbonisation, batteries as electricity storage devices are becoming one of the key enablers of a low-carbon economy, because of the flexibility they can provide to the system. Given their capacity to integrate more renewables into our energy and transport systems, global demand for batteries is expected to grow very rapidly, making the industry for batteries a very strategic one.

Policy support has been extended to the development of manufacturing capacity for automotive batteries. This reflects the dynamic development of battery technologies and the importance of Electric Vehicles (EVs) to achieve further cost reductions in battery storage for a multitude of applications. It also recognises the strategic relevance that large-scale battery manufacturing can have for industrial development.

How can the RHC add value in this area?

There are several ways in which the RHC could add value. This could include:

Current work (policy or regulation related)

The Government's Industrial Strategy Challenge Fund Faraday Battery Challenge has up to £317 million to help businesses and researchers to develop market-leading battery technologies. The fund is designed to inspire the growth of new technologies, companies, and skill development. The Government is bringing together a team to build on our strengths in automotive manufacturing and design, battery science and materials research. This step is already attracting global EV supply chain players and creating interest in the non-Automotive sector like Aerospace and Rail. New battery technology will benefit far more than the car market in the UK.

The Government has also recently announced that it will be relaxing planning legislation[1] to make it easier to construct large batteries to store renewable energy from solar and wind farms across the UK. Secondary legislation will remove barriers for storage projects above 50 MW in England and 350 MW in Wales, meaning more clean energy can be stored and used all year round.

[1] https://www.gov.uk/government/news/battery-storage-boost-to-power-greener-electricity-grid

Innovate UK, as part of UK Research and Innovation, has up to £10 million from the fund to invest in feasibility studies and in research and development into promising and innovative battery technologies.[1]

Regulatory opportunities

There may be opportunities around cross-government co-ordination where the RHC might be able to provide a productive convening power. However, significant regulatory opportunities were not identified from the engagement that took place.

What are the possible benefits for the UK if we get the regulation right?
Recent technology progress for battery storage in general has been boosted by the investment in EV innovation. Continued cost reductions are likely and are strongly linked to developments underway in the automotive sector, i.e., favourable changes in battery characteristics (chemistry, energy density and size of the battery packs) and the scale of manufacturing plants, that will decrease battery costs. The number of high capacity production plants are expected to increase significantly over the coming years.

Electric vehicles are an important recipient of battery technology. The market is very strong and growing. Electric-car sales in UK shot up by 220% in December 2019, and battery-electric vehicle registrations ended the year with a record 1.6% share of the overall market. The number of electric vehicles joining UK roads last year more than doubled from the year before, despite total car sales – which are still dominated by petrols and diesels – falling by 2.4% over the last 12 months.[2]

The automotive sector's period of major disruptive technology transition presents an opportunity for the UK's successful automotive sector to be at the forefront of new technology as the industry invests an estimated £230bn globally over the next five to ten years. The Advanced Propulsion Centre estimates that there are £24bn worth of opportunities for UK suppliers in batteries, electric machines and power electronics in the next five years.

The widespread adoption of EVs will bring significant environmental benefits through decarbonisation, especially as electricity production itself decarbonises and transitions to renewable sources. EVs waste less energy and produce no tailpipe emissions or air pollutants. Whilst there are still emissions from non-renewable electricity generation, these are spatially different as they are at the powerplant rather than a populated area. Hawkins et al. (2012) reported that life cycle greenhouse gas emissions from battery powered EVs charged using the average

[1] https://www.gov.uk/government/news/developing-new-battery-technologies-apply-for-business-funding

[2] https://www.drivingelectric.com/news/678/electric-car-sales-uk-near-7-market-share-september-2020#:~:text=A%20total%20of%2037%2C850%20electric,the%2012%20months%20of%202019.

European electricity mix of renewables and non-renewables were 17-21% and 26-30% lower than similar diesel and petrol vehicles, respectively.[1]

There is also potential for consumers to save money over time, as the cost of running an EV is cheaper than petrol or diesel alternatives, which works to offset the currently far higher purchase price of cars. The International Renewable Energy Agency (IRENA) also noted that between 2010 and 2016 the cost of Lithium-Ion batteries has fallen by as much as 73% between 2010 and 2016 for transport applications. As this purchase price is reduced, for which battery technology advancements are key, there is likely to be increased benefit for the consumer.

Timescale/ urgency

There is an urgency to ensure there is the correct regulatory framework, due to the exponential curve that battery uptake is on, particularly in transport. However, due to the international nature of many of the regulations surrounding battery technology, 'quick wins' in this area are less immediately apparent.

Are there any cross-cutting opportunities?

Yes, as batteries are an inherently cross-sectoral technology, there are many wider applications, not least for electrical demand smoothing of the grid for a whole host of uses.

As with MaaS, a road transport regulator could be a cross-cutting opportunity here (see Maas section).

Many of the regulations surrounding battery technology are international in nature and therefore we would need to further establish the degree of influence the RHC could have in shaping this sector.

Who have we talked to?

At this early stage our primary engagement has been with the BEIS and DfT policy officials. Many of the regulations surrounding battery technology are international in nature and would require wider engagement to understand.

[1] https://onlinelibrary.wiley.com/doi/full/10.1111/j.1530-9290.2012.00532.x

Possible future area: The use of Wireless Technologies in Food, Water and Agriculture (including 5G)

Introduction

5G is the latest technology with the potential to significantly impact the agriculture industry. 5G is the next generation (5th generation) of "mobile internet connection and offers much faster data download and upload speeds. Through greater use of the radio spectrum it will allow far more devices to access the mobile internet at the same time."[1] It could have significant economic benefits through increasing efficiency and reducing costs, whilst the societal benefits of increasing yields to meet increasing food demand and improving employment opportunities in rural areas are highly important.[2] Agriculture is rapidly adopting transformative 5G-powered precision agriculture solutions to monitor on-farm operational environments which inform the optimisation of plant growth and livestock wellbeing - even extending to milking robots for dairy cattle - without human intervention.[3] Other examples include the ploughing, sowing, feeding, health monitoring and harvesting of crops autonomously using 5G-connected farm machinery.

For example, Agri-EPI Centre is harnessing 5G to connect health monitoring collars on cattle at its monitor dairy farms, not only bringing economic benefits in terms of increased milk yields but also freeing up the farmer's time.[4] The autonomous monitoring of individual cattle behaviour informs the farmer about the likelihood of the onset of an illness in advance of criticality.[5] The use case demonstrates the benefits of high-speed 5G connectivity beyond the city and into rural areas, not just for citizens but also for businesses and industry, providing a positive impact on a key sector for the UK. The modern farm also has automated feeding machines and milking systems, all of which could benefit further from the reliable and higher capacity network 5G offers.

Tractors have been one of the key pieces of equipment on farms for many years, but 5G is a catalyst to extend their functionality and increase the return value from a significant investment for the farmer. The 'Hands Free Hectare' project and its successor 'Hands Free Farm' have been amongst the first to showcase how farms

[1] https://www.bbc.com/news/business-44871448

[2] https://www.mckinsey.com/industries/agriculture/our-insights/agricultures-connected-future-how-technology-can-yield-new-growth

[3] https://www.5gradar.com/features/ways-5g-will-change-farming-and-agriculture

[4] https://agri-epicentre.com/news/south-west-dairy-development-centre-in-new-5g-connectivity-film/

[5] https://agri-epicentre.com/news/south-west-dairy-development-centre-in-new-5g-connectivity-film/

may completely harvest a crop with no human contact. Trials in 2019 have confirmed the potential for 5G to enhance the scope of applications.[1] Collaboration of the information secured from real-time connected drones provides control signals to guide autonomous tractors to execute routine tasks such as the targeted application of fertiliser. The low latency afforded by 5G enables farmers to introduce increasingly sophisticated autonomous vehicles and execute an ever-increasing spectrum of processes.

How can the RHC add value in this area?
There are several ways in which the RHC could add value. This could include:

Current work (policy or regulation related)

At the Autumn Statement 2016, the Government announced its intention to invest in a nationally coordinated programme of 5G testbed facilities and trials, as part of over £1bn of funding announced to boost the UK's digital infrastructure.

The 5G Testbeds and Trials Programme is the Government's nationally coordinated programme of investment in 5G. The Programme looks to harness areas where the UK has a competitive advantage – such as in scientific research, engineering talent and our rich variety of technology businesses. It will explore the benefits and challenges of deploying 5G technologies in line with the following key objectives:

- Accelerate the deployment of 5G networks and ensure the UK can take early advantage of the applications those networks can enable;
- Maximise the productivity and efficiency benefits to the UK from 5G; and
- Create new opportunities for UK businesses at home and abroad and encourage inward investment.

Specifically, with regard to rural activities, the Department for Digital, Culture, Media and Sport (DCMS) funded two rural projects in its initial portfolio: 5G RuralFirst and 5G Rural Integrated Testbed (5GRIT).[2] These projects are designed to build the business case for investment in rural connectivity, through stimulating demand and providing innovative technological solutions.[3] Across the projects, various use cases are being tested, including in agri-tech and environmental monitoring.

All projects are also expected to align with, and benefit from, the work of the government's Barrier Busting Task Force, whose remit it is to identify barriers to fixed and mobile network deployment, and to work with industry, local authorities, and others to overcome them.

[1] https://www.5gruralfirst.org/wp-content/uploads/2019/10/5G-RuralFirst-New-Thinking-Applied-to-Rural-Connectivity-1.pdf

[2] https://www.5gruralfirst.org/what-is-5gruralfirst/

[3] https://www.5gruralfirst.org

DCMS has also committed £5 billion to subsidise the roll out of gigabit capable broadband in the hardest to reach 20% of the UK through this "Outside In" approach through its Rural Gigabit Connectivity (RGC) initiative.[1]

Through the Shared Rural Network Government is investing £500m to match a similar sum from the Mobile Network Operators. The deal will take 4G coverage to 95 per cent of the UK landmass by end of 2025.[2]

Regulatory opportunities

Access to spectrum is critical for wireless technology innovation; the regulatory framework needs to be flexible and support entry for new players. Ofcom introduced a new spectrum sharing framework in 2019 for shared and local access licences. It is important to keep this framework under review and consider further opportunities to support access for innovative 5G use cases and new network models. In engaging with some stakeholders, the difficulty and expense for smaller telecoms providers to get into the market was noted.

"Changing the way, we [smaller providers] can access the spectrum as shared frameworks has its challenges. You can't always get the best spectrum you want, and you need a license to use a bit of the spectrum from one of the providers. There is no geographical licencing in the UK. When auctions are made for spectrum, it is made for the whole country. Regulatory tweaks could allow smaller operators to enable community benefit via provision/licenced operators coming in via co-investment, helping to democratise connectivity across the UK."

What are the possible benefits for the UK if we get the regulation right?

There is widespread evidence and agreement on the significant and long-lasting economic benefits from improved connectivity. As such, any action to remove barriers to the deployment and adoption of these technologies would contribute to realising economic and social benefits:

- Work commissioned by the NIC estimated net benefits from investment in full fibre with 100% coverage of up to £28 billion (in present value terms) by 2050.[3] This is before taking account of the potential for full fibre broadband networks to deliver wider economic benefits, such as improvements in productivity;
- A study commissioned by Ofcom found that investment in broadband has had significant benefits to the UK economy and that increased connectivity has a positive relationship with economic growth and productivity;[4] and

[1] https://www.gov.uk/guidance/building-digital-uk

[2] https://www.gov.uk/government/news/1-billion-deal-set-to-solve-poor-mobile-coverage

[3] https://questions-statements.parliament.uk/written-questions/detail/2020-07-16/75471

[4] https://www.ofcom.org.uk/research-and-data/telecoms-research/broadband-research/economic-impact-broadband

- A study undertaken for Cityfibre has predicted that the total economic impact of deploying full fibre broadband networks across 100 distinct UK city and towns, could reach £120 billion over a 15-year period.[1]

5G will greatly aid how farmers digitally transform ways of working. Smart farming and precision agriculture are highly dependent on IoT devices to support communication between data from the field and smart devices used for farm management. The proliferation of IoT devices on farms will increase the volume, speed and accuracy of information available to farmers, enhancing their ability to measure and respond to crop and livestock conditions and therefore optimising operations.

Smart devices and sensors can help farmers increase yields, food security and efficiency, reduce waste, create new employment opportunities in rural areas and improve the quality of life for livestock but require immense resources and data speeds. With more devices and data, it will be challenging even for some 4G networks to cope. 5G can overcome this, providing real-time, high-speed communications among these sensors and devices.

Other examples of the potential benefits of 5G include:

- Access to greater connectivity and more possibilities, with farmers implementing a broad suite of technologies that are able to work in tandem, such as mobile apps, automated equipment, drones, sensors, and data transmission;
- Faster two-way communication and more accurate field operations by sharing data more quickly and efficiently;
- Ability to make faster and better decisions while improving machine performance for greater productivity, efficiency, and yields;
- 5G networks accelerating the current progress of agriculture digitalisation, helping countries meet increasing food demand, and revolutionise what is possible for farming; and
- 5G Fixed Wireless Access enabling remote areas to access gigabit connectivity.

Are there any cross-cutting opportunities?
There are lots of cross-cutting opportunities as wireless communications are the enabling technologies needed for the majority of agri-tech including drones, autonomous farm vehicles and precision agriculture. Agri-tech is also highly dependent on IoT devices to support communication between data from the field and smart devices used for farm management.

[1] https://www.theyworkforyou.com/wrans/?id=2020-07-16.75471.h

Who have we spoken to?

We have spoken with DCMS, Defra, Knowledge Transfer Network, Agri-EPI Centre and the University of Strathclyde.

Example Wildcard: 3D Printing in Manufacturing

Examples – Aerospace, Automotive, Bioprinting

Introduction

Additive manufacturing, also known as 3D printing, creates objects by adding layers of material one on top of another. It is starting to transform the way companies design, manufacture and even supply their products and presents an opportunity to radically change a variety of manufacturing business models. The technology has so far been mainly used for rapid prototyping and tooling but is now being used to manufacture, repair and replace end use parts.

The UK has world-class additive manufacturing experience in research, design and manufacturing expertise. Further developing this could help maintain the competitiveness of the UK's high value manufacturing sector. The sectors where the use of 3D printing is more developed are aerospace and automotive to produce high value and bespoke parts, consumer electronics and in healthcare for bioprinting.

How can the RHC add value in this area?

There are several ways in which the RHC could add value. This could include:

Current work (policy or regulation related)

From initial research, limited work is going on in central government to look at changing regulation for 3D printing, largely because it is a new method of production rather than a new product and many applications sit within existing highly regulated areas. Regulating for 3D printing does not obviously sit with any one policy team in government. Additive Manufacturing UK and the British Standards Institute (BSI) have been actively pushing for more co-ordinated and consistent standard setting for the UK which is seen as more of an issue for adoption and investment than legislation currently.

Regulatory opportunities

- Current IP and security methodologies and legal systems are not appropriate for the digital networks and ways of working required for additive manufacturing. Global IP leakage and cyber security concerns reference manufacturing systems are preventing rapid technology adoption.
- Perceived or actual lack of standards – all sectors / sector specific (especially aero / health / automotive), for processes / materials / software / products / applications.

- There are a number of areas where regulations are not designed with additive manufacturing methods in mind and in some aspects have become outdated i.e., traceability requirements for aerospace parts – large companies have often found workarounds to this but harder for smaller companies.
- Novel production methods and the products themselves challenge the existing boundaries in the healthcare regulatory sphere. It remains to be seen whether the 'mass customisation' that bioprinting allows will find the EU Advanced therapy medicinal products (ATMP) Regulation sufficient for bioprinting regulation.

What are the possible benefits for the UK if we get the regulation right?
There is a significant opportunity for the UK to gain considerable market share of a worldwide market for all additive manufacturing products and services which in 2017 was estimated to be over £6bn and growing rapidly. Whilst the directly attributable value of additive manufacturing products and services is currently a more modest £300m, it is experiencing a steady annual growth of around 30% and this is expected to accelerate as issues of standards, material consistency, IP protection and parts verification are addressed. However, this additive manufacturing share represents less than 0.05% of the world market for manufacturing ($11.4 trillion) and the opportunities presented as additive manufacturing becomes more broadly adopted are substantial.[1]

The UK's high value manufacturing sector could capture over £3.5bn per year (gross value added, GVA) of the rapidly growing global market for additive manufacturing derived products and services by 2025, potentially supporting 60,000 jobs in the knowledge economy and generating new highly skilled employment opportunities.[2]

Timescale
No obvious short term quick wins. Many aspects of the regulatory challenge are anticipatory and future orientated as the technology becomes more widespread i.e., intellectual property issues seem not to be a huge issue at present but could become so over the next 5 years.

Are there any cross-cutting opportunities?
Reform in this area crosses multiple sectors and has implications for several different Government departments. The RHC can add value by taking a broader view than most organisations would be interested in doing and join up the cross-cutting themes and implications of regulatory change in this area.

Who have we talked to?
We have been in contact with the Manufacturing Technology Centre and BEIS officials.

[1] https://am-uk.org/project/additive-manufacturing-uk-national-strategy-2018-25/
[2] https://am-uk.org/project/additive-manufacturing-uk-national-strategy-2018-25/

Robotics and Autonomous Systems

Introduction

Robotics and autonomous systems which perform tasks with a high degree of autonomy are already used across multiple sectors including food, water and agriculture, construction, and manufacturing, automotive, healthcare and aerospace with potential for high impact regulatory reform. In about 60 percent of occupations, at least one third of the role or activities could be automated and so the potential for transformational changes is significant.[1]

Modern farm machinery is changing rapidly through the increasing adoption of smart technology. Most experts believe that within ten years, at least for certain crops, robot tractors operating autonomously will be able to plant, manage and harvest without the need for a human driver. Robotic agriculture is widely predicted to take off by researchers, academics, and business (see for example, Robotic Business Review, 2016; Shamshiri et al.[2], 2018; Duckett et al., 2018[3]), but rigorous economic analyses of the economic feasibility of robotic farms are rare.

As more and more processes in *construction and manufacturing* are mechanized, machinery has gained a central role and has proved to be a strong driver of productivity gains. In construction this is particularly critical, as it is estimated that productivity only modestly increased between 1947-2010.[4] Excavators and bulldozers make it quick and easy to move large amounts of Earth; drilling rigs and piledrivers facilitate underground engineering; conveyers and pumps optimise concreting work; and mobile cranes lift and position heavy loads.

Cobots – collaborative robots – are robots designed to work collaboratively with humans. Whereas industrial robots are generally designed for specific tasks such as painting vehicles on a production line, cobots are designed to be interactive with humans and are built to be safe when operated alongside humans. They are designed to assist – not replace – human activity. Often these are the most laborious and least enjoyable tasks, meaning widespread use would free up time for more

[1] https://www.mckinsey.com/featured-insights/future-of-work/jobs-lost-jobs-gained-what-the-future-of-work-will-mean-for-jobs-skills-and-wages#

[2] Shamshiri, R. R., Weltzien, C., Hameed, I. A., Yule, I. J., Grift, T. E., Balasundram, S. K., et al. (2018). Research and development in agricultural robotics: A perspective of digital farming. International Journal of Agricultural Biological Engineering,11(4), 1–14. https ://doi.org/10.25165 /j.ijabe .20181104.4278.

[3] Duckett, T., Pearson, S., Blackmore, S., & Grieve, B. (2018). Agricultural robotics: the future of robotic agriculture. UK-RAS White Papers, EPSRC UK-Robotics and Autonomous Systems Network. Retrieved September 2, 2018, from https ://arxiv .org/ftp/arxiv /paper s/1806/1806.06762 .pdf.

[4] https://www.mckinsey.com/industries/capital-projects-and-infrastructure/our-insights/the-impact-and-opportunities-of-automation-in-construction

rewarding or valuable work.[1] The development and widespread use of cobotics promises significant improvements in many sectors, particularly the automotive industry, but there are opportunities for the use of cobots in assisting medical surgeries, agriculture and more generally for improving workplace wellbeing. But any wider consideration for the regulation for cobotics will need to consider safety, sectoral context, and public acceptability particularly as there is perception that these technologies will lead to a systematic set of jobs.[2]

How can the RHC add value in this area?
There are several ways in which the RHC could add value. This could include:

Current work (policy or regulation related)

From our engagement work to date there appears to be no planned systematic reviews of regulation for robotics. Stakeholder views have suggested that the ubiquitous nature of robotics across sectors means that Government, academia, and industry are missing an opportunity to work in a joined-up manner.

Regulatory opportunities

The UK moved away from the rules and systems of the EU's Common Agricultural Policy (CAP) and has worked towards a new system of rewarding farmers for delivering public goods in the UK Agriculture Bill (January 2020). The bill enables the government to help farmers invest in equipment, technology and infrastructure – for example, to improve productivity, manage the environment sustainably and provide other public goods. Public money may also be used to support research and development projects that facilitate more efficient, sustainable food production.

From recent engagement, there is a view that there is no primary or overarching concern regarding regulation with robotic thought leaders. But one of the challenges facing robotics innovators is different sectors have different business practices and regulatory environments. For example, a similarly capable robot in a rail setting would be regulated differently from one employed in oil and gas or waste management. Better and more readily available testing environments where developers, businesses and regulators can work together to safely develop new capabilities could help showcase and validate their new products with potential end users.

The underlying operating software or digital platforms and protocols that robots use is pertinent from a regulatory standpoint. ROS (Robot Operating Software) is universal and largely open source, and this may be insufficient for the varied applications businesses may be developing. Industry stakeholders devote a huge time and effort to build on it and to create the simulations, software tools and digital

[1] https://internationalfinance.com/cobotics-the-way-to-automation/
[2] https://www.oxfordeconomics.com/recent-releases/how-robots-change-the-world

twins they need to develop, operate, and test their robots. Once they hit 'real life', there can be issues with interoperability e.g., with data from the client, or collaboration with other robots or potential services. Increasingly, to be a robot company, the knowledge, skills and capabilities of tech software is often a prerequisite, and this can be a barrier for some start-ups. There seem to be no effective standards and protocols to enable companies to share these synthetic environments digitally, safely and protecting intellectual property with their co-collaborators or to get other innovators to build new services. Furthermore, SMEs may not be able afford the initial upfront costs required. The Centre for Digital Build Britain has begun an ambitious programme on this within the physical environment, and their Information Management Framework is an important approach to facilitating this.

What are the possible economic, social, and/or environmental benefits for the UK if we get the regulation right?

- Overall, there is a $15trillion potential boost to global GDP from AI, robotics and automation by 2030 - economic gains will be experienced by all sectors of the economy, with each industry expected to see a gain in GDP of at least 10% by 2030 in the UK (PwC)[1].
- Agri-engineering can help to increase UK productivity through the wider adoption of best practice, for example advanced nozzle design and GPS guidance. It can also help to increase the UK's share of emerging markets, through UK strengths in precision agriculture which is a concept that includes observing, measuring and responding to inter and intra-field variability in crops, remote sensing technologies and robotic applications.
- Technological advances in robotics open enormous new possibilities. New technologies in the digital space (such as unmanned aerial vehicles, low-cost sensors, remote operations and autonomous control systems) could become significant enablers of innovation in construction equipment. Semi-autonomous equipment is capable of carrying out complex tasks, though it still requires considerable human control. Autonomous equipment makes use of sophisticated digital tools and new technologies such as out-of-sight drones, leaving only "monitoring roles" for the human worker.
- Robotics is also set to revolutionize the logistics industry with e-commerce giants including Amazon engaging in the increased development of logistics robots for several functions in warehouses including packaging, storing, and picking. In addition, various players in the market are leveraging the inception of collaborative robots or cobotics which will be used for effective order fulfilment warehousing and delivery operations. Consequently, the rise of the Robots-as-a-Service (RaaS) subscription business model will allow retailers, third-party logistics firms, and e-commerce sites to use robots for addressing their fulfilment

[1] https://www.pwc.co.uk/economic-services/assets/macroeconomic-impact-of-ai-technical-report-feb-18.pdf

needs and as a result the global logistics robots market could witness significant growth.

- Cobotics could greatly improve employee productivity and wellbeing. It has been estimated that depression lowers the productivity and costs the UK £1.7–£2.8 billion a year.[1] "Health service costs of anxiety disorders in 2007 were £1.2 billion. The addition of lost employment brings the total costs to £8.9 billion." [2] Organisations across all sectors are struggling to address and promote health and wellbeing at work and beyond, with any significant advancements likely to have great societal benefits.[3]

Timescale/urgency

There is scope to increase the number of cobotic innovations in multiple sectors across the UK beyond the automotive sphere. There remain significant safety requirements which may be legitimate (e.g., the robot needs to be behind safety barriers) but nonetheless ensures that they are not currently well integrated into human workflows as they could be.

The timescale for potentially optimising the use of cobotics is not necessarily urgent but there are some significant opportunities in some sectors that are not currently being maximised. For example, the agriculture industry may face challenges on access to labour post EU-Exit, therefore robotics and automation will become increasingly important to alleviate concerns surrounding food security in the UK.

While labour supply is a key concern, particularly seasonal labour for harvesting - for the change to more automation to occur it would need both a strong economic case (the robotics would need to be cheaper than human labour with no loss of efficiency) and significant knowledge exchange and training to enable the sector to adapt.

Are there any cross-cutting opportunities?

Reform in this area crosses multiple sectors including food, water and agriculture, construction, automotive, healthcare and aerospace.

Who have we talked to?

We have met with BEIS, Defra, Government Office for Science, Knowledge Transfer Network and Agri-EPI Centre.

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1 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/215808/dh_123993.pdf

2 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/215808/dh_123993.pdf

3 https://internationalfinance.com/cobotics-the-way-to-automation/