

Public consultation on the draft OECD Recommendation for Agile Regulatory Governance to Harness Innovation

The OECD is launching a public consultation on the draft OECD Recommendation of the Council on Agile Regulatory Governance to Harness Innovation (set out in Annex A) to reach government officials, civil society organisations, international organisations and interested citizens and stakeholders from all over the world in order to ensure that the final text of the draft Recommendation reflects the experience, needs and aspirations of the international community.

The draft 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, which is critically important) 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 government's broader strategies for innovation.

Through the consultation, the OECD also aims to evaluate the relevance of the draft Recommendation and in particular its 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 future-proof regulation;
- Adapting regulatory enforcement activities to the “new normal”.

Views are also welcomed on the level of details in the draft Recommendation, which includes in brackets options for additional text, and on the draft Companion Document (set out in Annex B) which aims at supporting the implementation of the draft Recommendation.

The draft Recommendation and draft Companion Document are being developed through an inclusive and horizontal approach, involving a number of OECD committees and bodies. This draft is a work in progress. Its content is without prejudice to the final text that will be adopted by the OECD Council. Inputs collected during the public consultation will be taken into account to finalise the draft Recommendation. All comments will be considered public and may be published unless requested otherwise.

You are invited to comment on the draft Recommendation, including on the level of detail to be provided within the draft Recommendation (i.e. whether to include the sub-paragraphs set out in square brackets), and the draft Companion Document. Please send us your comments electronically by 2 July 2021 to the following email address: recoagilereg@oecd.org.

Annex A. Draft Recommendation of the Council on Agile Regulatory Governance to Harness Innovation

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 and Policy Governance [[OECD/LEGAL/0390](#)], the Recommendations 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 OECD 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 requires a paradigm 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 deterministic 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 that holistic, open, inclusive, adaptive and better-co-ordinated governance models enhance systemic resilience by enabling the development of agile, future-proof 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-centered 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 Companion Document [COTE TO BE INSERTED], developed by the Regulatory Policy Committee to support 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 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 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 rules, procedures and institutions introduced by government for the express purpose of developing, administering and reviewing regulation.

ADJUSTING REGULATORY MANAGEMENT TOOLS TO ENSURE REGULATIONS ARE FIT FOR THE FUTURE

II. **RECOMMENDS** that Members and non-Members having adhered to this Recommendation (hereafter the “Adherents”) **develop more adaptive, iterative and flexible regulatory assessment cycles**, while capitalising on technological solutions to improve the quality of evidence[, by:

- a) Using regulatory management tools in an agile and integrated fashion to inform a continuous learning and adaptation process throughout the policy cycle;
- b) Putting in place monitoring arrangements, as well as approaches and mechanisms for *ex post* reviews of regulation, that contribute to addressing the needs stemming from rapid and dynamic innovation;
- c) Enabling regulatory management tools to assess the impact of regulation on innovation to the extent possible, including within administrations and across borders;
- d) 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; and
- e) 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].

III. **RECOMMENDS** that Adherents **put in place mechanisms for broad public and stakeholder engagement in the regulatory process**, including citizens and innovative small and medium-sized enterprises (SMEs), from an early stage and throughout the policy cycle to enhance transparency, build trust and capitalise on various sources of expertise[, by:

- a) Structuring public and stakeholder engagement as an ongoing process from an early stage,

to build ownership, develop trust, and ensure relevant and timely inputs;

- b) Promoting transparency and participation by defining clear, government-wide policies on public and stakeholder engagement, with agility and inclusion as guiding principles, that foster engagement with the public and involve the full spectrum of stakeholders on a systematic basis, including citizens, academia and those with high innovation potential such as start-ups and innovative small and medium-sized enterprises (SMEs); and
- c) Engaging with foreign affected parties and other regulatory agencies, including in other jurisdictions, to help prevent unintended effects of regulations in innovation-related areas, notably across borders].

IV. RECOMMENDS that Adherents **consider the international innovation ecosystem** to draw on the most relevant evidence and regulatory approaches[, by:

- a) Gathering and assessing international knowledge, experience and existing policy approaches, from foreign jurisdictions or international fora, to enhance the evidence base and identify a wider range of options for action; and
- b) Taking into account relevant international instrument such as treaties, guidance, or standards in the development of domestic regulatory approaches and explaining and justifying taking bespoke regulatory approaches that depart from these].

LAYING INSTITUTIONAL FOUNDATIONS TO ENABLE CO-OPERATION AND JOINED-UP APPROACHES WITHIN AND ACROSS JURISDICTIONS

V. RECOMMENDS that Adherents **strengthen regulatory co-ordination and collaboration** across policy-making departments and regulatory agencies as well as between national and sub-national levels of government[, by:

- a) Enabling effective data and information sharing and promoting regulatory co-ordination at the international national and sub-national levels to identify cross-cutting regulatory issues and ensure regulatory coherence;
- b) Identifying and addressing gaps, overlaps and barriers affecting effective co-ordination across all levels of government and adapting relevant co-ordination mechanisms accordingly; and
- c) Favouring, whenever appropriate, the adoption of shared regulatory approaches across ministries and agencies].

VI. RECOMMENDS that Adherents **step up bilateral, regional and multilateral regulatory co-operation** to address the transboundary policy implications of innovation[, by:

- a) Developing a whole-of-government vision on international regulatory co-operation priorities related to innovation;
- b) Promoting continuous dialogue with other jurisdictions;
- c) Ensuring the complementarity between innovation-related domestic regulatory processes and international instruments for nascent policy areas more systematically;
- d) Considering the value of developing and/or utilising international instruments adapted to the scope and ambitions of policy priorities systematically; and
- e) Promoting forward-looking international instruments for innovation-related regulatory processes that match the pace, scope and needs of the policy issue at stake].

ADAPTING GOVERNANCE FRAMEWORKS TO ENABLE THE DEVELOPMENT OF AGILE AND FUTURE-PROOF REGULATION

VII. RECOMMENDS that Adherents **develop or adapt 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.

VIII. RECOMMENDS that Adherents **develop more outcome-focused regulatory approaches** to enable innovation to thrive by harnessing the opportunities offered by digital technologies and (big) data[, by:

- a) Limiting the use of prescriptive rules to cases where these are necessary, notably to afford appropriate protection for citizens and the environment;
- b) Providing clear implementation guidance and encouraging the complementary use of ‘soft law’ instruments such as voluntary standards wherever appropriate; and
- c) Capitalising on the opportunities brought by digital technologies and the emergence of new data sources to help develop, monitor, and enforce outcome-focused regulations].

IX. RECOMMENDS, under the condition that corresponding outcomes can be appropriately monitored, that Adherents **harness the opportunities provided by ‘soft law’ approaches** to complement other regulatory instruments[, by:

- a) 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;
- b) Considering, whenever relevant, co-regulation as a means of promoting collaboration between governments and innovators and fostering compliance by encouraging participation; and
- c) Developing guidance to help innovators navigate the regulatory landscape and reduce regulatory uncertainty, while ensuring that the approach remains fair and provides a level playing field for all relevant players].

X. RECOMMENDS that Adherents **enable greater experimentation, testing, and trialling** to stimulate innovation under regulatory supervision[, by:

- a) Facilitating the use of regulatory exemptions to enable controlled testing of innovations and foster regulatory learning;
- b) 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; and
- c) Proactively engaging with stakeholders on key points of the design, implementation (including monitoring and reporting mechanisms) and evaluation of testing initiatives].

ADAPTING REGULATORY ENFORCEMENT ACTIVITIES TO THE “NEW NORMAL”

XI. 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:

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

- b) Integrating enforcement-related considerations in legislative proposals and related assessments systematically;
- c) Fostering co-operation among authorities leading investigations and enforcement of regulations related to innovation, both domestically and, where practical and feasible, across jurisdictions; and
- d) Adapting regulatory mandates so that they are focused on managing risk and achieving outcomes rather than being defined primarily in terms of enforcement of specific rules and processes].

- IV. INVITES** the Secretary-General to disseminate the Recommendation.
- V. INVITES** Adherents to disseminate this Recommendation at all levels of government.
- VI. INVITES** non-Adherents to take account of and adhere to this Recommendation.
- VII. INSTRUCTS** the Regulatory Policy Committee, in consultation with other relevant committees, to:
 - i. Serve as a forum for exchanging information on policies and experience with respect to the implementation of the Recommendation, fostering dialogue with and among stakeholders, and improving the evidence base on agile regulatory governance to harness innovation; and
 - ii. Review and update the Companion Document over time to ensure it remains relevant;
 - iii. Develop further guidance and evaluation frameworks to support the implementation of the Recommendation;
 - iv. Review the implementation, dissemination, and continued relevance of the Recommendation and report thereon to the Council no later than five years following its adoption and at least every ten years thereafter.

Annex B. Draft Companion document to the Recommendation of the Council on Agile Regulatory Governance to Harness Innovation

1. This document drafted in the context of the development of the Recommendation of the Council on Agile Regulatory Governance to Harness Innovation (hereafter, “the Recommendation”). It provides more detailed and practical guidance to support Adherents in implementing the Recommendation.

Key considerations for the implementation of the draft Recommendation

2. The draft 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 (OECD, 2021^[12]). 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-coordinated governance models to enhance systemic resilience by enabling the development of agile, future-proof 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 and human-centered will also require stepping up efforts to more fully 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 (OECD, 2017^[13]). 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, governments should devote 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 of various sources of expertise should be leveraged in this regard. The additional strain that technological change places on both regulatory oversight bodies and enforcement and inspection authorities in terms of capacity and skills should also be acted upon (OECD, 2019^[15]).
- 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.

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

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

3. In light of the regulatory challenges raised by innovation, governments need to undertake a paradigm shift in their regulatory policy processes, whereby the traditional “regulate and forget” mindset must give way to “adapt-and-learn” approaches. Addressing the “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.

4. To that end, governments should:

- Use 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, governments should reassess how regulatory management tools are applied and related resources used. More frequent and iterative, if sometimes less thorough, instances of analysis may be a better fit in a number of cases. Digital tools (e.g. real time data flows and analytics) may be particularly useful in this respect. This approach should be coupled, however, with the much more active and early use of interim and *ex post* reviews to assess whether regulatory frameworks remain relevant and fit for the future. In addition, lessons learned from successful approaches in other jurisdictions and consistency with international instruments related to innovation should inform the development and review of domestic regulation;

- Put in place monitoring arrangements as well as approaches and mechanisms for *ex post* reviews of regulation contribute to address the needs stemming from rapid and dynamic innovation. Governments should, in particular, monitor the impact of regulations systematically and on a continuous basis, and engage in timely and proportionate reevaluation of regulatory approaches to keep pace with innovation. To the extent possible, governments should embed review requirements in the regulatory framework itself (OECD, 2020^[7]), and ensure that such provisions as well as related assessments are subject to systematic oversight and quality control;
- Develop 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 (see point no. 5 for more details).
- Encourage 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;
- Leverage 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. Governments should consider the data governance, 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;
- Achieve 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. As underlined above, governments should likewise explore avenues for increasing the flexibility of RIA processes in combination with subsequent evaluation as evidence becomes available. 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;
- Provide 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, governments 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. Put in place mechanisms for broad 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

5. In the face of economic, legal and social uncertainty resulting from innovation, stakeholder engagement is paramount for governments 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 should include the following:

- Structure 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;
- Engage with the public and involve the full spectrum of stakeholders on a systematic basis, including citizens, academia and those with high innovation potential such as 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;
- Engage 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 promote 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 societal deliberation on societal and ethical aspects of innovation;
- Consider, 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 can be instrumental in this respect;
- Consider 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. Consider the international innovation ecosystem to draw on the most relevant evidence and regulatory approaches

6. 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, governments should:

- Gather and assess international knowledge, experience and existing policy approaches, from foreign jurisdictions or international fora, to enhance the evidence base and identify a wider range of options for action;
- When international instruments such as treaties, guidance, or standards exist that relate to the policy objectives at hand, take them into account in the development of domestic regulatory approaches;

- When developing a bespoke regulatory approach that departs from existing international instruments, explain and justify the underlying rationale, and verify the costs of doing so based on stakeholder engagement and rigorous impact assessment.

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

7. Innovation transcends traditional sectors, administrative boundaries and even borders. To foster coherent and effective regulatory approaches, governments need 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, including across jurisdictions. Doing so is essential to avoid potential regulatory failures resulting from siloed approaches and lack of coherence across regulatory frameworks.

4. Strengthen co-ordination and collaboration across policy-making departments and regulatory agencies as well as between national and sub-national levels of government

8. In the face of innovations with wide-ranging and cross-cutting implications, governments should more than ever promote a whole-of-government approach to rulemaking through effective co-ordination across policy areas and between national and sub-national levels of government. To that effect, governments should:

- Enable effective data and information sharing and promote regulatory co-ordination between the international, national and sub-national levels to identify cross-cutting regulatory issues and ensure regulatory coherence (including along the innovation value chain) as well as the continued relevance of regulatory policies and frameworks related to innovation. To that end, governments should devise the appropriate institutional mechanisms to anticipate the risks and opportunities arising from innovation (see point no. 6 for more details) and develop joined-up regulatory approaches;
- Identify and address gaps, overlaps, and barriers to effective co-ordination across all levels of government (including to avoid innovation-stifling market fragmentation), and adapt relevant co-ordination mechanisms accordingly. Governments should ensure, 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;
- Consider 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;
- Favour, 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;
- Ensure 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. Step up bilateral, regional and multilateral regulatory co-operation to address the transboundary policy implications of innovation

9. 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, governments should:

- Develop 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 revise 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;
- Raise awareness about international regulatory co-operation tools available in the specific area of innovation and identify and address related capacity building needs;
- Promote 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;
- Ensure more systematically the complementarity between innovation-related domestic regulatory processes, as described under Pillar 1, and international instruments. In particular, ex ante and ex post assessments of impacts of regulatory options should be leveraged upon 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 technologies, governments should consider the development of joint approaches with other like-minded jurisdictions. These can take the form of international instruments 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, consider systematically the value of developing and/or utilising international instruments 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, promote forward-looking instruments that match the pace, scope and needs of the policy issue at stake. Countries should acknowledge the benefits and costs of the process, legal effects and institutional framework associated with different types of standard or instrument;
- 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, consider setting up a dedicated forum as a means of addressing shared regulatory policy needs and constraints.

Adapt the governance frameworks to enable the development of agile and future-proof regulation

10. The regulatory challenges brought by innovation call for more agile and future-proof 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, governments should expand regulatory capacity by reskilling their workforce as appropriate and adapt, whenever relevant, the mandate and powers of regulatory agencies and oversight bodies. 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, governments should explicitly identify and assess carefully any potential trade-offs associated with specific approaches, for example in terms of fairness, predictability or proportionality.

6. Adapt governance frameworks and regulatory approaches to be forward-looking

11. 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, governments should:

- Develop institutional capacity and assign 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;
- Implement a stepwise approach to strategic foresight that encompasses the following elements:
 - Conducting research to identify innovations with significant regulatory implications that are expected to emerge over a specified time horizon;
 - Engaging 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;
 - Prioritising 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;
 - Feeding the intelligence generated by anticipatory approaches into analytical work conducted by means of regulatory management tools (see point no. 1);
- Combine, as appropriate and under the conditions laid down in point no. 8, foresight activities with 'soft law' approaches, as part of a continuous cycle of learning and adaptation;
- Enhance co-operation across jurisdictions to harness international knowledge and expertise and enable a shared understanding of the implications of innovation from a regulatory standpoint.

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

12. 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, governments should, as a priority:

- Limit the use of prescriptive rules to cases where these are necessary, notably to afford appropriate protection for citizens and the environment. Consider 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. To enable the use of outcome-oriented approaches, governments should be able to define observable and measurable performance targets in line with relevant public policy objectives. Performance targets should be reviewed on a regular basis to ensure their continuous relevance and alignment with the desired outcomes;

- Provide clear implementation guidance and encourage the complementary use of ‘soft law’ 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;
- Capitalise 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. Harness the opportunities provided by ‘soft law’ approaches to complement other regulatory instruments

13. Non-binding standards, by being easier to adopt and offering more flexibility in implementation, can help address the regulatory challenges raised by innovation. ‘Soft law’ 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.

14. 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 ‘soft law’ 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, governments should:

- Promote, 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 a sufficient alignment between businesses’ and governments’ interests as well as the assurance of a level playing field for all innovators (including SMEs). Governments should, in particular:
 - Use the potential of technical standard development processes to facilitate innovation by fostering collaboration among innovators;
 - Have 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.
- Consider, whenever relevant, co-regulation to promote collaboration between governments and innovators and foster compliance by encouraging participation;

- Develop 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. Enable greater experimentation, testing and trialling to stimulate innovation under regulatory supervision

15. Given the speed, breadth and uncertainty characterising innovation, governments need to create space for experimentation to support innovation while also fostering policy learning and adaptation. They should, in particular:

- Enable 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, facilitate 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. Governments should, in particular:
 - 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;
- Promote 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;
- To identify potential behavioural barriers and biases in innovation-dominated policy areas, consider behaviourally-informed approaches throughout the policy cycle to issues of individual as well as organisational behaviour, and include behavioural solutions in the experimentation, trialling and testing of options;
- Whenever appropriate, develop time-limited regulatory initiatives to stimulate competition for the trialling and development of innovations that might face a regulatory barrier. In designing these initiatives, governments should in particular identify a clear and specific public policy goal that would benefit from an innovative solution and ensure a level playing field for all businesses;
- Proactively engage with stakeholders on key points of the design, implementation (including monitoring and reporting mechanisms) and evaluation of testing initiatives.

Regulatory enforcement activities in the “new normal”

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

16. 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. Governments should privilege approaches to regulatory delivery based on outcomes and risk-proportionality 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, governments should:

- Adopt data-driven, responsive approaches to identify, assess and manage risks, and revise existing risk governance frameworks as appropriate;
- Embed responsive regulatory considerations and regard for public values and concerns into regulatory enforcement by means of differentiated treatment based on the track record, internal set-up and demonstrated ethical values of regulated entities. To that end, governments should develop clear and proportionate enforcement guidelines based on risk-proportionality and compliance history;
- Integrate systematically 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. Governments should also ensure appropriate oversight of compliance with these requirements;
- Foster 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, provide 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;
- Adapt 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;
- Consider 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 for. 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 (OECD, 2018^[16]).
- **‘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.” (OECD, 2013^[17]).
- **‘Level playing field’** refers to a market or industry in which all businesses compete under the same conditions.
- **‘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 instruments’** refers to the broad range of documents adopted by international organisations as part of their normative activity. These cover legally binding requirements that are meant to be directly binding on members and non-legally binding requirements that may in some cases be given binding value through transposition in domestic legislation or recognition in international legal instruments and statements of intent or guidance (OECD, 2016^[18]).
- **‘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 (OECD, 2018^[16]).
- **‘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 (OECD, 2018^[16]).
- **‘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 (OECD, 2018^[16]).
- **‘Regulatory policy’** refers to the set of rules, procedures and institutions introduced by government for the express purpose of developing, administering and reviewing regulation (OECD, 2018^[16]).
- **‘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 (OECD, 2014^[6]).

- **'Stakeholder engagement'** refers to the process by which the government informs all interested parties of proposed changes in regulation and receives feedback (OECD, 2018_[16]).

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