

# Regulatory Horizons Council Meeting Minutes

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# RHC Meeting 14 August 2020

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## Location

- Virtual MS teams meeting

## Attendees

Regulatory Horizons Council (RHC) Members:

- Cathryn Ross (Chair), Group Regulatory Affairs Director at BT Group
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Programme Leader at the Medical Research Council's Harwell Institute
- Matt Ridley, Member of the House of Lords, Science and Technology Select Committee
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

RHC Executive and Better Regulation Executive Senior Officials:

- Chris Carr, Director of the Better Regulation Executive
- Sarah Montgomery, Deputy Director of the RHC & EU/ International Team
- RHC Secretariat

## Key Decisions

- The Council is content with taking a 6-month tranche approach as a timeframe for initially taking forward work on its priorities.
- The Council agrees to the below areas for its tranches of priorities working closely with the relevant stakeholders:
  - Genetic technologies
  - Fusion Energy
  - Medical Diagnostic Devices
  - Drones

## Potential Options for Tranche 2

*It was agreed that a decision on the exact composition of tranche 2 will be made following additional stakeholder engagement and discussion.*

- Artificial Intelligence in Health
- Technologies related to Space (e.g. satellites)
- Additional Areas TBC

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*Prior to this discussion of priority areas, there was a Council Induction Session where members discussed ways of working, were given the opportunity to get to know one another and the RHC Executive set out its methodology towards arriving at a set of possible priority areas for consideration.*

## The RHC's Broad Approach to Establishing Priority Areas

- The RHC needs to strike a balance between planning and also being capable of adapting to circumstances. With this in mind, adopting the suggested 6-month approach seems appropriate.
- The RHC will need to be innovative in how it funds and resources its work programme. This will include identifying partners who can assist with work, offer secondees, and perhaps even fund work. However, it will be critical to identify and proactively manage any actual or perceived conflicts of interest when taking this partnership approach.
- The RHC will be utilising convening, exploring, and examining approaches to different pieces of work. It will be important to be conscious and clear which of these 'modes' the RHC is in when progressing a particular piece of the workstream. It will also be critical to pick up cross-cutting issues such as how regulation is designed, proportionality, data issues, issues in going from start-up to scale.
- When deciding priorities, it will be necessary to balance the criteria of: where the RHC can best add value, the timeframe in which benefits will accrue, and the need for its focus to resonate well with wider stakeholders, including the government of the day.

## Genetic Technologies, Nuclear Fusion, and Medical Devices

- The RHC was commissioned by the cross-Whitehall Group on Gene Editing to look into gene-based technologies. Based on the evidence submitted and subsequent engagement with policy teams to scope the role of the RHC, the Council believes this is an area of innovation with significant regulatory opportunities to encourage technologies that can have substantial economic and societal benefits. As such, the Council decided it should be a priority tranche 1 area. It may be better to refer to genome-based or genetic technologies rather than gene-based. It would also be important to distinguish between genetic modification (GM) and genome editing.
- Nuclear Fusion is an interesting area that could be ripe for the RHC to add value. There are a tight group of actors in this area compared to other technological innovations which are more cross-cutting. Fusion technology may take longer to fully realise than other areas, but there could be a useful opportunity to influence an emerging regulatory landscape at an early stage.
- The role and importance of the hydrogen economy as well should not be disregarded and the RHC may want to consider hydrogen in its broader uses beyond solely that of mobility.
- COVID-19 has broadly demonstrated three issues in the health sector: 1) the sharing of data; 2) devices regulation, including test kits and ventilators regulation; 3) a specific deficit around AI systems and the utility of continually updating algorithms. In particular, COVID has demonstrated that approval for medical devices can potentially be accelerated and this area therefore could therefore be promising and timely for the RHC to consider.
- Robotics, Drones, Mobility as a Service, and 'In-Orbit' Technology
- The Council suggested that the regulation of drones technology merited further consideration. There's a lot of work currently taking place with Aerospace Technology Institute (ATI) and the Civil Aviation Authority (CAA) on this, and the CAA have already had positive meetings with the RHC on adding value in this area.
- Space ('In-Orbit') Technologies may also merit consideration by the RHC as the UK is leading on mini satellites. The Council thought that there were potential opportunities for RHC to add value/resource on space regulation, for example for the in-orbit economy.
- Based on this discussion, the Council concluded that Tranche 1 should include genetic technologies, nuclear fusion, drones, and the regulation of medical devices. It concluded that Tranche 2 could include space technologies, AI and big data in health. Although there would be merit in sharing the Council's thoughts more widely with stakeholders and getting their views to inform Tranche 2.

## Next Steps

- Council members can continue to email in feedback on the priorities document and highlight any networks that the RHC could make use of.
- The RHC Executive will be drafting a work programme that it can socialise with stakeholders. This will emphasise that the RHC now has its full complement of Council members and give a broad sense of the RHC's direction of travel.

# RHC Meeting 15 October 2020

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## Location

- Virtual MS teams meeting

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Cathryn Ross (Chair), Group Regulatory Affairs Director at BT Group
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Programme Leader at the Medical Research Council's Harwell Institute
- Matt Ridley, Member of the House of Lords, Science and Technology Select Committee
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

### Officials:

- Sarah Montgomery, Deputy Director of the RHC & EU/ International Team
- RHC Secretariat

## Key Decisions

- The Council agreed with the exam questions for each of the priority areas outlined in the minute below.

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### Updates on conflicts of interest

- Parag Vyas became director of Panitek Power Limited which commercialises renewable energy technologies in India. There will potentially be interaction with DfID and FCO in terms of grants and supports. Panitek Power is in the process of seeking support with partners from Innovate UK administrated competitions. These also include funding from DFID qualifying as Overseas Development Assistance
- Matt Ridley became a member of the [Innovation Expert Group](#). There is unlikely to be a conflict of interest.
- Risks have been mitigated via the official conflicts of interest form process.<sup>1</sup>

### Priority area updates and discussions

- There was an agreement that we need to be clear what the minimum viable product output is and keep in mind that iteration is key. Having a large project should not automatically mean that it must become slow-paced, and we can still work in an agile way at pace.

### Fusion Energy

- An update was provided on several meetings with key stakeholders including with Ian Chapman, head of the UK Atomic Energy Authority who provided an overview of the current landscape.

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<sup>1</sup> [See this link for the RHC's official Conflict of Interest process](#)

- There are two key exam questions on fusion energy. With the [STEP](#) programme gaining momentum, there is an imminent question on who should be the appropriate regulator and the role of the RHC in providing a recommendation. This decision will provide clarity for stakeholders. The second question is longer term and focuses on how the UK can continue to move towards an innovation friendly, long-term regulatory framework for fusion.

#### Unmanned Aircraft (including Drones)

- An update was provided on this workstream, highlighting that this is a vast topic area with a high level of complexity and multi-dimensional aspects so we must not underestimate the task we have set ourselves. There are a huge range of different scenarios of applications of unmanned aircraft and very different risk environments.
- Working closely with policy teams we have arrived at a shortlist of potential short-term and long-term exam questions and will be engaging with industry to further explore these.

#### Medical Devices

- An update was made to the Council on work around Medical Devices. The main exam question is around how the UK can encourage international investment, innovation and improve safety in the medical devices area through regulatory reform.
- The Council discussed how there is an opportunity for the UK to show international leadership in medical devices and how the Council's independence could make it well placed to consider this.

#### Genetic Technologies

- An update was provided to the Council on the work around genetic technologies. The key exam question is how 'should the UK's governance and regulation of the products of genetic technologies be undertaken in future to support their more rapid and effective translation to viable markets, with health, environmental and economic benefits for UK citizens'.
- The Council also discussed the possibility to add value in both the short term and long term by supporting the Department for Environment, Food & Rural Affairs (DEFRA) in its publicly announced intention to consult on precision breeding techniques in the autumn.

#### Risks and opportunities

- Lord Callanan, the BEIS Minister is keen to meet the Council in November and there was a discussion on how best to use his time.
- Recognising that there are many organisations within the space that the RHC operates, a brief update was provided to the Council on the work to communicate the purpose of the RHC across Whitehall. This included discussions with the Department for Digital, Culture, Media and Sport, the Emerging Technology Board in Cabinet Office and the upcoming 'RHC Challenge Group', a cross-Whitehall group that acts as a sounding board for the RHC.

#### Managing conflicting views from stakeholders

- The Council had a brief discussion on managing conflicting views from stakeholders. The point was made that dissenting views are important and critical to how the RHC operates. However, where possible, we would like to avoid a situation of dissenting opinions and reach consensus.
- In the event, consensus on a specific recommendation cannot be reached, the Chair will intervene.
- Council members highlighted that the RHC will always be engaging with political, cultural, ethical and identity conflicts across our priority areas and so should expect to

receive robust challenge from various interest groups. It will need to recognise this challenge and acknowledge where certain beliefs are coming from.

#### Measures of success

- The rationale for monitoring and evaluating the performance of the RHC was outlined. This is partly about maximising the Council's own learning, but also about generating evidence of impact to inform future funding decisions. The challenges we face in robustly evaluating the RHC and very broadly what a possible evaluation approach could look like were described.
- Council members were supportive of the points made. They suggested we should also be seeking to measure the RHC's impact on the international regulatory stage; and whether the RHC's agile approaches have led to culture/behaviour change in the wider regulatory community.

#### International considerations

- A paper was presented to the Council on options for engaging with international partners to achieve its objectives. The Council was enthusiastic about learning from other countries and the value that wider networking can have for building credibility domestically, evidence gathering and influencing but emphasised the importance of any international engagement being targeted as it can be resource intensive.
- There was agreement on exploring the feasibility of setting up an informal group of like-minded expert committees across the world and maximising our international networks to inform the current work across the priority areas.

# RHC Meeting 19 November 2020

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## Location

- Virtual MS teams meeting

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Cathryn Ross (Chair), Group Regulatory Affairs Director at BT Group
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Programme Leader at the Medical Research Council's Harwell Institute
- Matt Ridley, Member of the House of Lords, Science and Technology Select Committee
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

### Minister:

- Lord Callanan, Minister for Climate Change and Corporate Responsibility

### National Quality Infrastructure (NQI):

- Daniel Mansfield - British Standards Institution
- Steve Brunige - British Standards Institution
- Gareth Edwards - National Physical Laboratory
- Alex Connor - National Physical Laboratory
- Suzi Daley - United Kingdom Accreditation Service

### Officials:

- Sarah Montgomery, Deputy Director of the RHC & EU/ International Team
- RHC secretariat

## Actions

1. RHC to remain cognisant of the difficulty of recommending primary legislation due to pressure on parliamentary time.
2. RHC to provide views on policy development tools that could be used for the deep dives.
3. RHC to engage with subject matter experts from NQI partners (BSI, NPL, UKAS) on deep dive areas in order to consider the existing standards landscape as part of evidence gathering to inform possible recommendations.

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- A discussion about the benefits of the RHC was held. It was recommended that the RHC should be cognisant of the difficulty of recommending changes to primary legislation due to pressure on parliamentary time.

### Nuclear Fusion

- It is important to maintain a clear distinction from nuclear fission when considering the regulation of fusion energy.
- Reminder that we will want to use the phrase 'fusion energy' rather than 'nuclear fusion' due to potential associations of the word 'nuclear' with higher levels of risk.



- RHC will need to gather evidence from other examples of fusion plants (for example ITER).

#### Drones

- Still a challenge on how to get to those hard-to-reach stakeholders on the drones workstream.
- Important to keep a very iterative policy development approach where we put ideas out, test them, gather more evidence and so forth.
- Team has often used the word 'unmanned aircraft' rather than drone. This is to try and capture all technologies that fall under this bracket, including unmanned taxis. Also trying to align language more closely with what colleagues in the DfT use.

#### Medical devices

- There has been a high level of engagement including with the MHRA.
- The workshop on the 18<sup>th</sup> of November with ONS and MHRA went well – they made suggestions on where the RHC could have maximum impact. Also considered how best to utilise the international framework and lessons learnt from COVID-19.
- Possible criticism: we are still in the middle of COVID-19, so we may not be able to learn from it yet. However, we have an agile approach, and want to learn as we go. There is lots of data already being generated that we can use so we do not need to get primary data.
- Stakeholder engagement continues including with Centre of Regulatory Science and Innovation.
- Our approach: to convene, explore, examine in workshops and agile engagements; this is what we did in the recent workshop on the 18<sup>th</sup>.

#### Genetic Technologies

- BRE has been very helpful setting up a series of workshops with varied stakeholders from November to January.
- People who spread disinformation/ false information present a risk we must manage. We should not give validity and publicity to their ideas, and we need to help people to navigate this which will help control the risks. However, we should engage with some who have valid opposing views in a constructive way. Some NGOs have good points on risks, and the public may have similar concerns.

#### National Quality Infrastructure (BSI, UKAS, NPL)

- NQI would like to see increasing participation in standards and to build a framework of information sharing.
- It was noted that groups like the NQI have an important function. The RHC wants to learn from the NQI how to engage effectively with hard-to-reach stakeholders.
- As part of the Standards for the Fourth Industrial Revolution, the NQI will engage with the community of innovators to explore how they can best be drawn into the standardisation process.
- Standards can help people to meet regulations (i.e. Government can decide to recognise the implementation of a standard as a way to demonstrate compliance with regulatory requirements). This allows businesses to innovate whilst protecting important public safeguards. NQI also work with EU standards and co-regulation to help with accreditation.

# RHC Meeting 17 December 2020

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## Location

- Virtual MS teams meeting

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Cathryn Ross (Chair), Group Regulatory Affairs Director at BT Group
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Programme Leader at the Medical Research Council's Harwell Institute
- Matt Ridley, Member of the House of Lords, Science and Technology Select Committee
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

### Guest speaker:

- Julia Black, CBE FBA is the strategic director of innovation and a professor of law at the London School of Economics and Political Science

### Officials:

- Sarah Montgomery, Deputy Director of the RHC & EU/ International Team
- Jim Foudy, Deputy Director of Regulatory Development and Opportunities Team
- RHC secretariat

## Key Decisions

- The Council endorsed the idea of creating a Council-led blog.

## Meeting Minutes

### RHC Blog options

- The team explained the options for the RHC creating a blog, recommending it be hosted and administered by the Council (rather than be on Gov.UK and administered by the secretariat).
- The chair would be content to produce the first blog.
- Other Council members were broadly supportive. Discussion touched on utilising feedback we receive after putting content out, exploiting Council member's own networks and utilising social media to push. There was also some caution expressed about sharing opinions on particular sensitive areas and the need was flagged to make sure the blog is easily digestible.

### Focus on Fusion Energy

- It was explained that the RHC have begun developing high-level objectives for the regulator and drafting the report. The plan is to share and seek feedback on the criteria, including via ministerial engagement. ONR report states most other countries are regulating Fusion with the Fission regulator and taking lessons from Fission.
- A comment on public perceptions was made, in particular a lack of distinction between Fusion and Nuclear Fission in the public's mind.

- It was suggested that a certain Technology Readiness Level (TRL) was required to answer the question of who and how something should be regulated. Before this, standards and guidance could be used, and effort must be made to avoid being overly prescriptive.
- The roles that existing regulators already have and the need for choices to be made in that context was touched on.

#### Resourcing

- The uncertainty, context for, and implications of, mobilised members of the RHC as well as the outcome of the Spending Review was explained. There will be greater clarity in the new year – by the end of Q4 2020 - which can inform future RHC planning.
- BEIS' business planning narrative in relation to budgetary allocation was spoken on.
- The support for the RHC and the strength of the narrative was emphasised.
- It was suggested this could well make good blog material, which others supported.

#### Unmanned Aircraft

- An update was given, explaining the progress that has been made on the approach and the onboarding of external futures expertise in support of the deep dive. This included utilising driver mapping and multivariate analysis.
- The complexity of the system under consideration was touched on.
- Members are keen to leverage the learning and utility of trying this approach. Is it worth delineating between the physical and software elements of drones?
- Comments were made on this approach that will surface different views and the assumptions about what may happen in the future.

#### Medical Devices

- An update was given, touching on COVID-19 lessons learnt, international opportunities and stakeholder engagement (EU CE marked products).

#### Genetic Technologies

- An update was given on themes covered in two workshops, the first being mainly with industry and the second with academics. Discourse has been wide but informative and helpful. We have covered the process vs product basis of regulation and exposed a variety of views and complexity. Third workshop with policy makers and fourth with NGOs and public representing bodies to follow. Several scalable options are possible for us to take forward for deep consideration, in terms of the areas we work on to try and develop recommendations.

#### Risks, opportunities and project approaches

- An update was given on the risks and opportunities, referring back to the business planning and mobilisation discussed earlier in the meeting. Opportunities resulting from leaving the EU and COVID-19 need to be a central pillar of thought for the Council in their work.
- The reputation of the RHC was touched on.
- Possible policy development approaches were listed.
- An overview was provided of the key approaches for each of the 4 priority areas. Inviting comments from participants on these.
- It was remarked on how the aim is to learn and improve.
- It was emphasised that the clear exam question for fusion and the vast number of stakeholders and uses for drones as well as the need to look at which project approaches are working well as we go proceed.

## Guest speaker – Julia Black on innovation friendly regulation and regulators

- Overview of Julia's background.
- Julia explained her experience to the participants and her career focus on risk regulation along with innovative processes and systems. There is a balance to be struck within the framework used and there are core elements of regulatory systems. This is critical to innovation as the goal is to innovate to achieve the goal. We need to understand the domain such as the market, industry and so forth.
- It is important for regulators to calibrate for potential harm – using a risk probability times impact calculation. This work is about balancing precautions and resilience. We need to understand our ability to trial innovations in a contained space, such as via a sandbox. Incentives that lie around the system are important such as immunity to liability.
- A comment was made on how timely this presentation is and how the RHC are looking at impacts to regulatory frameworks. It is important to encourage regulatory systems to be learning systems and the RHC is part of this capability.
- Julia commented on how a blame culture can make near miss analysis less productive. There needs to be close engagement and partnership.
- It was mentioned that the regulator role covers assurance in some cases.
- Julia commented on how there is an inbuilt risk bias for different sectors. This can be corrected but we need to step back one level and then come back in to correct this.

## 7 Questions paper

- It was decided that this will be taken offline. In summary, the RHC has completed some great work writing up 7 questions and Council members will be invited to comment.

## RHC meeting 20 January 2021

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### Location

- Virtual MS Teams meeting

### Attendees

#### Regulatory Horizons Council (RHC) Members:

- Cathryn Ross (Chair), Group Regulatory Affairs Director at BT Group
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Programme Leader at the Medical Research Council's Harwell Institute
- Matt Ridley, Member of the House of Lords, Science and Technology Select Committee
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

#### Guest speaker:

- Stephen Gibson, Regulatory Policy Committee Interim Chair

#### Officials:

- James Phillips – No.10 Special Advisor
- Alex Hickman – No.10 Special Advisor
- Chris Carr – Director of Better Regulation Executive
- Jim Foudy, Deputy Director of Regulatory Development and Opportunities Team
- Stuart Sarson, Deputy Director of RPC Secretariat
- RHC secretariat

### Meeting Minutes

#### Discussion with James Phillips and Alex Hickman

- The importance of the RHC work was summarised, particularly in the context of the Build Back Better Committee around levelling-up, global Britain with an outward-facing competitive mindset and sustainability. These are essential to the Government's priorities for infrastructure skills and innovation.
- It was discussed that the RHC role is to complement other work in government but to do so in an independent fashion. The key to the work is being disruptive yet engaging the right people to ensure that key messages are landed and taken forward where appropriate. The work focuses on regulatory reform that will facilitate technological innovation in the economy. It has 'vertical' technology-specific strands that it is currently looking at via deep dives. It will also look 'horizontally' at cross-cutting themes that apply to several areas – for example, it could look at issues around the process for creating regulations or themes around how regulators should react to innovation.

- It was suggested that it would be good for the RHC to meet with the Secretary of State to discuss how the RHC work can feed into the science and innovation program on a more regular basis.
- A point was raised about the challenge for the RHC of working cross-government since many technologies impact numerous departments (for example, genetic technologies). Alex and James recognised the challenge and offered to assist where barriers occur.
- It was also suggested that the Global Green Investment Summit in October would be of great interest to the RHC, with topics such as fusion and unmanned aircraft fitting in well. Also suggested joining the cross-Whitehall working group on R&D that meets weekly.
- The Council went through the challenges and significant opportunities of the deep dive areas they are currently looking at. Several useful actions came out of this. James was interested in a theme that some of the deep dives were encountering about incumbents and large companies preferring existing regulations, even if burdensome, because this holds back smaller more innovative ones and thereby reduces competition.

#### RHC team update

- There was an update on resourcing and how the RHC remains a priority of BRE.
- There was also an overview of the collaboration work with Birmingham Health Partners and the benefits of this work along with points to consider for similar joint working. The Council discussed that perceived and actual conflicts are important considerations. The RHC needs to be transparent here and arrangements need to be put in place when collaborating to ensure issues are avoided. The RHC team can provide advice on conflicts from a BEIS perspective.
- The Council were invited to feedback on the frequency of Council meetings and the approach to agendas.

#### Further discussion – Genetic Technologies

- Discussed the planned workshops and how to approach them, as well as responding to the DEFRA consultation on genetic technologies.
- There was a general discussion about balancing risks against benefits when regulating and the issue of companies going beyond the required standards to 'gold plate' things. A theme from one workshop was the possibility of a 'societal benefit clause', but it was not clear how to operationalise something like this.
- It was agreed that for genetic technologies there would be a key perception difference depending on what first uses would be permitted by new regulations. First uses that have more obvious social benefits could lead to greater acceptance of the technology.

#### Further discussion – Fusion

- The different types of fusion reports were discussed. In terms of full Council involvement, it was agreed that reports shouldn't be drafted by committee, but the Council is there to help and challenge.
- The level of detail for the report was discussed. It was suggested that one potentially useful approach was to avoid attempting to determine all the answers but still providing views on the more complicated aspects.

#### Further discussion – Unmanned Aircraft

- A well-organised workshop had been held earlier that day. The format worked well and it developed several scenarios. There is now a need to decide how to interact with these scenarios. Many small points of interest came out of the process which will need to be picked out. Now need to interrogate these to see what value they produce in terms of assisting with regulatory approaches. More stakeholders were on the unmanned aircraft industry, so will need broader views as well.
- There was a workshop theme about public perception – some stakeholders were sure it would not be a problem, others strongly disagreed.

#### Further discussion – Medical Devices

- Discussion about potential overlap between genetic tech and medical devices. On medical devices, needed to prioritise areas when scoping the project. However, genetic technologies are used in medical devices.

#### RPC presentation

- The role of the RPC was introduced, including on impact assessments, post-implementation reviews, business impact targets and reviewing impact assessments for free trade agreements.
- The RPC informs government about best practice on evidence and analysis. Also provides support. It's key that the RPC is transparent. It also gives confidence to parliament, the public and external stakeholders on the quality of evidence required to meet government regulatory standards.
- Discussed benefits of complementary roles of the RHC and RPC. Can feed back concerns to government that both parties receive. Stephen proposed that: both sides exchange views on issues that impact each other; exchange regular updates; and consider if there are areas for joint work.
- Discussed how best to work together on overlapping policy areas, as well as operationally, such as on social media presence.
- There was a discussion about RPC's assessment of innovation. It is assessed, but not as part of a 'red rating'. It is published for all to see.

#### Summary and next steps

- Very helpful discussion with Special Advisors and the RPC.
- Reminder about seven questions feedback and views on Council meeting.

# RHC Meeting – 19 March 2021

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## Location

- Virtual MS teams meeting

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Cathryn Ross (Chair), Group Regulatory Affairs Director at BT Group
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Programme Leader at the Medical Research Council's Harwell Institute
- Matt Ridley, Member of the House of Lords, Science and Technology Select Committee
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

### Taskforce on Innovation, Growth and Regulatory Reform (TIGRR):

- George Freeman, Member of Parliament

### Officials:

- Chris Carr, Director of Better Regulation Executive
- Sarah Montgomery, Deputy Director of the RHC & EU/ International Team
- RHC secretariat

## Meeting Minutes

### Introduction from Chair

- No new conflicts of interest.
- The RHC will not have to definitively choose all its tranche two workstreams today, although it can scope out potential candidates for deep dives now.
- This is an interesting time for the RHC with deep dive reports in four areas being worked on.

### Preliminary discussion of next RHC workstreams (team will circulate a paper in advance)

- Deciding the balance between 'quick wins' versus government commissions versus RHC's own priorities will be key. The RHC can operate in different modes on its deep dives of explore, examine, and convene and these will require different amounts of resource.
- Although substantive work on tranche 1 should be complete by June, it's important not to view this as the absolute final stage. Additional work will still need to be done to communicate and land the recommendations after this.
- Potential to do a 'one year on' report down the line where we revisit our tranche 1 areas and look at what has happened in these policy areas since our reports were published.
- Having a cross cutting workstream where we look at general issues impacting the effective regulation of innovation is crucial for tranche 2, alongside more 'vertical' deep dives on specific areas like fusion energy, genetic technologies and so forth.



- Could there be scope for a 'societal benefit principle' for pro-innovation regulation. In contrast to the current precautionary principle.
- Considering how you regulate as well as what the regulations are is key.
- Evolution rather than revolution for the next wave of deep dives. For example, aiming for one cross cutting area and two more 'vertical' deep dives
- RHC will also want to consider strategic priority alignment with departmental or government objectives. For example, regulatory reform needed to enable innovation to help us achieve net zero
- Other potential deep dives could include how you regulate social media and mobility as a service (MaaS).
- On space and satellites and micro mobility it's harder to see what value the RHC could add.
- All enthused by human augmentation commission as a deep dive. No one enthused by micro mobility as an area for RHC to add value. Mobility as a Service is interesting but it's not completely clear what the exam question would be.
- AI in healthcare also a strong candidate for a deep dive with quick wins.
- Biodegradable plastics, neutron tech, hydrogen or something around financial services such as blockchain and cobotics also suggested as other possible candidates for deep dives.
- April Council meeting will be used to look at the criteria we used to decide tranche 1 and apply this to choosing a tranche 2 portfolio.
- Cross cutting – in explore mode consider what 'principles for pro-innovation regulation' would look like.

#### Fusion Energy Deep Dive

- Submitted the main fusion report to Secretary of State
- Supplementary fusion report to be completed on the question: 'to what extent does the wider commercial fusion sector require a similar regulatory approach to STEP'. Aim to publish this supplement by mid-May.

#### Unmanned aircraft 'reset'

- Current plan is producing two reports, the first one would be on futures and future plausible scenarios and how they might work and then in second part put forward key regulatory principles which we have been testing with stakeholders.
- Second report will be an international benchmarking report which will consist of a stocktake of how other countries deal with these issues and involve interviewing a range of industry and international stakeholders.

#### External speaker: George Freeman from TIGRR

- TIGRR have conducted around 70 roundtables zooms and found a phenomenal appetite to find dividends from leaving the EU.
- Several hundred ideas have been generated. Report will go to the PM at the end of April.
- One key idea is establishing different regulatory principle in the UK, 'innovation principle' as successor to precautionary principle. Encouraging regulators to have vital role in promoting innovation.
  - Really want Treasury to hold departments to account for what they are doing on promoting innovation.
- TIGRR ideas include regulation of drug resistant crops and blight resistant potato. As well as AI as a device – should be regulated as a medical device.
- RHC is also considering several issues that TIGRR are interested in: data interoperability, new innovations principles in regulation, and lack of clear boundaries in the life sciences.

- Regulators code focused on those that are regulated today and risks not thinking about the future.
- The RHC should be able to see an advance copy of the list of ideas TIGRR is working on.
- RHC could be instrumental in future policing of TIGRR recommendations.

# RHC Meeting 16 April 2021

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## Location

- Virtual MS teams meeting

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Cathryn Ross (Chair), Group Regulatory Affairs Director at BT Group
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Programme Leader at the Medical Research Council's Harwell Institute
- Matt Ridley, Member of the House of Lords, Science and Technology Select Committee
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

### Officials:

- Sarah Montgomery, Deputy Director, Strategy and International
- RHC secretariat

### Externals:

- Committee for Technological Innovation and Ethics (Komet):  
<https://www.kometinfo.se/in-english/about-us/>

## Meeting minutes

### Intro and update on conflicts of interest (COI)

- The Council noted that deep dives are moving close to recommendations.
- No conflicts of interest were declared by Council members.

### Tranche 2 discussion – Q&A with Neurotechnology team

- Conversations occurred around why the council should support the neurotechnology teams. It was explained to the Council that neurotechnology has a vibrant research community and regulation can play a key role in translating neurotechnology from research to societal benefit.
- The Council also asked about the knowledge transfer network (KTN) and what is the expectation around the RHC offer. It was explained that KTN are funded by Innovate UK and Other Government Departments. It's a wide pre-built network that the RHC can tap into and the timing for RHC intervention is optimal as there's some concern that the innovation could advance further than the regulation,
- The UK is in a good position to become a global leader on neurotech, and regulations are an important aspect of developing a global ethical framework around the technology.

### Tranche 2 discussion – Q&A with MaaS team

- Conversations occurred around why the RHC should support the Mobility as a Service (MaaS) team. The team's consensus was that MaaS is at a tipping point within the UK and lack of proper regulation could hinder innovation within the industry, in-turn impacting Net Zero 2050 target.

- Overall, the MaaS team believes that, with RHC assistance to drive the regulatory aspect, the UK can seize upon an opportunity to become a world leader in MaaS, through a supportive and innovative use of regulation.
- The Council discussed whether the RHC was best placed for this to work, as typically MaaS involves complicated commercial interests, which could be handled through commercial arrangements rather than regulation.
- The Council also asked whether the application of MaaS was concerned with new technology, or an application of pre-existing commercial enterprises.

#### Tranche 2 discussion – Deep dives

- Council agreed to take forward three deep dives initially, with a fourth when capacity allows.
- The Council discussed Mobility as service. It acknowledged that there was a great commission from the MaaS team to the Council on this and agreed that the topic would remain a potential deep dive area in future but identified a need to be clear on the scope of what would be investigated.
- The Council discussed hydrogen - identifying the space as complex, and acknowledging the many strands, and that there is existing work in this space. The Council identified the aviation and transport aspect of hydrogen as a topic of particular interest.
- The Council decided to make a preliminary decision but reserved the right to pivot on further investigation.
- The Council proposed to take forward neurotechnology and AI in healthcare, and to take forward hydrogen in explore mode with a focus on transport.

#### Tranche 2 discussion – Cross-cutting areas

- The Council confirmed that cross cutting work on how regulation could more broadly enable innovation has great interest from across Whitehall and business. The Council suggested that this is an optimal time and Covid-19 has allowed for public appetite to lean towards a more pro-innovation regulatory approach.
- The Council confirmed that they had a great deal of interest in this and that there is an opportunity and desire to move forwards and create what is useful. The Council should build on existing work and be aware of context as there is likely to be conflicting views.

#### Genetic technologies – emerging recommendations

- The genetic technologies deep dive champions responsible innovation, and the OECD regulatory principals. The deep dive identified that the problem is not choosing a product or process-based approach but what happens after this on innovation. The emerging recommendations suggest that some genome edited organisms should be exempt from GMO restrictions (except those that introduce 'foreign DNA', which would remain GMOs), and for all genetic technologies, the recommendations propose to take existing GMO regulations and adapt to needs of new tech or to have primary trigger be the nature of the product and the sector standards and work back from this.
  - Certainty is an important factor to consider for these recommendations - which recommends the first option, but smaller companies support the second as the current system is over-onerous. The first option would not need additional primary legislation, but the second certainly would.
- It is also important to consider the change of mindset- how to reassure the public that this change is a safe idea. The Council suggested that an emphasis on 'on-ramps' and 'off-ramps' is helpful.
- The genetic technologies deep dive's next steps will be to start putting these questions to interested parties and test ideas, with an aim to provide two options to provide clear benefits and drawbacks.

## Medical devices – emerging recommendations

- One Council member asked what determined the order of recommendations. One Council member asked the nature of the deep dives team's relationship with MHRA. The deep dive team confirmed that they have an in-house stakeholder group.
- One Council member asked the specificity of the recommendations, specifically for investment- will the medical devices team be recommending a specific amount, the council member questioned if this level of detail was part of the RHC's role.

## External speaker – Komet

- The Council heard a presentation with Komet and discussed the importance of international cooperation.
- Pacing problem - innovation and regulation on two opposite sides, question on how we can harness opportunities while mitigating risk. Technology beats politics - committee allowed to recommend to government.
- Focus on understanding the problem for stakeholders. Identified 4 themes.
  - Theme 1: Responsibility and ethics. You have to ensure the public approves of the tech.
  - Theme 2: Collaborative public governance. In between agencies and ministers is where opportunities and risk are.
  - Theme 3: Engage on specifics of regulatory development. Have set up mailbox where stakeholders can flag any difficulties they have had in regulatory processes.
  - Theme 4: Facilitating testing and experimentation
- Komet noted that they are currently monitoring 10 different country's methods of agile governance. For example, South Korea have free zones for different tech.
- The Council discussed how to increase appetite for failure in the public sector. The Council discussed creating discussions around the need for rapid change and the importance of monitoring incentives and evaluations, with an aim to look at overarching developments not individual failures. The Council noted the importance of a focus on learning processes not concrete outcomes.
- Komet speculated that if Sweden were to exit the EU, they may have an interest in Agile Nations and have been inspired by the Regulators Pioneer Fund (RPF)

# RHC Meeting 11 June 2021

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## Location

- Virtual MS teams meeting

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Cathryn Ross (RHC Chair), Director of Strategy & Regulatory Affairs at Thames Water
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Programme Leader at the Medical Research Council's Harwell Institute
- Matt Ridley, Member of the House of Lords, Science and Technology Select Committee
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

### Officials:

- Chris Carr, Director, Better Regulation Executive
- Sarah Montgomery, Deputy Director, Strategy and International
- RHC secretariat

## Meeting minutes

### Pro-innovation regulatory principles

- Officials provided an update on some work the Cabinet Office is coordinating. Highlighted a publication due in July on digital and innovation strategies. Following transition period, a TIGRR (Taskforce on Innovation, Growth and Regulatory Reform) proposals report is due for publication soon.
- Council members wondered what the implications could be from this for the workings of the Council.
- Regulators can on occasions take a long time to approve new tech and advances, this can sometimes kill impact and effectiveness of innovation and tech - timeliness is important.
- Agreed that ethics, morals and responsible innovation are key principles. Could be best for Council to focus on influencing the regulators and the discretion they have, rather than the policy makers.
- A Council member referred to Environmental, Social and Governance principles (ESG). The focus on and desire for ethical practices could be a key matter while delivering good regulation. Observation that some innovations may appear more fashionable and appealing but those with less spotlight may deliver important innovations.
- There was an observation that an individual or group may be abiding by all ethical and moral expectations but give poor performance and outcomes. Reference made that in instances regulation can unleash innovation. For example, in 1997 the Clinton administration's e-commerce policy in the US and historical airline deregulation led by economist Alfred Kahn.
- Some suggestions that we should seek case studies on how this has been done positively, while assessing and weighing the views expressed by the parties involved.

- There was some discussion around self-governance by regulators and potential negative receptions to it. Some form of external accountability is needed to ensure governance being followed seems important to have in place.
- Action: Any further points or comments to be sent to chair and to members, for potential further review and discussion.

#### Unmanned Aircraft / Remotely Piloted Aircraft Systems

- A number of productive interviews have been held. A futures report is due shortly. To clarify, 'Drones' is the wording currently used in working versions in reference to these aircraft. Discussions have been held with the Civil Aviation Authority (CAA). Large numbers of applications for drone licenses, both business and recreational, are being received by the CAA. Their various uses and license applications will need to be assessed on their merits.
- Some discussion that there are many critical uses of drones such as fast transporting of medical supplies (for example, blood and organs for transplant) and for visual assessment in emergency or disaster situations. On other hand, there are also wide commercial interests and opportunities, such as for delivery of food and online purchases.
- A funding subscription model for commercial use by airlines is currently in operation. Drone operators making applications for operations have been asked to provide a lot of data on safety. Recognition amongst Council members however, that drone operators and other businesses need to accumulate flying hours to be able to demonstrate meeting the safety requirements.
- Suggestion that Rwanda and Republic of Ireland are operating automatic approval processes for license applications.
- It was recognised that reducing incidents and maintaining safety are UK CAA's main priorities, so innovation is not the highest on their agenda as regulators. It was noted that the Rwanda CAA had been advised by their government to prioritise drone travel and had seen benefits in medical emergency transport, such as where potential 7-hour road journeys had been completed in 1 hour by drone flight.
- It was said that should commit to stimulate attitude and behaviour changes longer term.

#### Report publications and events

- Fusion publication – the secretariat advised that the publication is expected one week before parliamentary recess. A supporting event with ministers could be useful either just before publication or after. Minister Solloway or Lord Callanan could be approached for attendance and this event could be held in late July.
- Very good feedback was gained from stakeholders that were consulted, there was a positive article in Forbes for example. Less media coverage elsewhere. We may need to loop in further with government communications teams for future publicity. Another government announcement on fusion energy expected. We could aim to get further exposure and promote our publication in conjunction.
- An offer to liaise and endorse these aims with relevant communication teams if needed was made.

# RHC Meeting 4 August 2021

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## Location

- Virtual MS teams

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Cathryn Ross (RHC Chair), Director of Strategy & Regulatory Affairs at Thames Water
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Programme Leader at the Medical Research Council's Harwell Institute
- Matt Ridley, Member of the House of Lords, Science and Technology Select Committee
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

### Officials:

- Sarah Montgomery, Deputy Director, Strategy and International
- RHC secretariat

### Externals:

- Professor Chris Hodges, Oxford University Law Faculty

## Meeting Minutes

### Chris Hodges on Pro-Innovation Regulatory Principles and Ethical Considerations

- Linear approaches are taken by regulators as standard: make a rule, find a breach, impose sanctions with assumptions that this will be sufficient based on deterrent theory.
- Problem with linear approach – it doesn't look at behaviours and is not innovative. This more top-down approach can be perceived as condescending towards the community being regulated. Can achieve more if there is a common purpose between the regulator and regulated.
- More social trust leads to better ideas. Food sector has more codes of conduct and soft law than many other industries. Regulation through culture can work. Regulators often worried about using their discretion due to any potential fallout.
- Self-motivation, responsibility and autonomy. The global financial crash in 2007 brought some sharp focus on business models and ethics of operation. A Growth duty was put into regulators code a few years ago (March 2017).
- On regulatory capture, it was suggested this can be more of an issue in the US than the UK, with more political involvement in the US system.
- A positive example of a different regulatory approach is the Water Industry Commission for Scotland (WICS) – it applied a water pricing system very quickly and treated it as a shared problem creating common purpose with all relevant stakeholders.
- Recognition that in some areas such as food supply, many systems and regulators link as part of the cycle. Can be difficult to factor in what sits inside and outside of a boundary to regulate.



- By nature, and the remit with which they are formed, some regulators will be bound by statute, structure and need for conformity – with less latitude to enable for innovation.

#### Pro-innovation Regulatory Principles: Council Discussion

- Council met earlier today. They agreed to focus on gap analysis, in current regulations and PIRP thinking. Further discussions and structured sessions will follow to hear from industry expert voices on different sides of the precautionary-innovation discussion.
- The MHRA and Food Standards Agency were mentioned as relatable examples where regulation and innovation have worked well. The area of Genetically Modified Organism (GMO), with media and public perception having influence, was seen as an example where regulations have not delivered what is best. Public engagement was an area that our gap analysis will look at.

#### Tranche 2

- Council members were asked for views on Tranche 1 delivery. There was a recognition that working in Covid impacted environment has meant a great deal of virtual and electronic interaction and ways of working.
- There was some discussion on futures techniques. Some members felt it was a difficult undertaking and that it can hard to do this for beyond a short period, particularly in complex systems.
- External challenges prior to publishing were agreed to be beneficial, even though on occasions the RHC may get push back on the outcomes. The outsourced engagement approach on medical devices worked well and could be a model to use again.

#### RHC Forward look: Including publications and events

- Team is doing some thinking on how the RHC can have greater freedom in its comms work. Observation that there is often more license for the RHC to use trade associations for its comms than national level media.
- The open consultation on Reforming the Better Regulation Framework– open for response until 1<sup>st</sup> Oct. The RHC Team have suggested a coordinated RHC response to this.

#### AOB

- Early thinking will be done for what next tranche (tranche 3) of RHC work will be.

# RHC Meeting 18 October 2021

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## Location:

- Hybrid meeting at the Culham Science Centre invited by the UK Atomic Energy Authority (UKAEA)

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Cathryn Ross (Council Chair), Thames Water Strategy and Regulatory Affairs Director
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Programme Leader at the Medical Research Council's Harwell Institute
- Parag Vyas, Director of PV10 Consult
- Joyce Tait, (via VC) Professor and Co-Director at the Innogen Institute, University of Edinburgh

### Officials:

- Chris Carr, Director, Better Regulation Executive - BEIS
- Sarah Montgomery, Deputy Director, Strategy and International
- RHC secretariat

## Meeting Minutes

### Introduction and RHC Achievements

- Warm welcome to the first in-person RHC meeting and an introduction of the agenda. Introductions made by all.
- Value and importance of the RHC's work and how we engage with stakeholders mentioned. Officials were asked for their view on how the Council is coming across to government. They responded by saying the Council and its work has been well received.
- The RHC fusion report was very well received across the sector and there was only pushback from a very small minority of stakeholders. Work of the Council and their reports has been internationally recognised and has influenced UK govt policy, the RHC is seen as a credible valuable committee. EU representatives have asked how the RHC was set up, the Agile Nations group is also interested, and the CDEI made approaches directly.
- It was mentioned that at an external conference recently where a gap in the event proceedings arose, a Council member took the opportunity to speak to the audience about Pro Innovation Regulatory Principles (PIRP) and the RHC's work around this. Attendees really engaged and appreciated this and many commented that it was the best session of the day.

### Neurotech Initial Scoping Discussion

- Five interviews with experts. The U.S. seems to be ahead of us in this area, public attitudes also need looking into. UK notified bodies are inundated with requests at moment. In the US the regulators speak openly with innovators in this sector whereas it can be more challenging in the UK.

- Royal Society research demonstrates that the public support use of neurotech if therapeutic benefits can be pointed to.
- There is a need to balance any concerns over regulatory capture with the need for regulatory bodies to have good engagement with SMEs at the forefront of developing innovative tech.

#### Better Regulation Framework Consultation Response

- Officials advised 195 responses received, 75% of them on deadline day. Responses went across the full range of themes.
- We want regulators to be agile and make reasoned judgements but also a challenge in balancing this with investors and firms' desire for clarity.
- Recognition that Net Zero is a shared agenda for all and that huge opportunities and space exist here for private firms to innovate.

#### Hydrogen in Transport Initial Scoping Discussion

- Trials happening in Japan and Scotland (Orkney) in hydrogen in maritime.
- There's a question on how viable hydrogen in aviation is likely to be for the foreseeable future. Hydrogen has a high volumetric density which makes it difficult to be able to store on planes. Ships can be retro fitted to use hydrogen more easily than planes.
- RHC agreed to conduct this deep dive in 'explore mode'. Work on maritime for the next few months, produce initial findings, then decide whether to build these into a full report on maritime or to pivot to aviation work.

#### Forward look and AOB

- The Next Council meeting is on the 25 November in the Centre of Life Newcastle.
- There will be no December meeting planned; January 2022 would be next date.

# RHC Meeting 25 November 2021

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## Location:

- Hybrid meeting at the Centre for life in Newcastle

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Cathryn Ross (Council Chair), Thames Water, Strategy and Regulatory Affairs Director
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Programme Leader at the Medical Research Council's Harwell Institute
- Parag Vyas, Director of PV10 Consult
- Joyce Tait, (via VC) Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Matt Ridley, Member of the House of Lords, Science and Technology Select Committee

### Officials:

- Sarah Montgomery (via VC), Deputy Director, Strategy and International
- RHC secretariat

## Meeting Minutes

### Introduction

- It was remarked that the Council is at a pivotal moment, with a new tranche of priorities to identify and a new Chair and several new Council Members to be appointed next year.

### Future direction of the RHC

- The discussion was opened by identifying priorities, with the view to develop a process to select tranche 3 priorities that is proportionate and considers the learnings and experience from previous horizon scanning activity.
- The value of taking a multifaceted approach was outlined, including scans of the literature, discussions with stakeholders and receiving commissions from across government. It was highlighted though that this process has been resource intensive in the past and did not produce dissimilar results from existing horizon scans. There is therefore an opportunity to make the process more efficient by incorporating relevant lessons.
- The number of organisations undertaking their own horizon scanning was also raised, and it was agreed that the RHC should make use of this existing material whilst continuing to add value through employing a regulation-specific lens.
- A 'scan of scans approach' is therefore suggested for these reasons.

### *Does the Council agree with this approach?*

- The point was made that the scan of scan process is appropriate as long as it is not the only determinant for which areas the RHC investigates. Stakeholder engagement will also be a key input into decision making for example.

- The RHC could also use a website to encourage stakeholder engagement on the mood of this 'scan of scan' approach, whilst also including mechanisms to filter out unhelpful responses.
- Less resource on scanning freezes up time on being able to do other evidence gathering, such as stakeholder engagement. These other methods will also help ensure the RHC is more likely to capture those unexpected, but potentially very impactful technologies that a horizon scan might miss.
- Scan of scans will also allow the RHC to get to the list of interesting topics for deep dives quicker.
- It was noted that the RHC's main purpose is to consider future tech and it may not be best placed to consider current tech as other government departments specialise more in this. But it would be good to remind government on this.
- The RHC is also proactively reminding Whitehall/government that they have the option to commission the RHC to look into a technology area.
- Clear consensus in the Council on the scan of scans approach.

*Future direction – is the RHC exam question still valid? What do we need to be successful?*

- Different approaches were outlined in this segment for the future of the RHC: maintaining the status quo, evolution, or revolution.
- The point was made that if the RHC expands its work then the Council may need more members.
- It was expressed that the Council should not see its role as simply that of a consultancy function.
- There are aspects of the National Institute for Health and Care Excellence NICE's operating model that we may wish to emulate, such as having academic volunteers to look at the evidence around specific challenges the RHC is interested in.
- Further thoughts on the evolution column were raised, specifically the RHC considering how to further support the commercialisation stage of innovation.
- Agreement between Council members that international engagement is important.
- In order for the RHC to continue being successful it needs to ensure it continues to be unbiased to any stakeholders, including industry, as we do not want to become a spokesperson for any one body.
- The importance of having thorough retrospectives on where the Council has had most impact was raised, to support decision-making on the Council's future direction.
- Clear support for the 'evolution' approach.

*Post report influencing*

- Different options for influencing government following the publication of the reports, including the associated risks and expected impacts of each option were outlined.
- It was emphasised that this is likely to be a challenge given the future-facing nature of the work since the areas may not be an immediate priority for resource constrained departments.
- It was questioned whether we may want to differ our approach for each report, with one consideration being that crosscutting reports without a single departmental owner may require greater post report influencing and stakeholder engagement to push through.
- The point was raised that the Council's recommendations often seek a culture change, and the need to influence broad stakeholders as well as government. It was suggested that the reports could go further in emphasising cultural changes required.
- The potential to transform the Pro-innovation Regulatory Principles work into a form of matrix that regulators could be assessed against was raised.

- General concern was expressed about the setbacks in obtaining full government responses, and the missed opportunity that this has created, particularly for the medical devices and genetic technologies reports.
- There was some discussion on whether stricter timeframes for responses could be set out in the governance terms, but the Secretariat raised concerns that this could increase the likeliness of government automatically rejecting recommendations.

#### Artificial Intelligence as a Medical Device – Initial Scoping Discussion

- Initial thinking for a deep dive to undertake a gap analysis of the regulation of Artificial Intelligence as a Medical Device (AIaMD) was outlined. It was highlighted that existing reports have been more theoretical in nature, so this report provides an opportunity to look at the regulatory angle of a field which is rapidly moving both nationally and internationally.
- It was highlighted that a key focus of the report will be distinguishing between perceived gaps and actual gaps, and of these, to what extent they are covered by existing work being undertaken by regulators. To address the remaining gaps, the report will look at measures that can be taken from other industries as well as work in progress internationally.
- It was raised that some exploration may be needed to determine what the desired end state on regulation of AIaMD will look like.
- The Council were broadly supportive of the approach and proposed structure of the deep dive.

#### Speaker – Alastair Balls – Chairman of the Centre for Life

- Presented on the Centre for Life as well as regulatory hurdles for the emerging area of SMR/AMR nuclear technologies

# RHC Meeting 12 January 2022

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## Location

- Virtual MS teams meeting

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Cathryn Ross (Council Chair), Thames Water, Strategy and Regulatory Affairs Director
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Honorary Research Lecturer, Nuffield Department of Women's & Reproductive Health, University of Oxford
- Parag Vyas, Director of PV10 Consult
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Matt Ridley, Writer on innovation and founding chairman of the International Centre for Life

### Officials:

- Gavin Lambert and Caleb Deeks, Directors General, Market Frameworks
- Chris Carr, Director, Better Regulation Executive
- Sarah Montgomery, Deputy Director, RHC & EU/ International Team
- RHC secretariat

## Meeting Minutes

### Introduction

- Introduction from Market Frameworks new Directors General (Gavin Lambert and Caleb Deeks)
- It was noted that Market Frameworks has been thinking ahead on regulatory reforms, post Brexit, since it thinks that as a nation the UK is forging its own path in an agile environment. Expert outside views and ideas of the Council will be very important and appreciated.

### Future Direction of the RHC Recap

- This built on the Council's previous discussion in November, to capture a summary of the Council's position and any additional ideas.
- A reminder of previous Council preferences included reviewing reporting processes and not support for moving to a consultancy type model.
- A point was made about the slow speed of decision making by regulators being frustrating for entrepreneurs.
- A reference to the Pro-Innovation Principles (PIRP) work was made on the cost of regulators delaying, as the PIRP report will have sections on 'timeliness' and 'cost of delay'.
- Several suggestions were made on alternatives to regulations such as guidance and standards. It was also mentioned that lawyers need to consider quicker solutions to amending current regulations rather than implementing new regulations.
- A point was made about not relating the speed of the regulations to accuracy. It should be about getting it right more quickly.

- If organisations had the skill and expertise to regulate more effectively, making regulations quicker and more accurate would not be an issue.
- A comment was made about regulators needing to be more comfortable with ambiguity as not everything can be tied down and predicted.
- It was acknowledged that this was a good discussion but will not result in decisions at this time.

### Communications Strategy

- The RHC's current social media channels were presented to the Council, including the RHC's new LinkedIn page.
- The RHC secretariat feels its current comms strategy has multiple strengths but could be optimised further by, for example, being more consistent.
- Options for maximising current social media channels were discussed including getting accounts such as twitter verified, highlighting achievements of Council members and progress in deep dives.
- An idea for a quarterly evaluation matrix was mentioned and how this could potentially be discussed at future Council meetings.
- Changing the current strategy will require a shift in resource allocation.
- For the RHC's newsletters, engagement suggestions such as maximizing engagement with ministers was mentioned.
- The RHC secretariat were keen to find out what the Council members use to promote their work.
- A comment was made that all the above suggestions were feasible and practical. It was also suggested that the RHC's engagement should be tailored depending on the target stakeholder. Suggestions included improving the frequency of communication and transparency of information.
- A comment was made about the PIRP report being an appropriate piece to promote in papers such The Economist.
- Potential exploration of alternative channels was discussed, including examples such as podcasts, event panels, seminars and a government blog. Other examples included increasing the RHC's presence in BEIS' internal comms.
- A comment was made about ensuring the RHC commits to a strategy that will not only stand the test of time but also does not require intense resourcing.
- A suggestion was made about a potential SME outreach in order to make SME's aware of the RHC and its relevance to them.

### Update on hydrogen in maritime

- So far, the RHC has liaised with Government, regulators, universities and industry on hydrogen in maritime.
- The UK has a naval marine industry with focus on smaller specialised boats and has notable involvement in the servicing of offshore wind turbines.
- It was suggested that the exam question for this deep dive will need to be made clearer over time.
- The regulatory approach of long distance and international shipping will be difficult for the RHC to have influence on compared to smaller vessels.
- It was felt that it would be best for the RHC to focus on where the MCA has jurisdiction - for example, the UK and mainland.
- The RHC can focus on working with stakeholders such as those involved in the Orkney hydrogen projects. If the RHC was to reach out to international stakeholders, it could work with a neighbour such as Norway. This is due to Norway having a high value, small shipping industry.



- There was a consensus within the Council and secretariat that hydrogen in maritime should remain a short deep dive, focusing on coastal inland.
- The relevant Council members suggested remaining neutral to types of fuels, focusing on the innovation challenges.
- It was mentioned that there is currently no regulatory sandboxing in industry that the Council or secretariat has learnt of, and this could benefit the sector.
- One of the lead Council members on this mentioned that the RHC is not far away from a first report. In March some other reports are also due relating to Hydrogen.

#### RHC priorities to June

- The RHC secretariat explained that the recruitment process for new Council members and Chair is lengthy and, at times, resource intensive.
- A member of the secretariat is leaving and so the secretariat will liaise with the Council to have further discussions around this.
- A question was asked about the connection between the new chair and new Council member recruitment. A further question was asked on whether there would be any scope for the size of the RHC to change?
  - The secretariat responded by saying that the ratio of civil servants and Council members needs balancing. Size unlikely to increase.
- No action needed for Council members who wish to stay another term at the moment. The secretariat will keep the Council updated on the process.

#### Forward look and AOB

- Ed Humpherson of OSR has been invited to speak at an upcoming Council meeting.
- Pro Innovation Regulatory Principles (PIRP) - Chair updated attendees by saying that they are updating some of the look and structure of the report, following discussions and learning that came out of the gap analysis sessions held with stakeholders.

#### Action

- Chair asked Council members to give further thought to if there are particular deep dive areas, we could focus on moving forward. In 2-3 years, what would the RHC want to be remembered for?
- Chair to share updated PIRP report with Council members and secretariat.

# RHC Meeting 15<sup>th</sup> March 2022

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## Location

- Virtual MS teams meeting

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Cathryn Ross (Council Chair), Thames Water, Strategy and Regulatory Affairs Director
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Honorary Research Lecturer, Nuffield Department of Women's & Reproductive Health, University of Oxford
- Parag Vyas, Director of PV10 Consult
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Matt Ridley, Writer on innovation and founding chairman of the International Centre for Life

### Officials:

- Sarah Montgomery, Deputy Director, RHC & EU/ International Team
- Jim Foudy, Deputy Director [Reg dot?]
- RHC secretariat

### Guests

- [Professor Zion Tse](#), The Royal Society
- [Dr Jonathan Sinclair](#), The Royal Society
- Ed Humpherson, Director General for Regulation UKSA

## Meeting Minutes

### Ed Humpherson external speaker

- Ed Humpherson introduced himself and spoke about the importance of statistics being regulated to ensure trustworthiness.

### Royal Society guests' presentation

- Professor Zion Tse and Dr Jonathan Sinclair introduced themselves and the work they do, alongside how their work coincides with the RHC deep dives.

### Closing the Gap Report

- It was highlighted that the RHC are in a strong position with the main report. The next step would be testing recommendations with key stakeholders, decision makers across government including Brexit Opportunities Unit, HMT, BEIS (more specifically BRE), and stakeholders referenced in the report. A mid to late April for publication was mentioned.
- It was highlighted that it would be valuable to lift out and highlight the general point: the idea of pragmatic ambition in the executive summary of the report.
- It was agreed that the report is not another set of principles added into the discussion of regulation, but how to use existing ones.
- It was recognised that we have a primary focus on regulators and policy makers, but there are points in the report for disruptors and innovators. A question was posed to

the Council on how they felt we could best disseminate the report to this group, acknowledging that this will be a more difficult task.

- The Entrepreneurs network was highlighted as an organisation to send the report to pre-publication, as they are well plugged into innovators.
- It was highlighted that when communicating to innovators, the executive summary for the policy community might not be the best set of points for entrepreneurs and innovators. It was recommended that a different set of points should be brought out, for example a separate document or summary. A point was made that we want to be cautious not to give two different messages to different groups, that we want them to be complimentary.
- It was questioned whether to do this in the report itself, or as a communications tool, and that the Council needs to have a think about this.
- An idea for the Council to have a press release or conference to launch the report, such as potential in-person launch was mentioned.
  - possibility of someone else hosting the event, such as the Institute of Regulation or a think tank, and that there are many ways to do this.
- A further idea to have an exclusive in the Financial Times was mentioned.
- It was mentioned that competition isn't explicitly spoken about in the recommendations.
  - It was noted that the executive summary can draw on competition to cater for this.
- It was advised that the Council order the Closing the Gap recommendations by priority
- The Council will see a product of the digital version of the report on 21<sup>st</sup> of April.

#### Forward look and AOB

- Council reviewed the RHC's Forward look, and the things coming up between March and August. It was acknowledged that this would be a busy period, and that Tranche 2 is ending.

#### Actions

- Secretariat to look at an in-person meeting at the drone's commercial corridor in Reading
- Council and secretariat to look into international dimensional opportunities for the Closing the Gap report. Other spaces to look in to include the OECD Regulatory Policy Committee, and the NER.

# RHC Meeting – 13<sup>th</sup> April 2022

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## Location

- Virtual MS Teams meeting

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Matt Ridley, Writer on innovation and founding chairman of the International Centre for Life
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Honorary Research Lecturer, Nuffield Department of Women's & Reproductive Health, University of Oxford
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

### Officials:

- Jim Foudy, Interim joint-Director
- RHC secretariat

## Meeting Minutes

### AI as a Medical Device - Discussion on early findings, next steps and future direction

- High level findings so far - no gap for distinct regulator to fill. We need to bear in mind that if not EU, which big player do we align to. Perfect storm of approved bodies status could occur; EU validated and then UK requirement. Often players are from tech side, rather than regulatory.
- Big call for softer tools from those that gave feedback. Chair echoed on the point about no specific regulator being needed in this space that a Lords AI committee 3-4 years ago agreed that no specific regulator needed.
- NHS have started funding with MHRA being in this space. Some discussion has taken place on horizontal and vertical regulation. EU is horizontal, the FDA in US being a vertical model. Sector specific principles may help.
- There was a question around which regulators could join up in this area and who doing post market surveying. MHRA, NICE, CQC were mentioned.
- We should be mindful that we don't want industry to have to answer same questions while having to give different evidence to bodies involved. - to help joining up, a Multi Agency Advisory Services (MAAS) has formed.
- Observation made that there isn't much ongoing quality assurance in medical field. Verification of screening services and clinical trials done at early stage, not much real-world assessment happens post that. For A.I. area, suitable quality assurance would be needed.
- Some discussion on data ownership: Google deep mind based at Moorfields eye hospital London and Google Health were mentioned. Google deep mind did two major projects, one was kidney injury predictor

– project generated some criticism and concern; didn't seem to do public engagement very well.

- Comment that having all data in one place may be bit risky if for instance a cyber-attack occurs. NHS refers to being a custodian rather than owner of patient data. NHS would enforce and deliver AI as a medical device, with DHSC possibly providing guidance.
- On good machine learning practice, MHRA initiated work on 10 principles being proposed. US, UK, Australia and Health Canada were all involved.
- Options for phase 1 and a phase 2 discussed. Some Parallels exist between this and Neurotech work Chair felt. May therefore be value in both reports referring to each other.
- Recollection that the Fusion report was a 2-stage approach, worked well. Pro; further outreach and dissemination opportunities. Con: once 1st report out, picking up momentum can be hard.
- The lead Council and team members on this will be speaking to patients and patient groups further. June aimed for publish of initial report.

#### Neurotech - Emerging findings and outstanding questions

- Our aim and approach here is for non-excessive balanced regulations. Future of Neurotech is bit unclear, much could happen. Lots of stakeholder interviews have been held to understand the area and implications. There are international organisations who have commented and made recommendations in this field, such as the OECD, Council of Europe and UNESCO.
- Use of the phrase 'human augmentation' (causes some concerns) used by government, but we use Neurotech.
- Discussions show need for consideration of whether devices are invasive or wearable; do they record basic health and fitness data or modulate brain function? If they modulate brain function, should they it best be classed as a medical device, is one area of discussion.  
Lots of case studies are available and can be placed in the intended report.
- Non-medical applications and modulating mental states – some acknowledgement of a grey area and that a range of scenarios could constitutes coming under this bracket. One option could be to regulate all Neurotech as medical device.
- Mention of false positive results that can occur and that 100% accuracy may not be guaranteed for every test and device use. – could this then cause uncertainty and harm to general population in the bigger picture? Recognition that devices can be bought from internet and retail channels by the public.
- US medical firms have the culture and policy that data collected belongs to them, not the patient. UK approach would differ. MHRA could be best fit as the regulator, with a role for the ICO to be involved. We have protections like GDPR, but concerns around mental health data privacy exist.
- Mention of the HFEA model and regulatory oversight - a stewardship role, that enables new technology to be introduced with public confidence.  
Some discussion followed on the CDEI and potential role they could play. They have evolved to be more advisory in a public facing role, rather than providing recommendations and reporting to HMG.

- Regulation based on impact ranking could be considered. Acknowledgement that this a complex developing area. Engagement and development of report to continue.

#### Ideas for meeting wide-ranging demand for RHC input

- As the RHC's reputation has grown we are being approached more frequently on various workstreams about advice for innovation friendly innovation.
- Although currently the demand is not enough to justify a formal process, it means the RHC needs to assess what we wish to prioritise. In this prioritisation the current chair recruitment needs to be taken in to account.
- A list of options to handle this demand include:
  1. Whether someone else should deal with these requests? e.g., regulators, Brexit Opportunities Unit
  2. Increasing the RHC secretariat - although for the short term a large recruitment is unlikely.
  3. An extended network of RHC contacts. e.g., Alumni members.
- There is currently a bottleneck of innovation involving new technology where there are regulatory issues, therefore meaning this isn't a trivial exercise and has the potential to benefit the UK PLC.
- It was mentioned that in the 2019 White Paper on 'Regulation for the Fourth Industrial Revolution' an idea for a setup of a 'one stop shop' was drafted. The RHC could incorporate this idea going forward.
- In reference to option three for there being an 'extended network of RHC contacts'; A co-option was mentioned on specific people assisting on set deep dives rather than there being an official advisor.
- A question was raised on whether there is a consistent pattern on what we're currently doing. It was mentioned that perhaps the RHC can write a report on occurring patterns of gaps in capability across departments and regulators.
- An additional question was raised on whether there is a way by which particular industries could write to us and express their regulatory concerns. This would then allow the RHC to write to regulators and ask for a response with the regulator having the responsibility to tell the RHC what they've done as a result of these concerns.
  - However, it was pointed out that if we take on such request there could be a risk of the RHC by default becoming an outsourcing agency.
  - It was highlighted that this current outsourcing pattern is existing in regulators who delegate workstreams to subsidiaries and additional organisations but have overall authority.
    - It was suggested that as the RHC spotlights such issues already we should be careful as to not change our current ways of work.
- A final suggestion was made for the RHC's home department (BEIS) gaining greater responsibility due to the RHC's strong link of innovation friendly work and consideration.
- It was mentioned that this increase in demand could mean the RHC would have the opportunity to become reactive to current affairs rather than await commissions or carry out horizon scanning.

#### Alternatives to Regulation - Presentation and feedback/discussion on the CTG report

- The Alternatives Team introduced themselves and the work they do

- A point was made about industry highlighting concerns that alternatives to regulation such as guidelines produced by regulators which have not been through the parliamentary process and are ostensibly soft law or 'blue tape' are being mistaken for legislation that has to be followed due to the reputational damage and repercussions that happen from regulators when they are not.
  - It was highlighted as a result of this point that for the Closing the gap report there should be clarity at the start of the report for terminology such as 'soft' and 'hard' law.

#### Team updates: Forward Look and AOB

- Chris Carr BRE's former director has left and moved to the Cabinet Office Brexit Opportunities Unit. Jim Foudy and Sarah Montgomery are interim director's for BRE.
- To look at in person meeting for June

#### Next steps

- Draft a high-level summary paper on the options discussed for the RHC's future for the Council to comment on.

# RHC Meeting 25<sup>th</sup> May 2022

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## Location

- Virtual MS teams meeting

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Cathryn Ross (Council Chair), Thames Water, Strategy and Regulatory Affairs Director
- Matt Ridley, Writer on innovation and founding chairman of the International Centre for Life
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Honorary Research Lecturer, Nuffield Department of Women's & Reproductive Health, University of Oxford
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

### Officials:

- Jim Foudy, Interim joint-Director
- RHC secretariat

## Meeting Minutes

### Neurotech - Emerging recommendations

- Emerging recommendations on the medical application of neurotechnology were presented. Council members were invited to provide feedback.
- It was noted that there is a drawback of using regulatory equivalence as this can lead to first mover disadvantage. It was further noted that neurotechnology has capacity to use technology to meet a required safety level rather than using regulation, noting this approach has been taken in the field of pesticide. In response, this idea was noted as something to explore further, with more work needed to understand what this would mean in practice.
- It was questioned whether there was a clear difference between modulating and recording neuroethology. In response it was noted there is a clear difference, and this had been supported by stakeholders. It was asked whether prescribed sleeping-aid apps would be considered modulating or recording technology. In response, it was noted that it would be considered recording device, with the key difference to consider being whether the technology delivers energy directly to the brain or only indirectly to the brain.
- It was asked whether a recorder app that provides medical advice should be regulated by MHRA. In response it was noted that this would usually fall under wellness advice.

### AI as a Medical Device - Emerging recommendations

- Emerging recommendations on AI as a Medical Device. Council members were invited to provide feedback.

### Hydrogen in Maritime - Emerging recommendations

- Emerging recommendations on hydrogen in maritime were presented. Council members were invited to provide feedback.



#### External speaker: BRE Digital Projects

- External speakers from the Better Regulation Executive Digital Transformation and Regulation team attended the meeting to introduce the work that they are doing to the Council, in particular their Open Regulation Platform (ORP) project.
- The team described the BEIS vision for digital transformation of regulation, including more intelligent use of regulatory data to make regulation easier to understand, design and comply with.
- The team discussed their journey so far, and their agile delivery method. They presented key findings from their initial research and next steps and top priorities.
- The team then presented questions for the Council, including their views on how to balance ensuring a product meets sector-specific needs vs. creating a scalable product, and how artificial intelligence could contribute to the goals of ORP in future. The session was then opened up for a discussion between the team and the Council.
- The Council noted that they are very enthusiastic about this project and are excited to see how it progresses. They then thanked the team for their presentation.

#### Tranche 1 updates

- The secretariat provided an update to the Council on Tranche 1 work how it is progressing, with a particular focus on the genetic technology work. The Council noted that they are very happy with the progress and thanked the team for the update.

#### Team updates: Appointments, Forward Look and AOB

- The secretariat provided updates regarding appointments the meeting was opened to any other business to discuss.

# RHC Meeting 20th June 2022

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## Location

- Hybrid meeting at the University of Birmingham Hospital

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Cathryn Ross (Council Chair), Thames Water, Strategy and Regulatory Affairs Director
- Matt Ridley, Writer on innovation and founding chairman of the International Centre for Life
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

### Officials:

- Rhiannon Harries
- Jim Foudy, Deputy Director for the Innovation Team
- RHC secretariat

### External speaker:

- Professor Melanie Calvert

## Meeting Minutes

### Introduction and discussion with BRE's new director, Rhiannon Harries

- The Closing the Gap report was praised and BRE's new director, Rhiannon Harries talked about her previous roles, including as Deputy Trade Commissioner in India and working on nuclear regulation. She also emphasised the importance of regulation as a driver for innovation.
- A question was asked regarding the role of the UK driving regulation forward internationally and whether there is still appetite to learn from the UK on regulatory best practices.
  - It was thought there is still appetite to learn from the UK's customs and general approach towards regulation, but less in the area of technology and regulation where the international community is looking more towards other countries such as Israel. More work needs to be done to increase the influence of the UK internationally in this regard.
- A question was asked about the general direction of travel of government regarding regulation.
  - It was thought that government is prioritising innovation and enterprise. Government is broadly interested in how regulation is supporting the innovation agenda and whether it is the right approach to do so. It is also very interested in considering alternatives to regulation.
- The Council is looking forward to establishing a new relationship with Rhiannon and is keen to build a relationship based on open dialogue.

## The chair's reflections on the RHC

- Being Chair of the RHC has been one of the two most exciting things she has done in her career.
- The RHC has a very good exam question, and everybody agrees on its importance. There are many experts on regulation, and many experts on innovation, but there is an increasing demand for understanding the interface between these two areas and RHC adds unique value by marrying expertise in both.
- The chair is very proud of the people that have been involved in the work of the RHC, emphasising the passion of Council members and professionalism of the BRE secretariat. Amazing people doing very interesting work has made other people interested in getting involved, driving change.
  - In her opinion, the reports of the Council are quality work that we can be proud of, but the Council is not about writing reports but effecting change. It is therefore good that the Council has not overfocused on producing reports, but on the conversations and the process necessary to write them since these have provided a platform to enact change. The RHC's Civil Service Live presentation was a moment the Chair is particularly proud of as the Council received very good feedback. The RHC add values by acting as a role model for regulators, leading the way in horizon scanning, anticipatory regulation, public engagement, alternatives to regulation, etc. It is not only about the vertical deep-dives, the RHC's cross-cutting work is also critical.
- Keeping the momentum is critical going forward. In meeting a with N10 on regulation, stakeholders highlighted the importance of implementing the RHC recommendations. Momentum should not be lost during a time of change and transitions. There is always a reason to hold off but stopping engagement can lead the Council into a vicious circle. The Council should push the Chair to keep engaging.
- Leveraging networks is also really important. A small organisation can enact massive change if it invests on its network. The suggested Alumni network will be a very good way of doing this. However, there is more the RHC can do to leverage its networks. For instance, the RHC could do more to (1) engage internationally (just a bit more of resource would help with this) and (2) create an easier way for people to contact the Council directly (gov.uk is a key limitation for this) – this requires investing on a proforma to filter unnecessary requests but could unleash the RHC's potential and improve the Council's story telling. There is also room to do more on partnerships, leveraging the successes of medical devices report. Partnerships can help the Council do more without increasing its resource very much.
- The chair was asked what the Council can do to hear more from innovators.
  - The chair suggested that the Council needs to find the events and forums innovators attend, go to them and make the connections. It is important that new members of the RHC have those networks and contacts. Setting a public portal could also help with this.
  - It was pointed out that engaging with innovators is a more complicated task that what it may initially look like. Many innovators are hesitant to question and confront regulators.
  - The chair agreed and thought the Council could act as a safe space innovators can go to.
  - It was mentioned that the broad scope of medical devices report, increased the profile of the Council. Innovators are now approaching him directly to discuss AI as a result.
- The Chair was asked what the RHC can do to engage more internationally.

- The Chair thought it is key to partner with the key people in government so that the Council can feed into the relevant discussions at the right time. It is key to get involved in discussions that require cooperation to drive change even if achieving results is more challenging in this context.
- It was argued that the idea of the RHC acting as a 'safe space' can be enacted by proactively advertising this fact as part of the Council's engagement.
  - It was mentioned that the Council should engage with the innovator who hasn't innovated since innovators that work within the existing regulatory framework are already comfortable with regulation and are therefore less keen to change it.

#### 'Closing The Gap' Post-publication plans

- The chair thanked the team for all their work and effort pulling the report together given its complexity.
- The team gave an overview of the engagement carried out so far to raise the profile of the report. Going forward, engagement will focus on policymakers, regulators and innovators.
- The team presented a list of organisations the team is considering engaging with, grouped according to the type of stakeholder they represent.

#### External speaker – Prof. Melanie Calvert

- Prof Calvert presented on the importance of regulatory science for the UK and introduced the work of the Birmingham Health Partners Centre for Regulatory Science and Innovation, including what they think the priority areas for UK regulatory science should be and their vision to establish a Centre of Excellence for Regulatory Science and Innovation in the UK (similar to the FDA 'hub and spoke' model).
- Prof Calvert was asked about the things the UK Government could do to drive international engagement.
  - Prof Calvert thought the MRHA needs more people specialised in the regulatory science space as they do not have the capacity to engage more internationally.
- Prof Calvert was asked whether the world has learned about the successes of MHRA' parallel (rather than sequential) approval process for drugs e.g. Covid-19 vaccine.
  - Prof Calvert that MHRA could do more to capitalise this, but that we must do more to support them.
  - Alastair thought that the main issue are resources. The process worked so well during Covid-19 because the entire MHRA sifted its attention to this issue.
- The Council reflected on the importance of learning about general lessons as part of the regulatory science work. The RHC has identified quite a few cross-cutting and general issues that have emerged when discussing different emerging technologies.
- Prof Calvert was asked how the regulatory science hub would work in practice
  - Prof Calvert thought that the hub would add value by coordinating the approach to policy and teaching. The hub could help by linking policy-interested people with experts across the UK to help them drive their proposals forward.
- Prof Calvert was asked if there is anything the UK can learn from other countries that do not have a sit at the table as part of a block, but still influence international regulation.
  - Prof Calvert thought that there is a lot the UK can do to learn from other countries.

- It was suggested that the RHC could undertake a study to prove quantitatively how much investment on innovation is unleashed from every pound invested on regulation.
- It was mentioned that automation can help regulate effectively without needing much more resources and asked about the challenges of ensuring engagement is representative of all patient groups.
  - Prof Calvert thought that patient advocacy groups can become 'experts' by attending many scientific meetings and therefore become not representative of the wider patient population. It is important to reach out to underrepresented groups.
- Prof Calvert was asked about the role of the RHC within the hub model, including partnerships and collaborative working.
  - Prof Calvert thought that the RHC could contribute by highlighting the areas academics could research further through qualitative research, literature review, etc. Successful partnerships are those that agree deliverables upfront to help collaboration and align expectations. The model of the medical devices report worked quite well in her opinion.
  - The team agreed on the importance of agreeing deliverables as well as roles and responsibilities, including a clear demarcation between the role of the Council and that of academic partners.
- The Chair thanked Prof Calvert for her presentation and for the work of Birmingham Health Partners on the medical devices report.

#### 'Closing The Gap' recommendation implementation plans/discussion

- The Council and secretariat discussed how to influence and get acceptance from regulators and innovators with regards to the Closing the Gap report. The idea of a less tangible output of responses was also discussed.
- It was mentioned that there needs to be a way to measure engagement with the report and consideration needs to be made on how best to engage with regulators as legally they are not required to respond to the Council.
- The point was made that the Council's engagement of the report needs to be targeted and stakeholders should be prioritised during this targeted engagement.
  - It was suggested that between engaging regulators and innovators, the council should spend more time on engaging with innovators.
  - However, it was also highlighted that not all recommendations were aimed at innovators.
  - There are forums the Council could the report share with.
  - The Council could suggest to regulators when engaging about the Closing the Gap report that they should target chairs to relevant select committees.
- It was suggested that when tranche 2 reports are published the secretariat should send out the Closing the Gap report alongside any published tranche 2 reports.
- It was pointed out that it could be possible to link the closing the gap report to the no10 summit forums that will be taking place later on in the year.
- It was suggested that the Council and secretariat should follow up with interviewees of the Closing the Gap report to add a personal post publication follow up encouraging them to share the report within their network and creating a space for these stakeholders to share their view of the report.

#### AI as a Medical Device report overview

- The Council and secretariat discussed the report overview of AI as a medical device.
- It was asked whether stories like the google case would affect the report outcome.
  - This is something the team need consider, including things such as public perception. A reference was made to the House of Lords select committee report on AI.

- All these problems can be linked with other AI reports with regards to fairness.
- It was mentioned that there is uncertainty in whether the UK wants to be a leader in within this AI as Medical Device field.
- It was recognised that AI as Medical Device is an extremely technical subject, but it was questioned whether the RHC has a 30 sec ministerial pitch.
  - It was noted that this action could be worked on.
  - It was also noted that the report may be more specific than to other areas not only due to it being the deep dive leads expertise but because it is a mature area and requires signposting of what work is already going on.
  - It was highlighted that if the report drops information or recommendations there is a chance of missing things out.
- A further discussion took place on giving medical regulators a non-medical use in neurotech. It was questioned on how this would this work and whether this is similar with AI as a Medical Device.

#### Tranche 1 updates

##### *Genetic tech*

- The Council is hoping for response to the genetic technology report in June.

##### *Fusion*

- Fusion response out today 20/06/2022, with a complete acceptance of recommendations. It was noted that this is a massive achievement for the RHC.

##### *Other updates*

- The Closing the Gap report has been published.
- There has been recent interest from ministers wanting to come to the August - September meeting.

# RHC Meeting 2<sup>nd</sup> August 2022

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## Location

- Hybrid meeting at BEIS 1 Victoria Street

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Chris Hodges (Council Chair), Emeritus Professor of Justice Systems at the University of Oxford and a Supernumerary Fellow of Wolfson College, Oxford.
- Matt Ridley, Writer on innovation and founding chairman of the International Centre for Life
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Honorary Research Fellow, Nuffield Department of Women's & Reproductive Health, University of Oxford
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

### Ministerial attendance

- Lord Callahan, Minister for Business, Energy and Corporate Responsibility

### Officials:

- Jennifer Powers, Special Advisor for No10
- Rhiannon Harries, Director of the Better Regulation Executive
- Jim Foudy, Deputy Director for the Innovation Team
- RHC secretariat

## Meeting Minutes

### Introductions

- The Chair welcomed attendees, expressed his excitement for taking over Chairmanship of the Regulatory Horizons Council and thanked previous Chair, Cathryn Ross, and outgoing member, Matt Ridley, for their work.

### Opening remarks from Lord Callanan

- The Minister echoed thanks to Cathryn Ross and Matt Ridley for their contributions towards the RHC.
- The Minister welcomed RHC contribution towards creating better and smarter regulation following the UK's exit from the EU. The Minister congratulated the RHC in their positive response from DfT on the Drones report and encouraged the RHC to continue to challenge Government to rethink the status quo on regulation.

### Chair's vision for RHC

- The Chair laid out his initial vision for the RHC, emphasising his desire to be an ambassador for the RHC and noted the importance he places on engagement and outreach in achieving impact from work. The Chair noted his preference for Outcome Based Cooperation (OBC) to build consensus between regulator, government, and industry to create a productive regulatory environment. The Chair noted the need for regulators to shift focus toward testing things and encouraged regulators and industry to work together to undertake sandboxing.

- The Minister noted the importance of criticism and challenge to regulators as well as consensus building to achieve better regulation.

#### RHC work to date - successes and current challenges

- Officials presented successes and current challenges facing the RHC highlighting positives covering Council ethos, reputation, high-quality reports, and clear impact and influence, as well as challenges with delays on government responses, broader comms and engagement.
- The Council noted the important role the RHC plays in championing people who are pushing for change and innovation in a sector, finding people without a voice and giving them a voice.
- The Council highlighted how well regarded the RHC is internationally, and the burgeoning partnerships it is forming with international stakeholders.
- The Council noted the occasional issue of departmental readiness for report publication, with the view expressed that departmental readiness should not be barrier to report publication.
- Council members identified the use of engaging with UK industries operating internationally rather than in the UK as important insights into regulatory barriers in the UK.
- Council members noted the desire for greater commercial trials between regulator and industry to support commercialisation of emerging technologies.
- The importance of creating a regulatory regime that encourages investment into the UK was raised, with the increased opportunity for investment highlighted following UK exit from the EU. The Council discussed the usefulness of engaging with the financial industry to further understand the opportunities here, as well as discussing the scope for non-device deep dives into technology for example financial software.

#### Neurotechnology Deep Dive update

- The progress of the report to date was outlined, noting that this was originally commissioned by Emerging Technology board (no longer in existence) in the Cabinet Office. The team has engaged widely with 61 stakeholders in developing the draft report which is currently undergoing external review.
- It was noted that an area that was explored early on was engaging with the public. This was found not to be feasible, and an update was provided on the approach taken instead which drew on a previous public engagement exercise drawing stakeholders together to discuss regulatory implications in a roundtable. The aims of the interactive taxonomy that will be published as a supplementary output to the report were introduced.
- An overview was provided of the key recommendations provided in the report and feedback was welcomed from the Council.
- The team provided an update on plans to launch and raise awareness of the report when published.
- There was broad support for the report and recommendations from the Council and Chair
- There was some discussion around the number of recommendations, and it was agreed that what is important is being able to provide a clear narrative which could be supported by grouping recommendations into themes.
- The Council noted the challenges in governing a technology such as neurotech that does not have a clear owner within Government. There was some preference for a stewardship model and the Chair offered to provide examples where similar approaches have been taken in the past.



### Tranche 3 selection process and early ideas

- The secretariat outlined the current approach planned to select areas for tranche 3, which is focused on utilising existing work from across government in a 'scan of scans' approach, combined with broad stakeholder engagement and a portal for stakeholders to submit suggestions. It was also noted that the 7 technology families developed through the innovation strategy could provide a good starting point to guide engagement.
- The secretariat also provided the context and rationale for this approach, noting that the previous full horizon scan completed by the RHC was particularly resource intensive.
- The secretariat also outlined the approach to Government commissions, which the Council has freedom and discretion to approve but have been accepted in the past for previous reports on Genetic technologies and Neurotechnologies.
- The Council were supportive of the overall approach proposed.
- Specific suggestions for potential tranche 3 areas included: the use of cell free DNA, wellbeing and lifestyle apps (which have arisen as an issue through the AI as a Medical Device and neurotechnology reports), Net Zero (particularly in regard to informing consumer and training of engineers) and the financial sector.
  - It was discussed that the Council should not limit itself to hardware innovations and should also consider the regulation of processes and services which was raised in the context of the financial sector.
- There was particular interest in looking into what regulatory issues exist in the field of bioinformatics and genomics.
- The Council discussed ways to maximise stakeholder engagement as part of the tranche 3 selection and expressed interest in engaging more widely with investors and financiers. It was suggested the Office for Investment could act as a facilitator.
- It was suggested that the Council could combine insights from all of its previous deep dives to produce a general reflection or crosscutting report on how regulatory behaviours can best foster innovation.

### Team updates

- The team provided an outline of current challenges and opportunities, particularly in connection to the upcoming change of Prime Minister
- The Council and secretariat added their thanks to Matt Ridley who is standing down as a Council Member having completed his term.
- It was confirmed that the RHC will operate an 'alumni' scheme for outgoing members to remain in contact and provide flexible support to the RHC where they are able and willing to do so. This was agreed as a good mechanism to expand the RHC's network and ensure continuity where members leading on particular reports move on.

### Forward look and AOB

- The team provided an outline of upcoming RHC milestones and activities.
- It was also added that there may be value in spacing out tranche 2 publications with the view to maximise uptake and impact.

# RHC Meeting 12th September 2022

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## Location

- Hybrid meeting at BEIS 1 Victoria Street

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Chris Hodges (Council Chair), Emeritus Professor of Justice Systems at the University of Oxford and a Supernumerary Fellow of Wolfson College, Oxford.
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Honorary Research Fellow, Nuffield Department of Women's & Reproductive Health, University of Oxford
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

### Officials:

- Jim Foudy, Deputy Director Better Regulation Executive
- RHC secretariat

## Meeting Minutes

### Introductions

- The Chair welcomed attendees, introduced the September meeting and welcomed new members of the secretariat team.

### Outcomes-based Cooperative Regulation (OBCR)

- The Chair outlined his model of Outcomes-Based Collaborative Regulation (OBCR) and detailed recent independent engagement that he has done on the topic.
- He shared his view that there was broad appetite and opportunities for adopting OBCR.
- The Council agreed that there are elements of OBCR that are beneficial for the Council to be aware of and applicable to our work though recognised that there are multiple models in existence including findings from the Council report on Closing the Gap

### Working with regulators and challenges

- The Council reflected on the fine balance between developing and maintaining good relationships, whilst also acting as a disruptor. They noted that the RHC's remit is not only to collaborate but also to challenge.
- The Chair offered to act as a moderator during challenging conversations in future.

### Neurotechnology launch event

- The Council discussed the merits of a launch event to disseminate a forthcoming report on neurotechnology.
- Recognising some of the risks and resource associated with facilitating an event, the Council agreed to explore alternatives to a single launch event.

### Hydrogen in Maritime deep dive

- A Council member updated on the Hydrogen in Maritime deep dive, including an overview of the recommendations in the report, before inviting comments.

- Members noted that several recommendations appeared to require government spending and questioned where the funding might come from and raised the possibility of requesting detailed advice on this from government economists, which might include cost benefit analysis.
- A different Council member felt that the recommendations reflected their view that greater attention should be given to supporting industry to commercialise R&D findings.
- Before closing the item, the Council lead for Hydrogen in Maritime requested that members contact him to suggest case studies that could be useful for the report.

#### 'Closing the Gap' report update

- The secretariat updated attendees on its engagement with BEIS policy teams regarding next steps for the publication of the Government's response to the Council's recent Closing the Gap report.
- The secretariat gave a brief update on other forms of engagement for the Closing the Gap report, such as upcoming events and meetings, and welcomed further suggestions for future engagement.

#### Team updates and forward look

- The secretariat offered an update on BEIS' new ministerial appointments, with whom the secretariat had not yet had an opportunity to engage. The secretariat also updated the Council on the movement of the Brexit Opportunities Unit from the Cabinet Office into BEIS and noted potential opportunities for closer working, should the Council desire this.
- The team updated the Council on their engagement with other departments regarding Government responses to Tranche 1 work.

#### AOB

- The Council agreed to respond to the Office for AI's call for evidence on regulating AI.

# RHC Meeting 19th October 2022

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## Location

- Hybrid meeting at BEIS 1 Victoria Street

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Chris Hodges (Council Chair), Emeritus Professor of Justice Systems at the University of Oxford and a Supernumerary Fellow of Wolfson College, Oxford.
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Honorary Research Fellow, Nuffield Department of Women's & Reproductive Health, University of Oxford
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

### Officials:

- Jim Foudy, Deputy Director Better Regulation Executive
- Phillipa Sharma, Deputy Director, Technology Strategy and Security (for item 2 'Quantum Technology Commission to the RHC' only)
- RHC Team
- BEIS policy advisors (for item 2 'Quantum Technology Commission to the RHC' only)

## Meeting Minutes

### Quantum Technology Commission to the RHC (Phillipa Sharma, Deputy Director, Technology Strategy and Security)

- Phillipa presented a commission to the Regulatory Horizons Council, asking members to consider a review on the future regulation of quantum technologies. Council Members felt that the RHC could add value in this space and agreed in principle to taking forward a deep dive.

### Update on workshop with Chair and BEIS Team

- The RHC Team summarised the output of its ongoing work with the chair to refine his vision for the council, pointing to the opportunity for the council to make greater use of its convening role, and to potential challenges in monitoring the impact of the councils growing number of published deep-dives.
- Members reflected on the practicalities of convening stakeholders with conflicting views or interests and on the extent to which the council should continue to engage with reports beyond the publication of a government response.

### Office for Science and Technology Strategy work: 10 big things

- Attendees discussed the Office for Science and Technology Strategy's views on the enablers to scientific progress in the UK and were pleased to learn that the importance of the regulatory environment had been recognised.

### Tranche 3 update

- The council and secretariat agreed principles for identifying the councils next suite of deep dives, including:
  - a qualitative approach to information gathering and decision making considering the regulatory opportunities associated with a technology or

sector, the viability and impact of the technology itself, and the value of an independent intervention.

- referring to existing government technology horizon scans to ensure stakeholder engagement reflects the UK's areas of comparative advantage, and to gather information about technological readiness.

Updates and forward look:

- Council members gave updates on reports still in progress relating to neurotechnology, AI as a medical device and hydrogen (propulsion) in maritime and raised no significant risks or issues.

AOB:

- Council members agreed to review the minutes of the previous meeting and revert to the secretariat by email.

# RHC Meeting 10th November 2022

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## Location

- BT Adastral Park

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Chris Hodges (Council Chair), Emeritus Professor of Justice Systems at the University of Oxford and a Supernumerary Fellow of Wolfson College, Oxford.
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Honorary Research Fellow, Nuffield Department of Women's & Reproductive Health, University of Oxford
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

### Officials:

- Jim Foudy, Deputy Director Better Regulation Executive
- RHC Team

### Guests

- Paul O' Brien, Research Director at Adastral Park.
- Chris Handford, Director of Regulatory Policy, Solicitors Regulation Authority
- Warren Davis, Solicitors Regulation Authority

## Meeting Minutes

### Introduction to applied research within BT

- After the council and team's tour of BT's research facilities at Adastral Park, Paul O'Brien shared an overview of BT's applied research with the council, set out the organisation's strategic priorities for research and development and offered reflections on how regulation might support or hinder them.

### Solicitors Regulators Authority's Innovation Function (SRA Team)

- Following the SRA's successful bid for government funding under the Regulators' Pioneer Fund, Chris set out the SRA's work to foster innovation in the legal sector, which aims to widen access to justice.
- Many of Chris' reflections on effective practice, such as on the value of fostering collaboration between regulators and of enabling open dialogue between regulators and business, echoed the council's own recommendations and they were pleased to hear about a different application of these principles.

### RHC Team Updates

- The team reminded the council of the Chancellor's commitment to '[asking] the Government Chief Scientific Adviser and National Technology Officer, Sir Patrick Vallance, to bring together the best minds to advise how the UK can better regulate emerging technologies, enabling their rapid and safe introduction.'
- The team and council discussed RHC communications, including the potential merits of an overarching strategic report, and an update on publication and engagement plans for AI as a Medical Device and Neurotechnology reports.

- The Chair and RHC team updated the Council on their November engagement, which included engagement to identify potential further deep dives for the council.

#### Forward Look and AOB

- The Council and team agreed the minutes of the previous meeting.
- No new conflicts of interests were declared.

# RHC Meeting 10<sup>th</sup> February 2023

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## Location

- BEIS 1 Victoria Street

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Chris Hodges (Council Chair), Emeritus Professor of Justice Systems at the University of Oxford and a Supernumerary Fellow of Wolfson College, Oxford.
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Honorary Research Fellow, Nuffield Department of Women's & Reproductive Health, University of Oxford
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

### Officials:

- Jim Foudy, Deputy Director Better Regulation Executive
- RHC Team

## Meeting Minutes

### Update on and discussion of machinery of government changes

- The team gave a short update on recent machinery of government changes, explaining that the RHC would now sit in the Department for Science, Innovation and Technology, and that the RHC would no longer sit within the Better Regulation Executive but would continue to work closely with them.
- The council sought clarity on whether this change would limit the scope of work to regulatory reform of technologies for which DSIT are responsible. The team confirmed the Council retains the ability to define its work programme and focus on regulatory reform of new and emerging technologies regardless of where they nominally sit within Whitehall.

### Update on Patrick Vallance review of the regulation of emerging technology

- Jim Foudy provided a brief update on the progress of Sir Patrick Vallance's work to review the regulation of emerging technology, with which some council members had already engagement. All indicated an interest in further participation.

### Discussion of Tranche 3 selection

- The RHC team had spent the previous quarter undertaking stakeholder engagement based on the seven technology families listed in the government's *Innovation Strategy and* taking account of the National Science and Technology Council's priority technologies<sup>2</sup>.
- The team set out its criteria, focusing on the extent regulation was a critical enabler and/or barrier and also whether the Council's involvement would add value.
- The team set out different potential areas of work for the council in order of priority. The council were asked whether they agreed with the team's assessments, and to indicate their interest in leading on options identified as highest-priority.

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<sup>2</sup> Artificial Intelligence, Quantum, Future Telecoms, Engineering Biology, Semiconductors



- The council agreed to having more than one decision-point on the work that it would undertake in 2023, affording greater agility in responding to emerging HMG priorities. In previous years, the annual RHC programme of work had been decided at in the first quarter of the year. Members also agreed with the team on the value of varying the 'style' of the RHC's activities, to encompass convening workshops with stakeholders, shorter reports and other outputs, and longer deep-dive reports.
- Immediate priorities, on which work should begin immediately, were agreed as:
  - The completion of the council's report on the use of hydrogen in the maritime sector;
  - the already-commissioned report on quantum technology, and;
  - a programme of work to further develop and embed learning from the council's cross cutting report *Closing the Gap*.
- Space, Robotics in agriculture, non-health genomics, and industrial biotechnology were all agreed to be high-priority areas, and it was decided that the council and team would work with policy leads and other stakeholders to scope activity further.
- The team agreed to continue to monitor progress in the following areas, for further council discussion in 6 months: fintech; metaverse & web 3.0; energy islands; autonomous mobility solutions; Trust and Net Zero: Carbon Markets; Radiopharmaceuticals; Artificial Intelligence.

# RHC Meeting 13<sup>th</sup> March 2023

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## Location

- BEIS 1 Victoria Street

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Chris Hodges (Council Chair), Emeritus Professor of Justice Systems at the University of Oxford and a Supernumerary Fellow of Wolfson College, Oxford.
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Honorary Research Fellow, Nuffield Department of Women's & Reproductive Health, University of Oxford
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

### Officials:

- Jim Foudy, Deputy Director Better Regulation Executive
- RHC Team

## Meeting Minutes

### Presentation from Leo Ringer and Andrew Bennett, Form Ventures

- Form Ventures is a capital fund, which invests in very early-stage tech companies, and seeks to provide public policy and regulatory strategy support to SMEs that would normally struggle in these areas.
- They gave a presentation and Q&A to the council, highlighting the perspective of SMEs and investors they work with regarding regulation of emerging technologies.

### Update on the publication of the UK Science and Technology Framework

- Regulation and standards feature prominently in the recently published UK Science and Technology Framework.
- The council discussed the government's identification of 'five technologies of tomorrow' (quantum, AI, engineering biology, semiconductors, and future telecoms), and what this means for the council. It was broadly agreed that the RHC should take these priorities into account when selecting its programme of work, recognising that not all technologies have specific regulatory issues or challenges, and that discussion on regulation is typically most effective when focussed on the different applications of technologies rather than the technologies themselves.

### Updates on Tranche 2 reports

- The RHC's report on the regulation of hydrogen propulsion in the maritime sector is due to be shared with Ministers soon, in advance of publication. In addition, a summary of the report's recommendations will be presented at the Society Maritime Industries annual conference on Wednesday 15 March. The team are exploring further opportunities to share and discuss the reports' findings.

### Updates on Tranche 3 priority areas

- The team and council members have begun engagement with quantum stakeholders to understand current regulatory issues and challenges and define the scope of the council's report on quantum. Options are being explored regarding cooperation with

experts during the deep dive, including informal groups as sounding boards, experts delivering specific work, and potential procurement frameworks.

- The team discussed topic areas in which to convene regulators and other bodies following on from the Closing the Gap report. We are currently scoping three areas; how can regulators engage with innovators, the practicalities of 'doing nothing' as a legitimate response to regulating the application of new and emerging technologies and finally the role of regulation in the journey from start up to scale up.
- The team attended an event to mark the launch of the Centre for Finance, Innovation and Tech (CFIT), which will be a private sector-led body focussing on financial innovation in the UK by bringing together experts from across the finance and technology ecosystem. Their aim will be to identify and address opportunities and barriers to growth for UK fintech. CFIT will incorporate the interests of a range of interested parties, including from the broader financial services, technology, and innovation sectors.
- GO-Science have engaged with officials in other departments on genomics and expect to commission the RHC to undertake work in this area at the next council meeting.
- Scoping has begun on a short RHC project on robotics in agriculture.

#### AOB

- No new conflicts of interest were declared.
- Minutes from the previous meeting were confirmed.

# RHC Meeting 24<sup>th</sup> April 2023

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## Location

- Edinburgh University

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Chris Hodges (Council Chair), Emeritus Professor of Justice Systems at the University of Oxford and a Supernumerary Fellow of Wolfson College, Oxford.
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Honorary Research Fellow, Nuffield Department of Women's & Reproductive Health, University of Oxford
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

### Officials:

- Jim Foudy, Deputy Director Better Regulation Executive
- RHC Team

## Meeting Minutes

### Update on Closing The Gap (CTG) follow on

- Work has begun on three projects as part of the RHC's CTG follow series:
  - How regulators can engage with innovators
  - The practicalities of 'doing nothing' as a legitimate response to regulating the application of new and emerging technologies
  - The role of regulation in the journey from start up to scale up

### Update on Quantum

- The team and council members are continuing engagement with quantum stakeholders to understand current regulatory issues and challenges and define the scope of the council's report on quantum. Options are being explored regarding cooperation with experts during the deep dive, including informal groups as sounding boards, experts delivering specific work, and potential procurement frameworks.

### Presentation of x-cutting regulation for innovation recommendations, Regulation for Innovation Review Team

- The Innovation Review team presented its x-cutting regulation for innovation recommendations and council report to the council.

### Presentation on Genomics beyond health from the Government office for Science (GO-Science)

- Go-Science, in January 2022, published a report exploring how genomics will affect our lives in the future, how the genome can influence people's traits and behaviours beyond health and how studying our DNA presents both benefits and challenges to society.
- Go-Science highlighted the potential for an RHC deep dive in this area. The key exam question would be to understand current regulation, who in the UK should

regulate non-health genomics, and ensure society is able to harness the beneficial applications of genomics – such as health - safely while mitigating risks and without damaging public trust. Possible sectors include DTC tests, forensics/criminal justice, education and employment.

- The council asked the team to engage with colleagues to explore what the benefits and likely impact of the RHC undertaking such work might be.

Discussion on how the RHC should respond to fast-moving developments in technology & regulation (e.g. AI)

- The council discussed whether it should move beyond its project-based work on specific technologies to offer opinions on broader technological developments and agreed to continue to consider this question.
- The council moved on to discuss the specific question of whether a letter should be published regarding the proposed AI moratorium, and if it would have any value or simply add to the noise in an already crowded space. It was agreed that more discussions were needed before any decisions made.

Chair and team updates

- The secretariat gave an update on a meeting hosted by the Chair to discuss RHC priorities and also OBCR.
- The Chair highlighted the NAO's recent publication of the 'Regulating to achieve environmental outcomes' report.
- The secretariat gave a short update on plans to convene stakeholders to discuss regulatory reforms to enable the safe adoption of agricultural robotics.

AOB

- No new conflicts of interest were declared.
- Minutes from the previous meeting were confirmed.

# RHC Meeting 21<sup>st</sup> June 2023

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## Location

- MS Teams virtual meeting

## Attendees

### Regulatory Horizons Council (RHC) Members:

- Chris Hodges (Council Chair), Emeritus Professor of Justice Systems at the University of Oxford and a Supernumerary Fellow of Wolfson College, Oxford.
- Alastair Denniston, Consultant Ophthalmologist at University Hospitals Birmingham NHS Foundation Trust
- Andy Greenfield, Honorary Research Fellow, Nuffield Department of Women's & Reproductive Health, University of Oxford
- Joyce Tait, Professor and Co-Director at the Innogen Institute, University of Edinburgh
- Parag Vyas, Director of PV10 Consult

### Officials:

- RHC Team

## Meeting Minutes

### Welcome: Dr Lucy Mason, Updates to the Register of Interests and Chair updates

- Welcome and Introduction of the RHC's newest council member Lucy Mason.
- The chair and members welcomed Lucy Mason to the council; Lucy is a Director at Capgemini Invent, an innovation-focussed consultancy, with previous experience in the civil service and police force and broad experience of emerging technology policy.
- Parag Vyas has taken a new role as CTO at Flexergy, a sustainable energy start-up. The public register of interests will be updated accordingly.
- The RHC held a roundtable during London Tech Week to understand the regulatory barriers and challenges faced by SMEs looking to scale their businesses. This is part of a broader programme of crosscutting work to explore specific topics raised in the RHC's Closing the Gap report. A note will be published on gov.uk in due course.

### Discussion of Project Evaluations

- The team presented project evaluation findings for Tranche 2 deep dives on neurotechnology and AI as a Medical device.
- The presentation provided valuable insights gathered from interviews conducted with stakeholders who contributed to the RHC's deep dive projects. Stakeholder feedback was broadly positive, and most felt the RHC filled an important gap in focusing on regulation. A range of views were shared on whether the RHC should focus future work on cross-cutting areas and or specific emerging technologies.
- Evaluation findings will be shared publicly over the coming months.
- The Council was keen to explore how to evaluate the impact of tranche 1 work, ensuring consistent assessment of future projects.

## Genomics Beyond Health

- The team had carried out further work to assess the desirability of accepting a commission on the regulatory implications following a publication on 'Genomics Beyond Health' from the Government Office for Science. The team had engaged with Departments with a policy interest in genomics, and concluded that a full deep dive would not be the best use of the RHC's limited resources.
- The Council were, nonetheless, pleased to have been approached by Go-Science, and keen to be commissioned again.
- The Council agreed that the following interventions may be of value, subject to further discussion with relevant stakeholders:
  1. Encouraging consistent use of terminology across government; the meaning of 'genomics beyond health' is ambiguous.
  2. Bringing together policy teams & scientists, to support coordination of the different policy & science interests in this area.

## External presentation by the Better Regulation Executive, Department for Business and Trade

- Members of the Better Regulation Executive presented their Open Regulation Platform (ORP), a digital product which seeks to provide a collated repository of UK regulation.
- The Council welcomed the greater accessibility of regulatory information that the platform would facilitate and sought reassurance that user research had been undertaken to consider the views of smaller innovators, and that there are mechanisms to easily update the data on the platform.
- It was noted how the platform may be useful tool to surface regulatory misalignments and tensions within specific sectors, through bringing all sector information into one easily accessible place.
- The Council was supportive of the work and eager to work with the team on any regulatory challenges that the platform identifies.

## Project updates

- The Council and Team will have delivered several workshops by the end of the month as part of work on the Closing the Gap Series. Readouts will be circulated to Council Members with opportunities to contribute to the findings and outputs.
- On the *Robotics and Autonomous Systems in Agriculture* project, the first of a series of workshops has taken place, to explore regulatory challenges in the field. The RHC is planning its own workshop with regulators on the 19 July to identify potential solutions to these barriers.
- Positive developments were noted on recommendations made in the RHC's report on *Neurotechnology*, including a commitment by the ICO to publish guidance on neurodata by 2025.
- Evidence gathering for the *Quantum Review* is underway, with four roundtables planned based on the four national quantum 'hubs'. A landscape review has been commissioned through Imperial College London to support the work.
- The Team is working with the *DSIT Engineering Biology* team to scope a project for the RHC on Industrial Biotechnology. Council Members shared views the best scope for this project, recommending it exclude human applications.
- The regulation of *space* technologies remains on the RHC's priority list.