Recommendation of the Council for Agile Regulatory Governance to Harness Innovation



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Background Information

The Recommendation for Agile Regulatory Governance to Harness Innovation was adopted by the OECD Council at Ministerial Level on 6 October 2021 on the proposal of the Regulatory Policy Committee (hereafter "the RPC"). The Recommendation aims to help governments develop and implement agile and resilient regulatory approaches and facilitate institutional co-operation in response to and to further stimulate innovation.

The need for a standard on Agile Regulatory Governance to Harness Innovation

The pace, scope and complexity of innovation pose far-reaching and interrelated regulatory challenges for governments. These challenges can be grouped around four broad categories: the "pacing problem"; designing "fit-for-purpose" regulatory frameworks; regulatory enforcement challenges, and institutional and transboundary challenges. The Covid-19 crisis has intensified these challenges and forced governments to rethink their approach to rulemaking. While recovering and adapting, governments should ensure that the innovation that will power economic growth and solve the world's most pressing social and environmental challenges is not held back by regulations designed for a different time.

Building on the 2012 Recommendation on Regulatory Policy and Governance [OECD/LEGAL/0390], relevant related guidance such as the Best Practice Principles on International Regulatory Co-operation, the long-standing expertise of the RPC and the Network of Economic Regulators (NER) on regulatory policy and the challenges raised by innovation and technological change, as well as broader OECD efforts and initiatives to help governments address the challenges raised by innovation such as the work undertaken by the Committee for Digital Economy Policy and the Committee on Scientific and Technological Policy (including the Going Digital Integrated Policy Framework), the RPC has developed this Recommendation to catalyse efforts to improve regulatory policy and governance in order to support government reform and facilitate co-operation in response to those regulatory challenges .

Process for developing the Recommendation

The work programme leading to the development of the Recommendation was overseen by a joint steering group composed of delegates from the RPC and the NER that provided guidance throughout the process. Other OECD policy communities have also been consulted, in particular in the area of digital policy and financial affairs.

A concept note on "Effective rulemaking in the Fourth Industrial Revolution" was presented at the 21st session of the RPC in November 2019 during which, delegates called for the development of principles for agile regulatory governance to harness innovation that would guide governments in using and adapting regulatory policy and governance in the face of the disruptions and opportunities brought by innovation. RPC and NER delegates discussed a first set of principles and policy recommendations in April 2021 and those were then embodied in the Recommendation, together with a companion document going into more detail with a view to supporting Adherents in implementing the Recommendation on the ground.

During the drafting process, consultations were undertaken with (i) relevant stakeholders (academics, government officials and representatives from civil society and the business community) and (ii) relevant OECD bodies (including the Public Governance Committee, the Committee for Digital Economy Policy, the Committee on Scientific and Technological Policy, the Competition Committee, the Committee on SMEs and Entrepreneurship and their relevant respective subsidiary bodies).

Scope of the Recommendation

The Recommendation aims at further strengthening regulatory governance by helping to update and enhance relevant instruments, processes, and institutions. More precisely, it seeks to provide a conceptual framework and relevant guidance for using and adapting regulatory policy and governance in the face of the regulatory challenges and opportunities arising from innovation. The Recommendation aims primarily at:

- Advancing knowledge and understanding of regulatory quality in light of the shortcomings in existing approaches as well as the high levels of uncertainty associated with rapid innovation and technological change;
- Agreeing on the basic core elements of modern regulatory frameworks in order to ensure that innovation serves fundamental societal goals and enhances prosperity and well-being on a sustainable basis. This includes deciding how stakeholder engagement, impact assessment, risk assessment, institutional co-operation (including international regulatory co-operation) need to evolve in a context of rapid innovation and technological change;
- Promoting effective cross-border regulatory action including enforcement, to ensure the coherence and interoperability of regulatory frameworks related to innovation;
- Promoting the key role of regulatory policy in governments' broader strategies for innovation.

To do so, it is organised around four main pillars:

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

Next steps

The RPC will support Adherents and follow up on the Recommendation's implementation through specific research and analysis and the development of resources such as practical guidance or practical tools. It will also promote the sharing of relevant experience and the dissemination of good practices.

A report on the implementation, dissemination and continued relevance of the Recommendation will reach Council five years after its adoption, and subsequently at least every 10 years. The RPC will also review and update the Practical Guidance over time to ensure it remains relevant .

For further information please consult: https://www.oecd.org/gov/regulatory-policy/regulation-and-emerging-technologies.htm

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Implementation

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

THE COUNCIL,

HAVING REGARD to Article 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Recommendation of the Council on Improving the Quality of Government Regulation [OECD/LEGAL/0278], the Recommendation of the Council on Regulatory Policy and Governance [OECD/LEGAL/0390], the Recommendation of the Council on Digital Government Strategies [OECD/LEGAL/0406], the Recommendation of the Council on Open Government [OECD/LEGAL/0438], the Recommendation of the Council on Artificial Intelligence [OECD/LEGAL/0449], the Declaration on Public Sector Innovation [OECD/LEGAL/0450], and the Recommendation of the Council on Responsible Innovation in Neurotechnology [OECD/LEGAL/0457];

RECOGNISING that, while not an end in itself, innovation can drive more inclusive and sustainable growth, promote well-being, help address social and global challenges including climate change and other environmental emergencies, and foster resilience;

CONSIDERING that realising the full potential of innovation in high-uncertainty contexts, enhancing its benefits for societies while addressing its risks, including the occurrence low-probability events that entail high impacts, requires a shift in regulatory policy and governance towards more agile and forward-looking approaches;

ACKNOWLEDGING the crucial role of innovation in overcoming global challenges such as the Covid-19 crisis and that, while the ravages of the pandemic will abate with time, the influence of emerging technologies on societies will only grow in the years to come;

ACKNOWLEDGING that innovation ecosystems and related value chains tend to cut across national and jurisdictional boundaries and thus require concerted governance approaches;

RECOGNISING the important contribution of new ventures and innovative entrepreneurs to innovation and the need to ensure a regulatory environment that minimises barriers for their establishment and access to markets and resources;

RECOGNISING that holistic, open, inclusive, adaptive, and better-co-ordinated governance models enhance systemic resilience by enabling the development of agile, adaptive regulation that upholds fundamental rights, democratic values, and the rule of law;

RECOGNISING that strengthening regulatory policy and governance to ensure that innovation is sustainable and human-centred is crucial and that addressing current challenges warrants adapting the design and application of existing regulatory management tools to ensure their continued relevance;

RECOGNISING that, while innovation-related challenges will often require more flexible and adaptive regulatory frameworks, increased flexibility may lead to more discretion in decision-making and case-by-case trade-offs for which creating societal buy-in by demonstrating that the selected approaches are evidence-based, fit for the future, and trustworthy, including through broad-based and continuous public stakeholder engagement and close monitoring of outcomes, will be crucial;

RECOGNISING that capacity and skills are key enabling factors for agile and innovation-friendly regulatory policy;

RECOGNISING that developing appropriate institutional arrangements, culture, and working methods is a pre-condition for regulatory policy and governance to help steer innovation on a desirable trajectory;

HAVING REGARD to the Practical Guidance on Agile Regulatory Governance to Harness Innovation (hereafter the “Practical Guidance”) [C(2021)99/ADD1], developed by the Regulatory Policy Committee to support Members and non-Members having adhered to this Recommendation (hereafter the “Adherents”) in

the implementation of this Recommendation and that may be modified as appropriate by the Regulatory Policy Committee;

On the proposal of the Regulatory Policy Committee:

I. **AGREES** that, for the purposes of the present Recommendation, the following definitions are used:

- '**Regulation**' refers to the diverse set of instruments by which governments set requirements on enterprises and citizens. Regulation includes all laws, formal and informal orders, subordinate rules, administrative formalities, and rules issued by non-governmental or self-regulatory bodies to whom governments have delegated regulatory power.
- '**Regulatory management tools**' refers to the different tools available to implement regulatory policy and foster regulatory quality including, in particular, regulatory impact assessment, stakeholder engagement, and ex post evaluation.
- '**Regulatory policy**' refers to the set of principles, rules, procedures, and institutions introduced by government for the express purpose of developing, administering, and reviewing regulation.

II. **RECOMMENDS** that Adherents **adjust regulatory management tools to ensure regulations are fit for the future** by:

1. Developing more adaptive, iterative, and flexible regulatory assessment cycles, while capitalising on technological solutions to improve the quality of evidence;

2. Putting in place mechanisms for public and stakeholder engagement in the regulatory process, including citizens and innovative small and medium-sized enterprises (SMEs) as well as start-ups, from an early stage and throughout the policy cycle to enhance transparency, build trust, and capitalise on various sources of expertise;

3. Considering the international innovation ecosystem to draw on the most relevant evidence and regulatory approaches.

III. **RECOMMENDS** that Adherents **lay institutional foundations to enable co-operation and joined-up approaches within and across jurisdictions** by:

1. Strengthening co-operation across policy-making departments and regulatory agencies as well as between national and sub-national levels of government;

2. Stepping up bilateral, regional, and multilateral regulatory co-operation to address the transboundary policy implications of innovation.

IV. **RECOMMENDS** that Adherents **develop governance frameworks to enable the development of agile and future-proof regulation** by:

1. Developing or adapting governance frameworks and regulatory approaches so that they are forward-looking by developing institutional capacity and assigning clear mandates accordingly, conducting systematic and co-ordinated horizon scanning and scenario analysis, anticipating and monitoring the regulatory implications of high-impact innovations, and fostering continuous learning and adaptation;

2. Developing more outcome-focused regulatory approaches to enable innovation to thrive by harnessing the opportunities offered by digital technologies and big data;

3. Harnessing, under the condition that corresponding outcomes can be appropriately monitored, the opportunities provided by non-legally binding approaches either as an alternative or as a complement to other regulatory instruments;

4. Enabling greater experimentation, testing, and trialling to stimulate innovation under regulatory supervision.

V. RECOMMENDS that Adherents **adapt regulatory enforcement strategies and activities to promote compliance, help innovators navigate the regulatory environment, and uphold public protection, including across jurisdictions** by:

1. Adopting data-driven responsive approaches to identify, assess, and manage risks, and revising existing risk governance frameworks as appropriate;

2. Integrating enforcement-related considerations in legislative proposals and related assessments as appropriate;

3. Fostering co-operation among authorities leading investigations and enforcement of regulations related to innovation, both domestically and, where practical and feasible, across jurisdictions.

VI. INVITES the Secretary-General to disseminate this Recommendation.

VII. INVITES Adherents to disseminate this Recommendation at all levels of government.

VIII. INVITES non-Adherents to take due account of and adhere to this Recommendation.

IX. INSTRUCTS the Regulatory Policy Committee, in consultation with other relevant committees, to:

a) serve as a forum for exchanging information on policies and experience with respect to the implementation of this Recommendation, fostering dialogue with and among stakeholders, and improving the evidence base on agile regulatory governance to harness innovation;

b) review and update the Practical Guidance over time to ensure it remains relevant;

c) develop further guidance and evaluation frameworks to support the implementation of this Recommendation; and

d) review the implementation, dissemination, and continued relevance of this Recommendation and report thereon to the Council no later than five years following its adoption and at least every ten years thereafter.

PRACTICAL GUIDANCE ON AGILE REGULATORY GOVERNANCE TO HARNESS INNOVATION[1]

This document was drafted in the context of the development of the Recommendation of the Council for Agile Regulatory Governance to Harness Innovation (hereafter, "the Recommendation"). It provides practical guidance to support Members and non-Members having adhered to the Recommendation (hereafter "Adherents") in implementing the Recommendation.

Key considerations for the implementation of the Recommendation

The Recommendation builds on the following considerations:

- While not an end in itself, innovation can drive more inclusive and sustainable growth, promote well-being, help address social and global challenges including climate change and other environmental emergencies, and foster resilience[2]. Realising the full potential of innovation in high-uncertainty contexts requires a paradigm shift in regulatory policy and governance, from the traditional "regulate and forget" to "adapt and learn". This notably involves more holistic, open, inclusive, adaptive and better-co-ordinated governance models to enhance systemic resilience by enabling the development of agile, technology neutral and adaptive regulation that upholds fundamental rights, democratic values and the rule of law. It will also involve acknowledging that innovation ecosystems and related value chains tend to cut across national or jurisdictional boundaries and thus require concerted governance approaches.
- Strengthening regulatory policy and governance to ensure that innovation is sustainable, human-centred and respects fundamental rights, democratic values and the rule of law will also require stepping up efforts to align with international best practices. In the same vein, addressing current challenges warrants adapting the design and application of existing regulatory management tools to ensure their continued relevance.
- Innovation-related challenges will often require more flexible and adaptive regulatory frameworks. Increased flexibility may however lead to more discretion in decision-making whereby trade-offs (including in terms of predictability, legal protection and stability) are assessed on a case-by-case basis. It will be essential to create societal buy-in by demonstrating that the selected approaches are evidence-based, fit for the future and trustworthy[3]. Ensuring broad-based and continuous stakeholder engagement as well as close monitoring of outcomes (possibly in real time) and sufficient investigative power for relevant bodies will be instrumental to do so.
- Capacity and skills are key enabling factors for agile and innovation-friendly regulatory policy. As part of their strategies to enhance the skills and capabilities of their workforce, Adherents should consider devoting appropriate resources to developing the necessary analytical and technological skills of civil servants (e.g. assessment of innovation impacts, understanding of technology applications and innovation ecosystems, knowledge of tools and approaches for strategic foresight) as well as their understanding of both the costs and benefits of innovation and their implications for their work. The opportunities provided by multi-stakeholder co-operation to capitalise on various sources of expertise should be leveraged in this regard. The additional strain that technological change places on both regulatory oversight bodies and

[1] This document has been approved by the Regulatory Policy Committee on 20 July 2021 [GOV/RPC(2021)9/REV2] [GOV/RPC(2021)14/FINAL].

[2] OECD (2021), *OECD Science, Technology and Innovation Outlook 2021: Times of Crisis and Opportunity*, OECD Publishing, Paris, https://dx.doi.org/10.1787/75f79015-en

[3] OECD (2017), *The Next Production Revolution: Implications for Governments and Business*, OECD Publishing, Paris, https://dx.doi.org/10.1787/9789264271036-en

enforcement and inspection authorities in terms of capacity and skills should also be acted upon[4].

- Developing appropriate institutional arrangements, culture and working methods is another pre-condition for regulatory policy and governance to help steer innovation on a desirable trajectory. A range of options, including combinations of approaches (e.g. outcome-based regulation combined with regulatory guidance, etc.) are available to governments, who will need to identify the best policy mix in each situation and adapt their response as the context evolves. Their success will notably depend on an appropriate integration into existing governance systems as well as strong leadership to champion the necessary changes – including by overcoming obstacles relating to the political economy of reform.

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

1. Developing more adaptive, iterative and flexible assessment cycles, while capitalising on technological solutions to improve the quality of evidence

In light of the regulatory challenges raised by innovation, undertaking a shift in regulatory policy processes will be essential, whereby the traditional "regulate and forget" mindset must give way to "adapt-and-learn" approaches. The capability to detect and understand innovations and their potential impact on existing regulations, or, more important, the public values that are at stake, is key. Addressing any "pacing problem" requires, in particular, shortening timeframes throughout the policymaking process and using regulatory management tools in a more dynamic, adaptive and iterative manner. In this new paradigm, stakeholder engagement, regulatory impact assessment (RIA), and ex post evaluation should not be seen as a series of discrete requirements to be conducted successively, but rather as mutually complementary tools embedded in the policy cycle to inform the appropriate adaptation of regulatory (or alternative) approaches.

To that end, the following approaches could be considered:

- Using regulatory management tools in an agile and integrated fashion to inform a continuous learning and adaptation process throughout the policy cycle. As this cycle becomes increasingly shorter due to the pace of technological change, reassessing how regulatory management tools are applied and related resources used will be crucial. More frequent and iterative, if sometimes less thorough, instances of analysis may be a better fit in a number of cases. New tools and methods including digital (e.g. real time data flows and analytics) may, when used wisely, be particularly useful too support more efficient regulatory analysis and management. This approach should be coupled, however, with the more active and early use of interim and *ex post* reviews to assess whether regulatory frameworks remain relevant and fit for the future and identify regulatory obstacles to investment in innovation. In addition, lessons learned from successful approaches in other jurisdictions and consistency with international approaches related to innovation should inform the development and review of domestic regulation;
- Putting in place monitoring arrangements as well as approaches and mechanisms for ex post reviews of regulation to contribute to addressing the needs stemming from rapid and dynamic innovation. Monitoring the impact of regulations systematically and on a continuous basis will be important, as will engaging in timely and proportionate reevaluation of regulatory approaches to keep pace with innovation. To the extent possible, embedding review requirements in the regulatory framework itself5, and ensuring that such provisions as well as related assessments are subject to systematic oversight and quality control represent good practice;
- Developing regulatory management tools that allow the impact of regulation on innovation to be assessed to the extent possible, including within administrations and across borders. The impacts of regulation along the entire innovation value chain should be carefully considered. These impacts should also be factored in when comparing the costs and benefits of unilateral approaches with those of joint approaches with other jurisdictions;

[4] OECD (2019), *11th OECD Conference on Measuring Regulatory Performance: Conference proceedings*, https://www.oecd.org/gov/regulatory-policy/Conference-proceedings-web.pdf

[5] OECD (2020), *Best Practice Principles for Regulatory Policy: Reviewing the Stock of Regulation*, *OECD Best Practice Principles for Regulatory Policy*, OECD Publishing, Paris, https://dx.doi.org/10.1787/1a8f33bc-en

- Establishing robust processes and structures to ensure that scientific evidence, and the assessment processes used to develop it, meet the highest standards of scientific integrity;
- Encouraging the identification of data and information needs and related responsibilities at the regulatory proposal stage to ensure the availability of robust evidence further down the line;
- Leveraging new data sources and continuous monitoring to better understand the effects of regulation and thus produce broader, more reliable and timely assessments of the impacts of regulations. Consideration should be given to the fact that outcome-based regimes reinforce the need for data-driven monitoring and evaluation. Data governance should also be considered, including the skills and the underlying infrastructure, and data management practices that will be needed to generate, access, collect and analyse relevant data throughout the regulatory policy cycle – while respecting data security and privacy;
- Achieving full implementation of key RIA components, such as the timely assessment of all relevant policy options, including non-regulatory alternatives, and related instruments (or mix of instruments). Doing so is crucial to identify the best approach to address regulatory policy problems involving innovations. In addition, appropriate risk assessment should be built into the RIA process. As underlined above, exploring avenues for increasing the flexibility of RIA processes in combination with subsequent evaluation as evidence becomes available may also be crucial. Moreover, regulatory experimentation and testing initiatives should be capitalised upon whenever possible to improve RIAs by extracting relevant information on the potential effects of regulatory measures;
- Providing competent regulatory oversight bodies with the mandate and necessary resources to allow for quality control from a holistic perspective, in support of the necessary adjustments to regulatory management tools. Regulatory oversight bodies should, in particular, be able to scrutinise regulatory assessments in innovation-related areas. They should also be able to scrutinise the decision-making process in its entirety as well as the application of the full set of regulatory management tools. In the same vein, Adherents could consider adapting the sequence of these bodies' interventions to the need for more agile approaches. As an example, iterative targeted statements throughout the process may in some cases prove a useful alternative to very comprehensive "one-off" statements or opinions.

2. Putting in place mechanisms for public and stakeholder engagement, including citizens and small innovative enterprises, from an early stage and throughout the policy cycle to enhance transparency, build trust and capitalise on various sources of expertise

In the face of economic, legal and social uncertainty resulting from innovation, public and stakeholder engagement is paramount for Adherents to fully understand the implications of technological advances, build trust and ensure that policy decisions are based on the best available evidence. Priorities in this regard may include the following:

- Structuring public and stakeholder engagement as an ongoing process (as opposed to a one-off exercise) from an early stage to build ownership, develop trust, and ensure relevant and timely inputs;
- Engaging with the public and involve the full spectrum of stakeholders on a systematic basis, including citizens and civil society organisations, academia and the scientific community, and those with high innovation potential including start-ups and innovative small and medium-sized enterprises (SMEs), who depend on clear and timely regulatory guidance to develop new ideas, products and business models. Advisory bodies, both formal and informal, should also be systematically considered as a source of evidence and expertise;
- Engaging with foreign affected parties and other regulatory agencies, including in other jurisdictions, to help prevent unintended (notably cross-border) effects of regulations in innovation-related areas;
- Further promoting transparency and participation in the regulatory process by defining clear, government-wide policies on public and stakeholder engagement, with agility and inclusion as guiding principles. In doing so, promote substantive public dialogue and deliberation on societal and ethical aspects of innovation;
- Considering, whenever appropriate, more agile and effective ways of engaging with stakeholders to facilitate, in particular, the engagement with small innovative firms. The use of one-stop shops as well as digital communication methods and tools (e.g. new forms of public participation in rulemaking, such as *crowdlaw* initiatives) can be instrumental in this respect;

- Considering enabling closer interaction between regulatory oversight bodies and stakeholders in situations where this can substantially improve regulatory quality (e.g. if access to external knowledge and expertise is required for meaningful scrutiny of regulatory management tools).

3. Considering the international innovation ecosystem to draw on the most relevant evidence and regulatory approaches

Many transformative innovations cut across jurisdictional boundaries. The resulting policy implications are therefore inevitably faced by several jurisdictions concurrently or nearly so. When addressing related regulatory challenges, the following approaches could be considered:

- Gathering and assessing international knowledge, experience and existing policy approaches, from foreign jurisdictions or international fora, to diversify the evidence base and identify a wider range of options for action;
- When international treaties, guidance, or best practices exist that relate to the policy objectives at hand, taking them into account in the development of domestic regulatory approaches;
- When developing a bespoke regulatory approach that departs from existing international instruments, explaining and justifying the underlying rationale, and verifying the costs of doing so based on stakeholder engagement and rigorous impact assessment.

Laying institutional foundations to enable co-operation and joined-up approaches, both within and across jurisdictions

Innovation transcends traditional sectors, administrative boundaries and even borders. To foster coherent and effective regulatory approaches, an enabling institutional and policy framework to ensure that the public institutions involved in rulemaking and regulatory delivery can engage in seamless co-ordination in their everyday work is essential, including across jurisdictions. Doing so is crucial to avoid potential regulatory failures resulting from siloed approaches and lack of coherence across regulatory frameworks.

4. Strengthening regulatory co-operation across policy-making departments and regulatory agencies as well as between national and sub-national levels of government

In the face of innovations with wide-ranging and cross-cutting implications, promoting a whole-of-government approach to rulemaking through effective co-ordination across policy areas and between national and sub-national levels of government is more important than ever. To that effect, the following approaches could be considered:

- Enabling effective data and information sharing and promoting regulatory co-operation between the international, national and sub-national levels to identify cross-cutting regulatory issues and ensure coherence between different regulatory approaches (including along the innovation value chain) as well as the continued relevance of regulatory policies and frameworks related to innovation. To that end, devising the appropriate institutional mechanisms to anticipate the risks and opportunities arising from innovation and developing joined-up regulatory approaches will be important;
- Identifying and addressing gaps, overlaps, and barriers to effective co-ordination across all levels of government (including to avoid innovation-stifling market fragmentation), and adapting relevant co-ordination mechanisms accordingly. Ensuring, in particular, that the knowledge and capabilities of economic regulators as well as subnational levels of government, which often operate closer to economic actors, are capitalised upon, should be prioritised;
- Considering the creation of one-stop shops to facilitate co-ordination across ministries and agencies and act as easy-to-access interfaces for business and governments;
- Favouring, whenever appropriate, the adoption of shared regulatory approaches across ministries and agencies, such as cross-sector regulatory sandboxes and common approaches to data-driven regulation;
- Ensuring that regulatory oversight bodies are empowered and have resources and capacity to play a co-ordinating and knowledge-brokering role in the context of regulatory initiatives at subnational, national and international levels.

5. Stepping up bilateral, regional and multilateral regulatory co-operation to address the transboundary policy implications of innovation

Broad-based co-operation among governments and policy makers across jurisdictions is essential to ensure the continued relevance of regulatory policies and frameworks regarding the complex and transboundary reach of innovation. International coherence of rules and, when possible, aligned approaches, are essential to ensure the effectiveness of policies, an efficient allocation of resources as well as the removal of unnecessary burdens from regulatory fragmentation related to innovation. Ultimately, co-operation is essential to foster an international level playing field, prevent regulatory arbitrage by companies and a "race to the bottom" among governments and protect consumers, society and the environment. To that end, the following approaches could be considered:

- Developing a whole-of-government vision on international regulatory co-operation priorities related to innovation that fosters a coherent and systematic approach across all government authorities engaging in such co-operation. Regularly revising strategic priorities for international regulatory engagement in the area of innovation in line with broader government policies and priorities. To that end, an enabling policy and institutional framework that is endorsed by the centre of government should be put in place;
- Raising awareness about international regulatory co-operation tools available in the specific area of innovation, including information exchange, mutual recognition or equivalence agreements, development of joint instruments and participation in international fora, and identifying and addressing related capacity building needs;
- Promoting continuous dialogue with other jurisdictions to ensure transparency, information and data exchange, mutual learning, regulatory co-operation and coherence on regulatory issues related to innovation and technological change;
- Ensuring more systematically the complementarity between innovation-related domestic regulatory processes and relevant international approaches. In particular, ex ante and ex post assessments of impacts of regulatory options should be leveraged to consider systematically the costs and benefits of unilateral approaches versus joint approaches with other jurisdictions. When the impact assessments confirm the insufficiency of domestic regulatory approaches to address transboundary effects of innovations, the development of joint approaches with other like-minded jurisdictions may be considered. These could be concluded at the bilateral, regional or multilateral level, either directly between governments or facilitated by international organisations;
- For nascent policy areas where domestic regulatory approaches are not yet entrenched, considering systematically the value of developing and/or utilising international treaties, guidelines or best practices adapted to the scope and ambitions of the policy priority, within multilateral or regional fora as far as possible to capitalise on existing networks and expertise;
- When participating in the development of new international instruments for innovation-related regulatory processes, promoting forward-looking approaches that match the pace, scope and needs of the policy issue at stake. The benefits and costs of the process, legal effects and institutional framework associated with different types of approach should be taken into account;
- When existing tools or frameworks for regulatory co-operation on specific policy issues related to innovation are not available and no existing forum can serve the intended purpose, considering setting up a dedicated forum as a means of addressing shared regulatory policy needs and constraints.

Adapting the governance frameworks to enable the development of agile and adaptive regulation

The regulatory challenges brought by innovation call for more agile and adaptive regulatory approaches. This creates, in turn, a need to adapt existing governance frameworks. Given the profound consequences of innovation for society, substantive public dialogue that creates trust and certainty for citizens and businesses must be a central element in this process. In addition, to support a more agile and forward-looking and governance architecture, expanding regulatory capacity by reskilling Adherent's workforces as appropriate and adapting, whenever relevant, the mandate and powers of regulatory agencies and oversight bodies is key. Given the complexity and uncertainty arising from innovation, appropriate regulatory responses will require a combination of approaches as well as periodic adaptations to keep pace with the dynamics of technological change. In addition explicitly

identifying and carefully assessing any potential trade-offs associated with specific approaches will be crucial, for example in terms of fairness, predictability or proportionality.

6. Adapting governance frameworks and regulatory approaches so that they are forward-looking

The pace and breadth of technological change requires a more anticipatory regulatory approach to innovation including the development of institutional capacity and mechanisms to anticipate and monitor innovation pathways. In order to achieve this, the following approaches could be considered:

- Developing institutional capacity and assigning clear mandates accordingly, to conduct systematic and co-ordinated horizon scanning and scenario analysis, anticipate and monitor the regulatory implications of high-impact innovations and foster continuous learning and adaptation. Oversight and advisory bodies' capacity to explore and evaluate the potential innovation pathways and outcomes are of particular importance;
- Implementing a stepwise approach to strategic foresight that encompasses the following elements:
    - Conduct research to identify innovations with significant regulatory implications that are expected to emerge over a specified time horizon;
    - Engage with innovators (including start-ups and SMEs), civil society and academia to help validate the outcomes of the horizon-scanning process and explore key implications of innovation for people, businesses and the environment;
    - Prioritise high-impact innovations where regulatory reform is needed to unlock potential benefits or minimise potential harms, by building on a robust methodology informed by an open dialogue with stakeholders;
    - Feed the intelligence generated by anticipatory approaches into analytical work conducted by means of regulatory management tools;
- Combining, as appropriate, and under the conditions laid down in "8. Harnessing the opportunities provided by non-legally binding approaches either as an alternative or as a complement to other regulatory instruments", foresight activities with non-legally binding approaches, as part of a continuous cycle of learning and adaptation;
- Enhancing co-operation across jurisdictions to harness international knowledge and expertise and enabling a shared understanding of the implications of innovation from a regulatory standpoint.

7. Developing more outcome-focused regulatory approaches to enable innovation to thrive by harnessing the opportunities offered by digital technologies and (big) data

Outcome-oriented approaches can help increase flexibility for businesses and encourage innovation. They also offer additional flexibility to governments in achieving public policy objectives. They are well suited to address the "pacing problem", favour the development of interoperable regulatory frameworks across countries and foster resilience. In this regard, the following priorities could be considered:

- Limiting the use of prescriptive rules to cases where these are necessary, notably to provide legal certainty. Considering systematically the use of outcome-based approaches to regulation (which can prove more effective in new policy areas on which limited evidence is available) as part of the policy mix to address the policy issues and potential risks at hand.
- Defining performance indicators in line with relevant public policy objectives to enable the use of outcome-oriented approaches, and reviewing performance indicators on a regular basis to ensure their continuous relevance and alignment with the desired outcomes;
- Providing clear implementation guidance and encouraging the complementary use of non-legally binding instruments such as voluntary standards wherever appropriate (while underpinning these instruments by liability law and provisions) – since outcome-based regulations can lead to regulatory uncertainty as to how to comply with existing requirements;

- Capitalising on the opportunities brought by digital technologies and the emergence of new data sources, particularly in terms of remote and real-time monitoring of compliance, to help develop, monitor and enforce outcome-focused regulations;

8. Harnessing the opportunities provided by non-legally binding approaches either as an alternative or as a complement to other regulatory instruments

Non-binding standards, by being easier to adopt and offering more flexibility in implementation, can help address the regulatory challenges raised by innovation. Non-legally binding approaches, given that they also involve potential underperformance and downside risks, should be predicated on governments' ability to access in a timely fashion the necessary data and information to monitor their outcomes.

Governments may choose to consider a range of approaches, whose expected advantages should be carefully weighed against potential risks and limitations. The case for resorting to non-legally binding options should be grounded on evidence and communicated clearly from the outset. While such approaches might be well-suited to help manage the opportunities and risks of technological changes at their early stages, their use should not become a default option in the face of regulatory challenges. In this context, the following priorities should be considered:

- Promoting, where appropriate, governance arrangements such as voluntary standards and codes of practice to stimulate innovation and leverage the role that innovators can play in the governance of innovation. Certain pre-conditions must be met when resorting to this kind of arrangements, such as the existence of sufficient alignment between businesses' and governments' interests as well as the assurance of a level playing field for all innovators (including SMEs). In particular, the following approaches should be considered:
    - Use the potential of technical standard development processes to facilitate innovation by fostering co-operation among innovators;
    - Acquire a precise understanding of the set of incentives that underpin participation in a voluntary regime;
    - Closely monitor practices and engage in regular reviews of technical standards and codes of practice in an open and inclusive way to avoid inappropriate market distortions. The success of these approaches critically hinges on the capacity of governments to access the necessary data to monitor and assess their effects;
    - Define credible sanction mechanisms to prevent and address potential misconduct.
- Considering, whenever relevant, co-regulation to promote co-operation between governments and innovators and foster compliance by encouraging participation;
- Developing guidance to help innovators navigate the regulatory landscape and reduce regulatory uncertainty, while ensuring that the approach remains fair and provide a level playing field for all relevant players;
- To avoid a reversion to a more stringent regulatory regime and a potentially more adversarial relation with governments, business should continually demonstrate evidence of their commitment to fair and ethical behaviour that will support the trust of governments and the public more broadly.

9. Enabling greater experimentation, testing and trialling to stimulate innovation under regulatory supervision

Given the speed, breadth and uncertainty characterising innovation, creating space for experimentation to support innovation while also fostering policy learning and adaptation is essential. In particular, the following approaches could be considered:

- Enabling the controlled experimentation, testing and trialling of new ideas, products or business models, through the use of mechanisms such as regulatory sandboxes, testbeds, innovation spaces and laboratories;
- If appropriate, facilitating the use of regulatory exemptions to enable controlled testing of innovations and foster regulatory learning. These exemptions should address a well-defined

regulatory gap and be time-limited to ensure a level playing field for all innovators. In particular, the following priorities could be considered:

  - Develop a detailed analysis of the rationale for the regulatory exemption;
  - Create the mechanism through which business can easily apply to a regulatory exemption and request corresponding regulatory support;
  - Define due diligence criteria to uphold a fair and unbiased process in choosing which businesses should benefit from the regulatory exemption;
  - Define appropriate safeguards of public protections for citizens and the environment;
  - Mitigate the risk of regulatory capture. To this end, the use of regulatory exemptions could for example be overseen by an independent entity such as an existing regulatory oversight body;

- Promoting cross-sector and multi-jurisdiction experimentation initiatives to provide businesses with an environment in which to trial cross-cutting innovations, enhance regulatory co-operation and promote interoperable regulatory frameworks;
- Disseminating and sharing lessons learned and best practices regarding regulatory experimentation, and promoting the use of results for regulatory improvement (e.g. by feeding them into regulatory assessments);
- To identify potential behavioural barriers and biases in innovation-dominated policy areas, considering behaviourally-informed approaches throughout the policy cycle to issues of individual as well as organisational behaviour, and including behavioural solutions in the experimentation, trialling and testing of options;
- Whenever appropriate, developing time-limited regulatory initiatives to stimulate competition for the trialling and development of innovations that might face a regulatory barrier. In designing these initiatives, identifying a clear and specific public policy goal that would benefit from an innovative solution and ensure a level playing field for all businesses is particularly important;
- Engaging proactively with stakeholders on key points of the design, implementation (including monitoring and reporting mechanisms) and evaluation of testing initiatives.

Adapting regulatory enforcement activities to evolving needs

10. Adapting regulatory enforcement strategies and activities to promote compliance, help innovators navigate the regulatory environment and uphold public protection, including across jurisdictions

Rapid and dynamic innovations make state-led enforcement a challenging task (e.g. disintermediation phenomena, transnational scope and effects of many innovations). Ensuring that regulatory management and compliance strategies are risk-based is therefore more important than ever. Where appropriate, approaches to regulatory delivery based on outcomes and risk-proportionality should be privileged instead of focusing primarily on rigid processes and detailed prescriptive rules, and help market actors to comply through targeted support and advice. They should also use the full potential of technological advances to enable more efficient, resilient and responsive enforcement activities by enhancing the evidence base (e.g. through real time monitoring and continuous data collection), optimising resource allocation and improving risk assessment. More precisely, the following priorities could be considered:

- Adopting data-driven, responsive approaches to identify, assess and manage risks, and revising existing risk governance frameworks as appropriate;
- Embedding responsive regulatory considerations and regard for public values and concerns into regulatory enforcement by means of differentiated treatment based on transparent and objective criteria, including the compliance track record of regulated entities. To that end, developing clear and proportionate enforcement guidelines based on risk-proportionality and compliance history is key;
- Integrating, as appropriate, enforcement-related considerations in legislative proposals and related assessments. These considerations include data and information requirements to verify compliance in self- and co-regulation settings as well as needs for institutional and cross-border

co-operation, into the use of regulatory management tools. Appropriate oversight of compliance with these requirements should be ensured;
- Fostering co-operation among authorities leading investigations and enforcement of regulations related to innovations, both domestically and, where practical and feasible, across jurisdictions. Co-operation modalities may include information exchange, joint investigations and more generally co-ordination among enforcement authorities to prevent avoidance of compliance by companies operating in several jurisdictions;
- To promote compliance and avoid stifling innovation, providing proactive support and advice to help innovators understand how existing regulatory frameworks apply to them and to whom within the administration they should speak; e.g. by means of one-stop shops or supportive innovation hubs;
- Adapting regulatory mandates so that they are focused on management of risk and achievement of outcomes rather than defined primarily in terms of enforcement of specific rules and processes;
- Considering the resources and the skills needed by regulatory, enforcement and inspections agencies in order to enable data-driven strategies to promote regulatory compliance and support innovation.

Glossary

- **'Ex post evaluation'** refers to the process of assessing the effectiveness of policies and regulations once they are in force. It can be the final stage when new policies or regulations have been introduced and it is intended to know the extent of which they met the goals they served. It can also be the initial point to understand a particular situation as a result of a policy or regulation in place, providing elements to discuss the shortcomings and advantages of its existence. Ex post evaluation should not be confused with monitoring, which refers to the continuous assessment of implementation in relation to an agreed schedule[6].
- **'Innovation'** refers to new or improved ideas, products and business models that have been or may be introduced on the market or otherwise brought into use.
- **'International regulatory co-operation (IRC)'** refers to "any agreement, formal or informal, between countries to promote some form of co-operation in the design, monitoring, enforcement or ex-post management of regulation"[7].
- **'Level playing field'** refers to a market or industry in which all businesses compete under the same conditions.
- **'Regulation'** refers to the diverse set of instruments by which governments set requirements on enterprises and citizens. Regulation include all laws, formal and informal orders, subordinate rules, administrative formalities and rules issued by non-governmental or self-regulatory bodies to whom governments have delegated regulatory powers[8].
- **'Regulatory impact assessment (RIA)'** refers to the systematic process of identification and quantification of benefits and costs likely to flow from regulatory or non-regulatory options for a policy under consideration. A RIA may be based on benefit-cost analysis, cost-effectiveness analysis, business impact analysis, etc. Regulatory impact assessment is also routinely referred to as regulatory impact analysis, sometimes interchangeably[9].
- **'Regulatory management tools'** refers to the different tools available to implement regulatory policy and foster regulatory quality. In particular, the 2017 Indicators of Regulatory Policy and Governance survey focuses on quality control of three regulatory management tools in particular: regulatory impact assessment, stakeholder engagement, and ex post evaluation[10].

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[6] OECD (2018), *OECD Regulatory Policy Outlook 2018*, OECD Publishing, Paris, https://dx.doi.org/10.1787/9789264303072-en

[7] OECD (2013), *International Regulatory Co-operation: Addressing Global Challenges*, OECD Publishing, Paris, https://dx.doi.org/10.1787/9789264200463-en

[8] OECD (2018), *OECD Regulatory Policy Outlook 2018*, OECD Publishing, Paris, https://dx.doi.org/10.1787/9789264303072-en

[9] Ibid.

[10] Ibid.

- **'Regulatory policy'** refers to the set of principles, rules, procedures and institutions introduced by government for the express purpose of developing, administering and reviewing regulation[11].
- **'Risk proportionality'** refers to allocation of resources being proportional to the level of risk, and to enforcement actions being proportional to the seriousness of the violation[12].
- **'Regulatory Sandbox'** refers to a limited form of regulatory waiver or flexibility for firms, enabling them to test new business models with reduced regulatory requirements. Sandboxes often include mechanisms intended to ensure overarching regulatory objectives, including consumer protection. Regulatory sandboxes are typically organized and administered on a case-by-case basis by the relevant regulatory authorities[13].
- **'Stakeholder engagement'** refers to the process by which the government informs all interested parties of proposed changes in regulation and receives feedback[14].

[11] Ibid.

[12] OECD (2014), *Regulatory Enforcement and Inspections, OECD Best Practice Principles for Regulatory Policy*, OECD Publishing, Paris, https://dx.doi.org/10.1787/9789264208117-en

[13] OECD (2020), *The role of sandboxes in promoting flexibility and innovation in the digital age*, Going Digital Toolkit Policy Note, https://goingdigital.oecd.org/toolkitnotes/the-role-of-sandboxes-in-promoting-flexibility-and-innovation-in-the-digital-age.pdf

[14] OECD (2018), *OECD Regulatory Policy Outlook 2018*, OECD Publishing, Paris, https://dx.doi.org/10.1787/9789264303072-en

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The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

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Since the creation of the OECD in 1961, around 460 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

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- **Arrangement, Understanding and Others**: several other types of substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.