UKSBS

Shared Business Services

Commissioning Letter

Nesta
58 Victoria Embankment
London
EC4Y 0DS

Tuesday 4th December 2018

Dear Sir / Madam

BIS Research and Evaluation Framework Agreement – Lot 5 Innovation-friendly Regulatory Approaches - Case Study Analysis CR18154

Thank you for your response to the Specification for the above commission by the Department for Business,Energy and Industrial Strategy (BEIS) (the Customer) through the Crown Commercial Service RM3745 Management Consultancy Framework between (1) Crown Commercial Services; and (2) Nesta (the Framework Agreement).

| Appendix: | A. | Tender response dated Friday 23rd November 2018. |
| | B. | Specification for Innovation-friendly Regulatory Approaches - Case Study Analysis |

| Annex: | A. | Annex A GDPR |

The Department for Business,Energy and Industrial Strategy (BEIS) accepts your Tender (Appendix A), submitted in response to our Specification (Appendix B).

The Call–Off Terms and Conditions for this Contract are those set out in Schedule 5 to the Framework.

The agreed total charges for this assignment are **£49,960.00** exclusive of VAT which should be added at the prevailing rate and in alignment with the following submitted price schedule

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BIDDER NAME

Please complete the shaded yellow sections only.

Section 1: Total Project Costs (Summary)

	Objective	Number of Days
1	Research	23
2	Data collection/compilation	25
3	Primary research/interviews	13
4	Drafting	17
5	Analysis	17
6	Project Management	3
7	Meetings	2
8	Any other costs	0
	TOTAL	**87**

£9,560.00

Section 2: Total Staff Costs (Please complete)

Job Title	Shared Rate/Fee rate (exc VAT paid)	Discounted Fixed Fee rate (exc VAT paid)	Objective Area (Please Select)	Number of Days	Travel and ...	Total Staff Cost (ex VAT)	Total Cost (ex VAT)
			5 Analysis				
			5 Analysis				
			4 Drafting				
			5 Analysis				
			3 Primary research/interviews				
			4 Drafting				
			5 Analysis				
			6 Project Management				
			7 Meetings				
			1 Research				
			2 Data collection/compilation				
			3 Primary research/interviews				
			4 Drafting				
			5 Analysis				
			1 Research				
			2 Data collection/compilation				
			4 Drafting				
			5 Analysis				
			Please Select				
			Please Select				
			Please Select				
			Please Select				
			Please Select				
			Please Select				

TOTAL STAFF COSTS

This varies project from project (PM to confirm)

All invoices should be sent to should be sent to finance@services.uksbs.co.uk or Billingham (UKSBS, Queensway House, West Precinct, Billingham, TS23 2NF).

You are reminded that any Customer Intellectual Property Rights provided in order to perform the Services will remain the property of the Customer. The following deliverables have been agreed:

The Services Commencement Date is Monday 12th December 2018.

The Completion date is Friday 29th March 2019.

The Contract may be terminated for convenience by giving 30 days' notice in accordance with clause 38 of the Call-off Terms and Conditions.

The Authorised Representative for this Commission will be

Until the date of publication, findings from all Project outputs shall be treated as confidential. Findings shall not be released to the press or disseminated in any way or at any time prior to publication without approval of the Department.

This clause applies at all times prior to publication of the final report. Where the Contractor wishes to issue a Press Notice or other publicity material containing findings from the Project, notification of plans, including timing and drafts of planned releases shall be submitted by the Contractor to the Project Manager at least one week before the intended date of release and before any agreement is made with press or other external audiences, to allow the Department time to comment on factual accuracy. All Press Notices released by the Department or the Contractor shall state the full title of the research report, and include a hyperlink to the Department's research web pages, and any other web pages as relevant, to access the publication/s.

This clause applies at all times prior to publication of the final report and within one month from the date of publication. Where the Contractor wishes to present findings from the Project in the public domain, for example at conferences, seminars, or in journal articles, the Contractor shall notify the Project Manager before any agreement is made with external audiences, to allow the Department time to consider the request. The Contractor shall only present findings that will already be in the public domain at the time of presentation, unless otherwise agreed with the Department.

Congratulations on your success in being selected to undertake this Commission.

Yours sincerely

Polaris House, North Star Avenue, Swindon, Wiltshire, SN2 1FF www.uksbs.co.uk FLALLSH APR 2015

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Category Specialist
UK Shared Business Services Ltd

BY SIGNING AND RETURNING THIS COMMISSIONING LETTER THE SERVICE PROVIDER AGREES to enter a legally binding contract with the Customer to provide to the Customer the Services specified in this Commissioning Letter and Annexes incorporating the rights and obligations in the Call-off Terms and Conditions set out in the Framework Agreement.
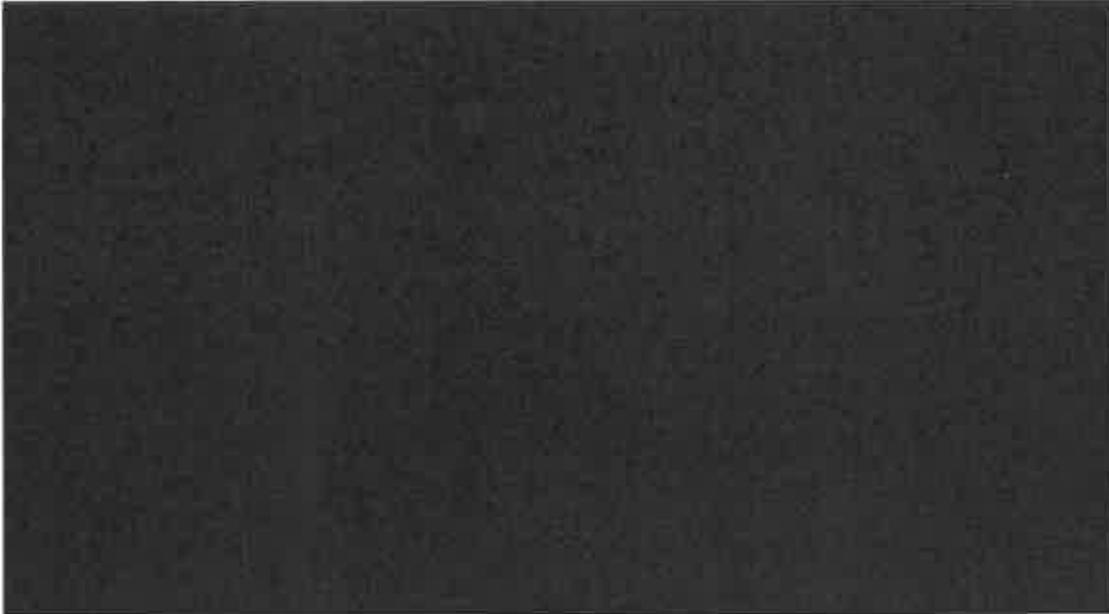
Appendix A – Nesta Tender Response

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Innovation-friendly Regulatory Approaches – Case Study Analysis UKSBS / BEIS CR18154

PROJ1.1 Approach/methodology

Our work has 4 main stages; (i) literature review and global case study identification; (ii) BEIS workshop to identify focus areas and measures of success and key characteristics of positive outcomes; (iii) Developing guidance to support the implementation of regulatory innovation; (iv) final report, slide deck and short method guides to inform best practice.

(i) Literature review and global case study identification

The first stage will build on existing work Nesta has already undertaken to collect global examples of regulatory innovation and provide a framework that identifies key traits and common themes across these examples.[1,2,3] This work has already involved an extensive, though by no means exhaustive, review of policy, academic and grey literature.

Using existing work as a basis we will explore the available literature further, putting particular emphasis on identifying existing evidence (empirical or otherwise) of positive outcomes, and collect further examples of innovation-friendly regulatory techniques. All information collected through the literature review and case study identification will then be analysed to surface common themes and characteristics. These insights will pulled together to inform the subsequent stages and as part of our final outputs (insights report and slide deck). Information collected on individual examples will also collated into spreadsheets which will be shared with BEIS.

(a) Sources of information and data

To identify these cases we will focus on four sources of information:

1. Policy documents. These will be identified and accessed primarily through relevant government and regulatory agency websites and databases. Existing knowledge and other sources of information (eg grey literature) will help identify where to focus our search, i.e. which regulatory agencies or governments are undertaking innovative approaches to regulation. However to ensure we focus our effort in the time available and ensure we work in areas where there is likely to be greater applicability to the UK we

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[1] https://www.nesta.org.uk/reports-working-model-for-anticipatory-regulation-a-working-paper/
[2] Regulation Renewed paper (forthcoming)
[3] AI governance work?

will bound the majority of our review to a set of key countries. We would propose the US, Canada, EU countries (e.g. France, Germany, Spain, Finland, Netherlands), Singapore, South Korea, Australia and the UK itself. The final decision on where to focus will be taken in collaboration with BEIS at the project inception meeting. We will also focus our search in areas where we already know regulatory innovation is taking place (for example in specific areas of healthcare, fintech and around key disruptive technologies like AI or blockchain). Policy documents will be particularly important sources of quality information outlining relevant initiatives and providing evidence of 'positive' outcomes via project evaluations;

2. Academic and policy journals. Our literature review will explore a range of well respected journals such as the *Journal of Law and Society* and *Regulation and Governance*. We will also focus on key departments in institutions, such as LSE's Centre for Analysis of Risk and Regulation, and key academics and commentators, such as Roger Brownsword or Joyce Tait;

3. Grey literature. Report, articles and blogs from international organisations such as the World Economic Forum and the OECD as well as consultancies and other NGOs. Due to the emergent nature of many of the examples we are looking for will also explore websites, news articles and blogs to gather information. Specific news channels, such as *Govinsider*, are useful sources of information;

4. Informal interviews. A number of informal advisory interviews (we estimate no more than 3-4) will also help direct our search and identify cases or literature we otherwise may have missed. This will be particularly important given the wide range of topics, countries and information we will be looking for. These interviews will be done early on with existing contacts who have a birds eye view of different regulatory systems such as ██████████ CEO of the Infocomm Media Development Authority (IMDA) in Singapore.

(b) Identifying relevant cases

We will primarily collect examples that neatly fit within the existing definitions of Advisory and Adaptive approaches (see figure 1) but will also record techniques/methodologies that are very closely linked to the goal and policy outcome of these two modes of practice.

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(Figure 1. Section of the AAA framework showing the goal and outcome of Advisory and Adaptive approaches. See [4] for original)

While we are likely to mostly surface examples from the past few years we include historical techniques (that may have fallen out of favour or only had limited use) if they fulfil the goals of the project (i.e. the identification and description of approaches to regulation that support innovation, lead to positive outcomes and are applicable in multiple contexts). We will collect at least 30 additional examples of innovative approaches to regulation on top of those already highlighted by BEIS. We estimate that at least 5 common approaches/themes will be surfaced through this literature review based on previous work.

Example of an emerging case study;
The Software Pre-certification Programme is an initiative of the US Food and Drug Administration.

In order to implement Congress' controversial 21st Century Cures Act of 2016, which aims to streamline the drug and medical device approval process, the FDA's Center for Devices and Radiological Health (CDRH) created a Digital Health Innovation Action Plan. The Plan issues guidance on the implementation of the legislation and included the launch of a pilot software precertification program to develop a new approach to digital health technology oversight. This program explores a potential voluntary pathway to assess the safety and effectiveness of certain Software as a Medical Device (SaMD) products by focusing on the manufacturer/developer, rather than primarily the product. Companies that undergo the assessment may receive pre-certified status, based on their demonstrated robust culture of quality and organizational excellence, as well as commitment to monitoring real-world performance of their products. As a result, pre-certified companies would have a less

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[4] https://www.nesta.org.uk/report/a-working-model-for-anticipatory-regulation-a-working-paper/

burdensome route to market. This is a new approach compared to FDA's standard method of individual product reviews and is meant to test the use of real-world evidence in evaluating the safety and effectiveness of new products.

The pilot is meant to inform the creation of a modern, flexible, risk-based approach to the regulation of quickly evolving digital health technologies, thereby reducing time and cost to market entry. It is an attempt at an innovation-enabling approach that still maintains the Agency's scientific gold standard and ensures patient safeguards. In September 2017 nine companies out of over 100 applicants were selected to participate in the development of the pilot program: Apple, Fitbit, Johnson & Johnson, Pear Therapeutics, Phosphorus, Roche, Samsung, Tidepool, and Verily. No products have been launched yet, but the FDA released its working draft of the pilot for public commentary and the program is scheduled to launch in 2018.

(c) Information and data collected

One of the key goals of the literature review and example collection is to surface common themes and characteristics that help to identify how and where they could be used to achieve similar or novel outcomes. To facilitate the development of a taxonomy we will aim to collect information on a number of key characteristics (possible attributes listed below) for each relevant case identified as part of the long list of examples. At this stage the information provided will be a short summary answer for each question/characteristic.

From Nesta's previous work, the key defining characteristics we think are likely to be most insightful are the project goal, existing regulatory frameworks, type of regulator and participants/stakeholders involved. Below is a longer list of important characteristics. The final list and priority areas will be confirmed in discussion with BEIS team at the project kickoff.

Characteristic/attribute		Examples
Focus area	Sector	Specific sector eg Energy, Health, aerospace: or cross sector issue/focus
	Technology/technologies	AI, autonomous vehicles, drones
	Type of disruption/ innovation	Product, service, business model, cross sectoral, incremental or novel
	Market readiness	Idea, prototype stage, first of its kind application, full commercial application
Environment	Regulator (type, remit,	Independent, part of government, strong

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and context	powers & capacity)	regulatory powers, small vs large regulators
	Regulatory and policy environment (including existing regulation)	Highly regulated vs emerging area, high political risk
	Reason initiative was started	To facilitate innovation, to capture benefits of an emerging market, political mandate...
Design, goal and impact	Participation (eligibility criteria)	Company size, level of market readiness, level of technology readiness
	Stakeholders involved	Regulator, businesses, government, general public
	Policy goal/ intended purpose of the initiative	Product adaptation to regulatory adaptation
	Desired outcome	More products to market, more businesses positively engaged with regulator, consumer/public benefits, access to services
	Positive outcome achieved (where data is available)	No of businesses supported, no of products or services approved to market

(d) Identification and classification of common themes

Common themes and approaches will be identified by mapping examples against different sets of characteristics recorded during the literature review (and outlined above). We will do this initially with a small sample to ascertain which attributes are more useful in terms of clustering similar approaches. Certain categories or themes will emerge as a more useful basis for a taxonomy and as we progress through this research phase we will focus on these. We will develop an initial framework, testing and iterating by applying it to a series of examples and evaluating how well it meets our research aims. This is an approach we have successfully taken with other projects in the past. At this point we will present our draft framework to BEIS for comment, review and suggestions. Once we have developed an agreed framework we will refine and finalise it so it can be applied across all examples and case studies. This will allow us to surface critical insights and success factors that will feed into stage 3.

(e) Potential challenges

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There are two main challenges with this stage; firstly the cases we are looking for are not commonly defined in the literature (for example as regulatory innovation) and the breadth of possible sectors, technologies and countries we could explore makes search a formidable task; secondly, because many of these innovative approaches are fairly new, robust evaluation in this context is difficult (if it is considered at all), and therefore good quality quantitative or qualitative data on positive outcomes is not always available.

The first issue we will overcome by directing our search and using a number of different approaches as we have indicated above. We feel that our existing knowledge and work puts us in an ideal position to frame this project and help us avoid this issue, as it is one we have already navigated in previous related projects on regulatory practice. The second issue will be harder to overcome. Where little information or evidence on outcomes exists we will need to prioritise interviews to fill these gaps. Through the literature review we will attempt to collect and record quantitative and qualitative data on outcomes (primarily from secondary sources due to the limited time) but for some cases anecdotal evidence (through interviews in stage 3) may be all that is available.

(ii) Workshop with BEIS

At the end of stage one we will meet with BEIS to discuss the outputs of the literature review, explore our proposed framework and agree on the focus of the next stage. During this meeting we will present our findings followed by a 1.5-2 hour workshop to outline focus areas and next steps. We primarily envisage this being with BEIS staff but would also be able to pull in other advisors if this was of interest to BEIS.

We would seek to use this meeting as an opportunity to:
1. Get feedback on the outcomes of the literature review, including the identification of salient themes across the examples collected and our proposed framework. We would be looking for commentary from BEIS on how helpful and useful the framework is, a response on the range of examples we have collected and specific feedback on any areas we should focus on, or de-prioritise.
2. Have an in-depth discussion about the evidence we have collected on positive outcomes. We would cover the range of evidence available, what it says and where key gaps exist. Through this discussion we would agree the types of positive outcomes we are interested in and then, from the literature review, the key characteristics and success measures (identified in the literature review and set out above) that are required to deliver these different types of positive outcome.
3. Decide on the areas (methods, approaches and practice) identified in the literature review that we would like to take forward in stage 3 and on which to develop deeper

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expertise to support UK regulators to be able to implement these techniques to achieve the desired outcomes. For example if we identified a number of cases that could be classified under the same theme of 'Adaptive sandboxes' through our literature review, we would decide, based on the characteristics collected, if we wanted to develop guidance to support wider implementation of this approach in stage 3. We estimate we would take forward between 3-5 areas/approaches like this and would form the basis for the practice guides in stage 4.

(iii) Developing guidance to support the implementation of regulatory innovation

While stage 1 will deliver substantial insight into impactful innovation-friendly regulatory technique and the success factors that lead to valuable outcomes, to support other regulators to implement and use these techniques we will need to supplement the literature review with interviews. The interviews will serve to give deeper insight into each case and fill any evidence gaps highlighted in the literature review, in particular a better sense of the regulatory and policy environment the examples exist in, more in-depth insight into any positive outcomes they have achieved and which key elements are important for wider applicability. We see building this deeper knowledge on specific approaches as one of the key values of this project. The focus areas of these interviews will be decided collaboratively with BEIS in stage 2.

We will draw on Nesta's collected network of global stakeholders to access key stakeholders and arrange interviews. We will undertake semi-structured interviews with stakeholders directly involved in the delivery and evaluation of specific projects. For each case or type of practice we will ensure we not only engage relevant regulators or government agencies but also hear from businesses or innovators who have been through the process. This will help us draw out further, potentially hidden, lessons or success factors. For each approach this would mean conducting at least 3 interviews.

At the same time we would also seek to use our existing UK network of regulators (and capitalising where possible on BEIS' access) to help us assess what key information they would need to implement these approaches.

(iv) Final report, slide deck and short practice guides

We will produce a final report for the research setting out the case studies and key themes from our analysis, within the BEIS research paper template. We will also produce a designed presentation slide deck to accompany the report.

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In addition, there is an opportunity to use some of the insights from the research to produce short best practice guides for a regulatory audience to help transfer the learning from case studies into actions regulators can take to embed these approaches. The format and content of these guides would be developed as part of the research through the literature review and interviews though we would envision them as no more than a few pages each. While the research element of this work is critical to developing the insights needed, one of the central challenges will be communicating the ideas, methods and opportunities effectively to government and regulators. This is where these short methods guides could play a vital role, as our other practice guides have done in different contexts.

Examples of how Nesta has approached this in the past include:
https://www.nesta.org.uk/toolkit/challenge-prizes-a-practice-guide/
http://toolkit.innovationgrowthlab.org/how
https://www.nesta.org.uk/toolkit/using-research-evidence-practice-guide/

As part of project initiation we would explore with BEIS the option of producing additional outputs beyond the final report.

Dissemination

In addition to an internal BEIS internal seminar, we propose the following options for further dissemination, which we would discuss and agree with BEIS staff at the project inception meeting. We think there is a lot of scope to position this as a novel and groundbreaking piece of research, promoting the UK (and the UK Government) as leading the field in this area. Timing would be after project completion, but we see these as an integral part of maximising the value of the research for both BEIS and Nesta. We would discuss with BEIS throughout the project, but some suggestions for wider dissemination include:

1. A joint Nesta/BEIS event to launch the report research, with relevant senior speakers from both organisations;
2. Use the research to contribute to wider public debates on the role of regulation through opinion pieces and editorials, participating in public events and giving more public facing talks;
3. Publicising the research using Nesta's online and social media presence, including adding to Nesta's Innovation Methods Compendium website - a global scan of best practice in supporting innovation;
4. A high level roundtable with UK regulators to discuss how the case studies and findings from the research are applicable in the UK context;
5. Presenting to and using existing networks, such as the UK Regulators' Network, to highlight the research and build support for its findings;

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6. Using Nesta's international contacts to reach a global audience for the research, including a workshop or panel session at Nesta's Innovation Growth Lab conference in Berlin in May 2019

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Innovation-friendly Regulatory Approaches – Case Study Analysis. UKSBS / BEIS CR18154

PROJ1.2 Staff to deliver

We propose to deliver this project using an integrated team of staff from across Nesta. Nesta will bring its expertise in innovation methods, innovation policy, emerging technology and regulation. Nesta will bring its deep expertise in using qualitative methods to understand how governments across the world can promote innovation using new approaches and practice.

Relevant projects include our expertise in:

Thought leadership:
Anticipatory Regulation: Nesta has published a working paper on anticipatory regulation[1], setting out a typology of methods that regulators across the world are using to create regulatory frameworks that are innovation-friendly whilst also protecting the public from harm. A forthcoming paper builds on this framework to layout 6 key principles of anticipatory regulation.
Designing new regulations for AI: Nesta has set out detailed plans for regulating AI including for a new Machine Intelligence Commission[2] and codes of principle to guide public agencies to ensure this technology is used to its full potential, but in an ethical way.

Learning from others:
Case studies of innovation teams (I-teams[3]): Nesta researched stories of 20 teams, units and funds established by governments and charged with making innovation happen. They work across the spectrum of innovation – from focusing on incremental improvements to aiming for radical transformations. With Bloomberg Philanthropies, 2015.
Innovation testbeds: Nesta has been researching case studies of innovation testbeds, to provide a framework and typology informing policy decisions on when and how an innovation testbed can be a useful intervention. Forthcoming, 2019.

Practical programmes:
Bringing together coalitions to design new rules: Nesta's Challenge Prize Centre runs The Flying High Challenge[4] to connect and encourage cities, people and businesses to work

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[1] https://www.nesta.org.uk/report/a-working-model-for-anticipatory-regulation-a-working-paper/
[2] https://www.nesta.org.uk/blog/a-machine-intelligence-commission-for-the-uk/

https://www.nesta.org.uk/report/i-teams-the-teams-and-funds-making-innovation-happen-in-governments-around-the-world/
[4] http://flyinghighchallenge.org/

together to shape regulation and decide how best to use drone technology in complex city environments to address local need.

Using open data to enhance competition and innovation: Nesta runs the Open Up Challenge[5], a £5 million challenge prize designed to inspire the creation of apps and tools that use access to a unique store of data of anonymised UK banking transactions to help small businesses compete in the digital economy. The challenge prize is part of a wider package of new reforms driven by government and the Competition and Markets Authority.

Working with governments on practical experiments: Through its States of Change programme[6], Nesta works with dozens of governments worldwide that are now applying innovation methods to regulation, including the UAE, Canada and Portugal.

Nesta delivery team

The project will be overseen by ███████████████████████████████
███████████████████████████████████████ Both have extensive experience of analysing and developing policy methods to support innovation.

The project will be led by ██████████████████████████████ sitting between Nesta's Explorations and Research, Analysis and Policy teams and drawing on expertise from his previous research on emerging technologies and regulatory practices across the world.

Biographies of delivery team

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[5] https://www.openupchallenge.io/
[6] https://states-of-change.org/

https://www.oecd.org/media/oecdorg/satellitesites/opsi/contents/files/OECD_OPSI-core_skills_for_public_
sector_innovation-201704.pdf

[a] https://www.nesta.org.uk/report/social-innovation-policy-in-europe-where-next/
[b] https://www.siceurope.eu/sites/default/files/field/attachment/d5.6_sou_report_part_2_-_14.12.17.pdf

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Innovation-friendly Regulatory Approaches : Case Study Analysis UKSBS / BEIS CR18154

PROJ1.3 Understanding the Project Environment

Technological innovation is driving rapid change in many areas of the economy across the world. Barriers to entry have fallen in many sectors and technology has allowed certain businesses to scale extremely quickly. This is particularly true of sectors such as software development and digital services[1] as well as some parts of highly regulated markets such as financial services.[2] Industries that have changed little in recent decades, from music production and distribution to hotel services, have suddenly been transformed in only a few years. This has been facilitated in part by the availability of large pools of capital to support the launch and rapid scale-up of innovative business models, many of which are designed to unlock untapped supply and demand in areas like transport.[3] Further progress in areas such as AI and robotics promise even greater disruption.

As well as clear benefits, rapid innovation has also created new potential sources of public harm, many of which we are only beginning to understand. The speed of change and the uncertainty it brings, combined with growing concerns about where power is concentrated, have increasingly thrown the role of regulators and regulation back into sharp focus.

Existing regulatory models are not particularly well adapted to keeping up with this pace of change. On top of this regulators are understandably reluctant to see themselves as key players in the innovation process given the perceived risk of overreach. But this negative view of the relationship between regulators and innovation - as either stifling innovation or not protecting the public - misses the many ways regulation and regulators can and do enable valuable innovation. Regulatory practice is a particularly powerful and valuable tool available to policymakers to enable, stimulate and guide innovation that serves the public good.

Part of the problem is cultural, but a big part of it is the absence of a regulatory framework that can guide regulators through these issues and support them in implementing innovative practice. New kinds of regulatory practice can enable a regulator to support the emergence of valuable innovation without compromising its other goals. For example the UK has enjoyed a surge of innovation in consumer-focussed financial services since 2009 relative to the US, and

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[1] BEIS, Modernising Consumer Markets: Consumer Green Paper, April 2018
[2] For example Stripe, whose software enables businesses to take online payments, has scaled since its founding in 2010 to a recent $9 billion valuation. See also Angela Strange, Making sense of mortgages: the problem and the opportunity, Andreessen Horowitz, May 2018
[3] Todd W. Schneider, Analyzing 1.1 Billion NYC Taxi and Uber Trips, with a Vengeance, March 2018

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this is in part due to the purposeful strategy and innovative approaches pursued by the UK financial regulator. New ways of using regulation to enable or spur innovation are already emerging, with countries like Singapore leading the way, but these are yet to be captured and presented in such a way that they can inform best practice elsewhere.

These innovative approaches to regulation are not only supporting new ideas, business models, products or services to emerge but are also helping regulatory bodies to respond to new pressures and challenges. While different sectors face unique challenges, such the energy system's transition to more sustainable sources of power, there are an increasing number of common regulatory issues. These may not all be felt in the same way by different sectors or have the same implications for different regulators but together they highlight the need for new forms of regulatory practice as fast-paced change continues to be the norm

Despite the growing interest in this area not enough has been done to systematically pull together lessons and insights from global examples of innovation-friendly regulatory techniques. Very little has been done to understand the kind of positive outcomes that can be achieve through these new ways of operating or how different approaches need to be implemented to achieve these desired outcomes. We have seen this first hand through our practical work with regulators as part of projects such as Flying high and Open Up as well as our ongoing work through the Regulator's Pioneer fund. As a result this work could not come at a more important time, particularly for the UK. Rather than simply looking at what others are doing around the world we need to build deeper expertise to better understand firstly what the benefits are and then how we can implement them in other contexts to achieve our desired regulatory and innovation outcomes. We believe the work program we have proposed will do this in a way that not only gathers critical insights but presents them in a way that will inform and support regulators to implement these innovative approaches.

In recent decades the UK has enjoyed a strong reputation for effective regulation based on careful assessment of evidence, well-designed, consultative processes and the development of innovative processes. For example, the UK has been an attractive destination for private investment in privatised regulated utilities such as energy and water; the UK was seen as a leader in internet policy, making it an attractive environment for investment and innovation; UK regulatory impact assessments were influential in shaping EU legislation; and the FCA's Regulatory Sandbox has inspired similar initiatives among regulators across the world.
Today's technological disruptions, with their attendant risks and opportunities, do not fundamentally change the principles of good regulation. But they do likely change what these principles mean for good regulatory practice.

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No longer leading innovation in this area will undermine the UK's reputation for world class regulation, a problem at a time when, post-Brexit, the UK will need to work hard to attract innovative businesses.

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Innovation-friendly Regulatory Approaches – Case Study Analysis UKSBS / BEIS
CR18154
PROJ1.4 Project Plan and Timescales

Below we present a detailed breakdown of our proposed timings for delivering this work, including milestones, deliverables and key decisions to be made with BEIS.

Proposed Timeline:

		December				January				February				March			
		10th	17th	24th	31st	7th	14th	21st	28th	4th	11th	18th	25th	4th	11th	18th	25th
Milestones/ deliverables	Literature review and initial development of framework completed								•								
	Framework taxonomy finalised										•						
	Final report																•
	Slide deck and presentation																•
	Short methods guides																•
	Completion of all interviews															•	
Stage 1	Literature Review																
	Informal interviews																
	Analyse common themes and develop framework																
Stage 2	BEIS Workshop																
Stage 3	Interviews																
	Drawing out case study lessons																
	Finalising framework																
Stage 3	Final report																
	Slide deck																
	Short methods guides																

* W/C 24th December and 31st Jan include public holidays

A detailed breakdown of how we will approach the work is included in the methodology section (1.1), but in summary the stages include the following tasks:

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1. Literature review and global case study identification;
2. BEIS workshop;
3. Developing guidance to support the implementation of regulatory innovation; Interviews, drawing out lessons on implementation etc
4. final report, slide deck and short method guides;
5. Dissemination.

Project Management
To ensure successful delivery of the project, we propose the following management meetings:
- A project inception meeting to formally begin the work and agree a joint understanding of required outcomes from the project
- A fortnightly project management call with BEIS staff to review progress (as required)
- Review meeting after literature review to agree success measures and focus for subsequent work
- Final project meeting to sign off deliverables and agree dissemination plan

Potential risks involved in delivering this project are outlined below, including information on how Nesta propose to mitigate them:

Risk	Proposed mitigation strategy
Delivery Risk	
Literature review scope	As set out in our methodology section, in acknowledgement of this emerging nature of this set of policy interventions, we envisage a literature review that covers academic, grey and policy sources. Our previous work in this area gives us a good grounding in where to look for literature, but as a sense check we propose a small set of informal interviews with other experts to ensure we have covered all available sources.
Data on positive outcomes	As many of the examples we will be collecting are relatively unestablished policy interventions, we acknowledge that evaluation and evidence of their effectiveness will be limited. In discussion with the BEIS team we will develop a set of guiding metrics to establish a wider sense of the type of positive outcomes we are searching for
Scheduling interviews	Although the timescale for identifying and arrange to speak to interviewees is tight, we will start to prepare for these in the case study collection by identifying key individuals involved in each

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	example. We will draw on Nesta's extensive UK and international network, and reputation for insightful research to ensure we speak to the most relevant stakeholders for each case.
Operational Risk	
Staffing – staff turnover/absence	Nesta is very experienced in managing teams of project delivery staff and has access to sessional staff that can effectively fulfil the roles created by the project, should core staff be absent.
Requirement of more staff days than allocated in planning	We have allocated staff days and subsequent costs based on similar previous projects and limited the scope of inquiry to fit within the available time so we expect no issues. However, if there is an indication that time requirements are moving beyond this agreement, Nesta will flag this with BEIS at the earliest stage and suggest some potential alternative options.

Appendix B – Tender Specification

- **Section 4 – Specification**

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1. Background

The UK Industrial Strategy committed to 'develop an agile approach to regulation' that supports innovation, while ensuring effective protections for citizens and the environment. The UK has strengths in developing innovation-enabling approaches to regulation. Our regulators have pioneered new techniques that allow businesses to test innovative products, services and business models. They have also supported the deployment of new technology into the markets they regulate by providing specialist advice and guidance to innovators. Some examples of these regulator-led initiatives are:

- The Financial Conduct Authority's Regulatory Sandbox has helped contribute to the growth of the FinTech industry by giving innovative start-ups a safe space to undertake real-world trials of new technologies.
- The Medicines and Healthcare Products Regulatory Agency's <u>Innovation Office</u> provides a 'one stop shop' to help organisations of all backgrounds and sizes develop innovative medicines, medical devices or novel manufacturing processes.
- Ofgem's <u>Fast, Frank Feedback</u> service provides written advice to businesses looking to introduce new or innovative propositions to the energy sector.

As new technologies and emerging industries begin to affect a wider range of sectors, it is important that regulators are ready to meet the opportunities and challenges that arise. Emerging technologies challenge traditional regulatory structures in a number of ways. Regulatory approaches often struggle to keep pace with technological development, hindering the translation of R&D into innovative products and services that can be brought to market. Conversely, innovative start-ups often do not have the knowledge or resources to navigate or influence the regulatory environment.

Regulators have devised a variety of different approaches to directly support businesses to bring new products or services to market, to enable the testing and development of new products, and to allow new business models. These regulator-led initiatives have been categorised as 'advisory approaches' and 'adaptive approaches'.

Through a detailed study of these innovation-friendly regulatory approaches around the world, we hope to enhance our knowledge of how these approaches can be used to enable innovation, whilst maintaining protections for businesses, consumers, and the environment.

Advisory approaches

Advisory approaches are designed to assist businesses with new products or services to approach regulators and work with them to test and adapt them under the existing regulations.

Adaptive approaches

Adaptive approaches are when a regulator facilitates the development of new products or services by adapting existing regulatory requirements in response to learning from testing or trialling.

2. Aims and Objectives of the Project

The objective of this study is to provide a taxonomy that sets out the different types of approach that can be taken to address the accommodation of innovative products, services and business models into regulatory frameworks.

This project will provide advice on the applicability of the various types of innovation-friendly regulatory approaches; for example, the types of initiative that regulators should employ to promote innovation in a certain sector or to support a certain technology. The project should include what/when/how to use these approaches to encourage innovation. The project will also cover the limitations of these new approaches and make recommendations on best practice.

Regulators have adopted a variety of new approaches in recent years to support innovation and the deployment of new technology in the industries they regulate, but there has not been

a robust analysis on the effectiveness of these innovation-friendly approaches. Because many of these new regulatory approaches have only been operational for a short time, there has not been an assessment of the impacts and we do not know what the counterfactual is. That is why there is a need for a dedicated study into the types of approaches that are being adopted by regulators globally.

In order to compare the approaches of regulators in different sectors and countries, it will be necessary for the contractor to take account of various factors, including: level of market development; regulator powers/capacity; eligibility criterion; terms of participation; types of innovation (incremental, disruptive, product, service, business model), among others. The effectiveness, operating model and risks of these various approaches will vary across countries, and sometimes sectors, depending on numerous factors.

This project will gather intelligence for policy development. The learnings will help create a best practice guide which will be used:

1) To ensure that the Regulators' Pioneer Fund (RPF)[1] achieves maximum impact to support innovative businesses across the economy. The project will help determine the success measures of impactful initiatives and will be drawn upon to give practical guidance to regulators on how to design and implement new approaches that drive innovation. The findings of this project will be shared with regulators that are launching new initiatives using RPF funding where appropriate.

2) To inform all regulators of the range of best practice in innovation-friendly approaches and help them identify future areas where new approaches could be used to support innovative businesses and facilitate the deployment of new technologies.

3) To underpin our wider work on innovation-friendly regulation by building a robust evidence base and an understanding of what the most impactful regulatory approaches are. This will also help our understanding of what practical steps need to be taken to ensure the successful implementation of innovation-friendly regulatory approaches.

4) **Suggested Methodology**

Suggested Methodology (main methodology)	1. A literature review of policy documents, academic literature and policy journals. This will help the winning contractor identify cases where innovation-friendly regulatory techniques have achieved positive outcomes. The contractor should identify defining characteristics and common themes across these case studies which make them compatible with different regimes/outcomes. The detailed case studies should span a range of countries and sectors. Any quantitative and qualitative data on the existing regulatory approaches would be useful. This review should focus on those countries who have been identified as being actively engaged in innovation-friendly approaches to regulation.
	2. We expect the contractor to report back to us after

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[1] The RPF is a new £10m fund announced at the Autumn Budget 2017 which will deliver against the government agenda UK to become the world's most innovative economy. The fund will invest in regulator-led initiatives that support businesses to bring innovative products/services to the market. https://apply-for-innovation-funding.service.gov.uk/competition/199/overview

the literature review to agree the success measures and key characteristics that are required for positive outcomes. This will then inform the focus of the subsequent study into how regulators should implement new approaches to achieve the desired outcomes.

3. In depth interviews with policy officials/regulators/academics/businesses that are working on designing/operationalising/evaluating or benefitting from successful regulatory techniques will inform the research. The individuals of interest for interviews would be identified in the literature review stage. These might involve up to 15 one-to-one conversations. The winning contractor should draw lessons from key stakeholders working in this area.

4. We would like the winning bidder to draw together and analyse outcomes, to inform a best practice guide on the back of the interviews and literature review. From this analysis, a report should be produced outlining the findings and conclusions drawn from the interviews and literature. We would also want the final outputs to include presentations on the findings and a spreadsheet of the sources that have been collated as part of the literature review stage.

The Report is expected to be carried out over a 3 month period with 1 month used for literature review, by 31st January 2019, and second and third months for interview and drawing out lessons, by 31st March 2019.

If applicable: **Total number of Participants (experimental design)** **Total number of Interviews (survey)** **Total number of Interviews (qualitative)** **Total number of Focus Groups** **Total number of Case Studies** Please add additional rows if more than one sample is required i.e. learners as well as employers.	**Insert numbers:** We would seek advice from the winning contractor We would seek advice from the winning contractor
Any other specific requirements	
Project completion date	March 2019

This is a suggested methodology but we would welcome bidders' alternative suggestions providing that they also meet the project aims and objectives. Bidders should also justify why they have suggested an alternative approach.

5) Deliverables

In order to increase awareness of research and evaluation reports, all contractors are to ensure the following are included in the costings for this project:

- Slide pack summary
- A succinct report setting out case studies and key themes emerging from analysis of innovation-friendly regulatory approaches nationally and internationally.
- Presentation at an internal seminar to share findings.

Publication

The final report for this research / evaluation project must be formatted according to BEIS publication guidelines, therefore within the Research paper series template and adhering to BEIS accessibility requirements for all publications on GOV.UK. The publication template will be provided by the project manager. Please ensure you note the following in terms of accessibility:

Checklist for Word accessibility

Word documents supplied to BEIS will be assessed for accessibility upon receipt. Documents which do not meet one or more of the following checkpoints will be returned to you for re-working at your own cost.

- document reads logically when reflowed or rendered by text-to-speech software
- language is set to English (in File > Properties > Advanced)
- structural elements of document are properly tagged (headings, titles, lists etc)
- all images/figures have either alternative text or an appropriate caption
- tables are correctly tagged to represent the table structure
- text is left aligned, not justified
- document avoids excessive use of capitalised, underlined or italicised text
- hyperlinks are spelt out (e.g. in a footnote or endnote)
- Datasets to support those to be published in the final report must be provided in an accessible format (CVS, Excel) on submission of the report.

Annex A – GDPR

Annex A

Drafting guidance in square brackets and in blue should be deleted following completion.

Description	Details
Subject matter of the processing	In depth interviews with policy officials/regulators/ academics/businesses that are working on designing/operationalising/evaluating or benefiting from successful regulatory techniques will inform the research. The individuals of interest for interviews would be identified in the literature review stage. These might involve up to 15 one-to-one conversations. The winning contractor should draw lessons from key stakeholders working in this area.
Duration of the processing	Processing will take place from Monday 12ᵗʰ December 2018 for the duration of the contract plus a duration of supplier retention period e.g. 12 month retention period. The contract will end on Friday 29ᵗʰ March 2019. *NB: The supplier retention period is the amount of time the supplier has been contracted to store the data after the expiry of the contract/agreement. This will not apply to most contracts/agreements. In most cases, data will be either securely destroyed or transferred back to BEIS at the end of the contract/agreement and stored within BEIS.*
Nature and purposes of the processing	The purpose of in-depth interviews is to gain in depth knowledge about best practices on innovation Friendly Regulation around the world. This will help inform our regulatory framework to encourage innovation. It will also help inform the operation of RPF.
Type of Personal Data	We expect names, telephones, address of interviewees.
Categories of Data Subject	In depth interview with policy officials/regulators/ academics/businesses that are working on designing/operationalising/evaluating or benefiting from successful regulatory techniques will inform the research.

Plan for return and destruction of the data once the processing is complete **UNLESS requirement under European Union or European member state law to preserve that type of data**	*The supplier retention period is the amount of time the supplier has been contracted to store the data after the expiry of the contract/agreement. This will not apply to most contracts/agreements.* *Please note that the capitalised words in this section may require amendment depending on the type of terms and conditions in your contract:* **The data will be retained by the Contractor for a duration of supplier retention period e.g. 12 month retention period, following which The Contractor will:** a) *To be used where BEIS wishes to retain the data:* provide the Authority with a complete and uncorrupted version of the Personal Data in electronic form (or such other format as reasonably required by the Authority) and erase from any computers, storage devices and storage media that are to be retained by the Contractor after the expiry of the Contract. The Contractor will certify to the Authority that it has completed such deletion. b) *To be used where BEIS wishes to have the data deleted all together:* delete the Personal Data and erase the Personal Data from any computers, storage devices and storage media that are to be retained by the Contractor after the expiry of the Contract. The Contractor will certify to the Authority that it has completed such deletion.