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CEPA strategy guidance note on

Regulatory impact assessment

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The [United Nations Committee of Experts on Public Administration \(CEPA\)](#) has developed a set of principles of effective governance for sustainable development. The essential purpose of these voluntary principles is to provide interested countries with practical, expert guidance on a broad range of governance challenges associated with the implementation of the 2030 Agenda. CEPA has identified 62 commonly used strategies to assist with the operationalization of these principles. This guidance note addresses regulatory impact assessment, which is associated with the principle of sound policymaking and can contribute to strengthening the effectiveness of institutions. It is part of a series of such notes prepared by renowned experts under the overall direction of the CEPA Secretariat in the Division for Public Institutions and Digital Government of the United Nations Department of Economic and Social Affairs.

In reading this guidance note, individuals in government ministries and agencies who are less familiar with the topic will be able to understand the fundamentals. Those who have perhaps taken initial steps in this area with limited follow-through or impact will be able to identify how to adjust elements of their practice to achieve better results and to better embed and institutionalize the strategy in their organizations. Those who are more advanced in regulatory impact assessment will be able to recognize the practices which contribute to its success.

Understanding the strategy

Regulatory impact assessment (RIA) is an evidence-based tool to support public decision-making. It is a systematic appraisal of how a proposed policy is likely to affect certain categories of stakeholders and a range of outcomes. Although this is not as yet current international practice, the outcomes can (and should, as this note will argue) include the Sustainable Development Goals (SDGs). This tool can be applied to primary legislation or secondary (implementing) regulation, or both; and to central government departments as well as independent regulators, regional governments and local authorities, where RIA can be combined with community-based and participatory forms of assessment.¹ Often described as a ‘whole-of-government’ tool, indicating that a single template can be applied to different types of policies and sectors, in its participatory dimension RIA may also be a ‘whole-of-society’ approach. The participation of societal actors in the policy process is essential to achieve the SDGs.²

RIA is mostly used during the policy formulation stage as it provides a set of formal steps in the policy formulation process.³ It is not a substitute for political decision-making and does not replace judgement or the balancing act between values and preferences that public choices imply. Rather, it informs the final choice of decision makers (be it elected politicians or independent regulators) with evidence and inputs from stakeholders.

Integration of SDGs and RIA

If properly used, RIA can contribute to achieving policy coherence and delivering on the SDGs. With regard to policy coherence, RIA is a process of appraisal that involves stakeholders and diffuse interests and fosters transparency; introduces formal procedures for those who are affected by proposed regulations to exercise their right to be notified and to comment; and contributes to public accountability and scrutiny of executive action. This potential is particularly relevant for developing countries seeking policy coherence in a multi-stakeholder environment. Stakeholders as varied as citizens, domestic companies, foreign firms, investors, and international donors equally demand tangible commitments in terms of

¹ Spaling, H., J. Montes and J. Sinclair, 2011, *Best practices for promoting participation and learning for sustainability: lessons from community-based environmental assessment in Kenya and Tanzania*. Journal of Environmental Assessment Policy and Management, 13(3), pp.343–366.

² RIA can also be adapted to incorporate empathy and other principles of design thinking. Allio, L., 2014, *Design Thinking for Public Service Excellence*. UNDP Global Centre for Public Service Excellence, Singapore. <https://www.undp.org/content/undp/en/home/librarypage/capacity-building/global-centre-for-public-service-excellence/DesignThinking.html>

³ OECD, 2020, *Regulatory Impact Assessment: OECD Best Practice Principles for Regulatory Policy*. Paris: OECD Publishing.

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predictability and quality of public decision-making – and are more likely to accept rules generated via a robust, evidence-informed process.

Integration of the SDGs, strategic thinking and a comprehensive policymaking vision are key to the relevance of RIA.⁴ The cross-national experience is still largely based on economic assessments, sometimes narrowed to the estimate of administrative burdens or direct compliance costs. In more sophisticated/integrated versions, RIA includes the calculation of the full range of costs and benefits across sectors, hence an assessment of the impacts of different policy options for the whole economy. In many cases, rudimentary checklists and paperwork (red tape) cost reduction strategies have been amplified over time to include cost-effectiveness analysis, multi-criteria analysis, risk-risk comparisons and benefit-cost ratios based on quantified and monetized benefits.⁵ Beyond benefit-cost ratios, distributive impacts are fundamental in relation to the SDGs. The next step is to mainstream the SDGs in RIA, by analysing, when appropriate, the impacts on social inclusion, health, gender, energy, jobs, climate, biodiversity and consumption patterns.⁶ Compassionate, inclusive regulations that respect human dignity need comprehensive RIAs, where both quantifiable benefits and broader qualitative considerations find their place.⁷

Better regulation

The overall strategy in which RIA is embedded is ‘better regulation’. The strategy is anchored to three building blocks of learning from evidence. The first fundamental building block is proportionality or targeting.⁸ The methods, and more generally the depth of the analysis, should be commensurate with the importance of the proposal under discussion – light analyses are sufficient for incremental policy changes. This is because RIA is also an investment in scarce resources like time and qualified officers. At the same time, RIA is also an asset to build capacity in the public sector for data generation and evidence-informed policymaking, as well as for the emergence of robust consultation practices.

The second building block is knowledge utilization. When international organizations talk about ‘making governments think’⁹ they refer to both RIA in terms of breadth and depth of

⁴ Morrison-Saunders, A., et al., 2020, *Gearing up impact assessment as a vehicle for achieving the UN sustainable development goals*. Impact Assessment and Project Appraisal, 38(2), pp. 113-117.

⁵ Sunstein, C., 2002, *The Cost-Benefit State: The Future of Regulatory Protection*. Chicago: American Bar Association.

⁶ In 2021 the OECD reported on the state of play with the integration of sustainability in RIA. OECD, 2012, *Sustainability in impact assessment*. Paris: OECD Publications. [http://www.oecd.org/gov/regulatory-policy/Sustainability%20in%20impact%20assessment%20SG-SD\(2011\)6-final.pdf](http://www.oecd.org/gov/regulatory-policy/Sustainability%20in%20impact%20assessment%20SG-SD(2011)6-final.pdf).

⁷ Sunstein, C., 2014, *Valuing Life: Humanizing the Regulatory State*. Chicago, University of Chicago Press.

⁸ OECD, 2020. Op. Cit.

⁹ OECD, 2008. *Building an Institutional Framework for Regulatory Impact Assessment: Guidance for Policy-Makers*. Paris:OECD Publications.

the appraisals, and to the impact of RIA as practical knowledge that is used by different actors in the policy process to formulate the final policy choice.¹⁰ A further, related learning factor is the provision of a database and evidence available to monitor laws and regulations after they enter into force – this makes RIA a ‘living’ planning document.

The third building block is integration with other policy instruments and institutional design.¹¹ RIAs are more effective if combined with policy evaluation, risk management, freedom of information and general principles of transparency and access to information held by public bodies. It is the overall ecology of procedures for appraising policy options that makes the difference.¹² As for governance, RIA requires political commitment, training, up-to-date guidance material and oversight mechanisms. Regulatory oversight bodies (in the executive branch or at arm’s length from government) and champions of regulatory reform at the ministerial level allow for scrutiny of the impact assessments produced by departments. Institutions for regulatory oversight exercise scrutiny and monitor implementation, as well as creating the conditions for learning¹³ and convergence across many different departments towards ‘whole-of-government’ standards and methods, thus stabilizing the expectations of citizens and stakeholders.

What is the underlying theory of change?

RIA generates change in three ways (see Text box 1). As a public document, it brings transparency on the early stages of policy formulation. While the explanatory memorandum that accompanies draft legislation details the legal dimension, RIAs report on the rationale for intervention, the results of consultation, the comparative analysis of different options, and how outcomes are likely to be affected. RIA, as a learning and capacity-building process, involves exchanges among different departments (at least for major rules); the mobilization of statistical offices and data repositories; coordination among different units on how to include previous studies and categories of analysis (economic, social, gender, and health impact assessments are cases in point); and dialogue with the stakeholders. Public managers, independent regulators and elected policymakers learn how to challenge their assumptions in light of the evidence made available via consultation and estimates of impacts and open their peripheral vision to feasible and comparable alternatives. As such, this tool supports the

¹⁰ Dunlop, C., O. Fritsch and C. Radaelli, 2014, "Étudier l'étude d'impact." *Revue française d'administration publique*, 149(1), pp. 163-178.

¹¹ OECD, 2008. Op. Cit.

¹² OECD – KDI Korea Development Institute, 2017, *Improving Regulatory Governance: Trends, Practices and the Way Forward*. Paris: OECD Publishing.

¹³ Senninger, R. and J. Blom-Hansen, 2020, "Meet the Critics: Analyzing the EU Commission's Regulatory Scrutiny Board through quantitative text analysis." *Regulation & Governance* Early View
<https://onlinelibrary.wiley.com/doi/abs/10.1111/rego.12312>

strategy of correcting the cognitive biases of regulators and decision makers, such as narrow framing, confirmation bias, overconfidence and availability.¹⁴

Text box 1: A regulatory impact assessment is...

- **A document** that supports decision-making with evidence on the advantages and disadvantages of alternative options in terms of their likely impacts on stakeholders and outcomes.
- **A process** to learn how to challenge prior beliefs, to learn about the likely consequences of feasible current and future interventions and to build capacity for appraisal.
- **A communication platform** to engage stakeholders, to facilitate legislative scrutiny of the executive, and to present evidence that supports the choice of a particular rule.

The third dimension of change is RIA as a communication tool. In this way, RIA contributes to the dialogue between the executive and the legislature and communicates evidence that may be considered by the courts in their judicial review of regulation. Most importantly, RIA structures the dialogue with stakeholders.¹⁵ In several OECD countries and some developing countries, it is customary to invite stakeholders to comment on inception or ‘road map’ RIAs. For important rules there can be two rounds of consultation – one for the inception RIA and another when the alternative options are clearer. Thus, RIA has the potential to be an agile platform for communication with a wide range of audiences and the wider society. In turn, transparent communication contributes to social legitimacy and compliance.

The theory of change is that “the quality of both the regulatory environment and regulatory outcomes is strongly dependent on the quality of processes for designing regulations”.¹⁶ SDG-oriented rules need to be produced through a process that is evidence-based, transparent and accountable. A robust appraisal of proposals is a necessary condition for better rules, and, by improving on their regulatory environment and process predictability, countries improve their business climate and become more attractive in terms of foreign direct investment. Beyond investment, good rules influence governance outcomes.¹⁷ With regard to SDG outcomes, it is critical to integrate them into the appraisals carried out within the RIA process. The evidence-based RIA operations, including consultation, should increase decision makers’ awareness of how certain choices will impact gender, social inclusion, poverty, sustainability, and the other

¹⁴ Dudley, S. and Z. Xie, 2020, *Designing a Choice Architecture for Regulators*. Public Administration Review 80, pp. 151-56.

¹⁵ The role of non-state actors is particularly important when governments try to integrate sustainable development in impact assessment. See OECD, 2012, *Sustainability in impact assessment*. Op. Cit. p. 7.

¹⁶ OECD, 2020, *OECD Draft Policy Framework on Sound Public Governance*. Paris, OECD Publishing, p. 6.

¹⁷ See the causal chain in OECD, 2014, *Framework for Regulatory Policy Evaluation*. Paris, OECD Publications.

SDGs. However, in practice, RIA can become unwieldy and very difficult to prepare if each time an assessment is carried out there are multiple impacts to check – recalling the previous point about proportionality.

Public sector situation and trends

The efficiency and quality of regulation affects the economic performance of developing countries.¹⁸ However, there are no systematic global or regional appraisals of the extent to which the RIA strategy for SDGs has been or is being implemented by countries.

The trend towards the formal adoption of RIA is clearly visible in the longitudinal data.¹⁹ However, actual implementation of the formal requirements varies depending on administrative capacity, institutional context and periods of time.²⁰ The political and economic costs for RIA range from on-paper adoption to implementation.²¹

Experience has shown that RIA is often geared towards basic applications. Since the 1990s, there has also been pressure to reduce red tape and administrative burdens that hinder investment and productivity. More recently, so-called offsetting mechanisms (such as the ‘one-in, one-out’ model) have taken root in various governments. These mechanisms do not consider the benefits dimension. This trend has led to some talk of an implementation issue about benefit neglect.²² Against this background, the SDGs are long-term and geared toward fundamental, benefit-oriented missions. It follows that wider types of impacts, including indirect costs as well as distributional impacts, should be integrated.

Challenges

Making reform sustainable is a well-documented problem. World Bank researchers suggest that RIA uptake in the Global South is increasing, but there are still important implementation

¹⁸ Jalilian, H., C. Kirkpatrick and D. Parker, 2007, *The Impact of Regulation on Economic Growth in Developing Countries: A Cross-Country Analysis*. World Development 35, pp. 87-103. Broughel, J. and R. Hahn, 2021, *The impact of economic regulation on growth: Survey and Synthesis*. Regulation & Governance. Early View.

¹⁹ De Francesco, F., 2012, *Diffusion of Regulatory Impact Analysis in OECD and EU Member States*. Comparative Political Studies 45, pp. 1277-305.

²⁰ Radaelli, C. M., 2005, *Diffusion without Convergence: How Political Context Shapes the Adoption of Regulatory Impact Assessment*. Journal of European Public Policy 12, pp. 924-43.

²¹ De Francesco, F., C. M. Radaelli and V.E. Troeger, 2012, *Implementing Regulatory Innovations in Europe: The Case of Impact Assessment*. Journal of European Public Policy 19, pp. 491-511.

²² Sunstein, C., 2020, *On Neglecting Regulatory Benefits*. SSRN.
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3541782

challenges.²³ An explanation of such challenges is that RIA is ‘unhinged’ from other instruments and governance reforms – a manifestation of the ecological nature of better regulation reforms mentioned above. The whole thrust of the next generation of better regulation reforms lies in explicitly connecting RIA to the SDGs – by showing stakeholders and citizens that there is a socially inclusive, sustainable vision behind the efforts to embed this tool in the policy process.

Another reason is the insufficient adaptation of the RIA templates generated by international organizations to meet the specific contextual conditions of implementation in developing countries. RIA templates must be translated and edited – in short, developing countries and donors providing technical assistance must think about the smart customization of existing templates.²⁴ Further, there is the challenge of not understanding the long-term nature of RIA reform, which implies adequate levels of commitment to receiving (the demand) the analyses and having the resources to carry out (the supply) analyses. This challenge often ties into the impatience of donors.²⁵

Easing the challenges

To ease these challenges, RIA should be embedded in the wider ecosystem of public management reforms and plans for coherent policymaking. On customization, experience suggests that practitioners should work with incentives. What incentives will public managers that engage with RIA benefit from – for example, training, promotion, influence on policy formulation? What can RIA do for elected politicians in government and in parliament – for example, through accountability and scrutiny? How do stakeholders benefit from RIA – for example, by facilitating the emergence of a whole-of-society approach alongside a whole-of-government approach? Does the business community sanction the absence of RIA, or weak or incomplete analyses?

Timing is as important as incentives. Developing countries should build up capacity with pilot programmes. They should learn from the pilots and then deploy RIA only to the most important proposals with a basic methodology, to be improved upon at a later time. In these stages of “RIA light”, governments should signal that the decision to implement the reform is long term.²⁶ A dense toolbox with many procedural and analytical requirements raises the

²³ The cases are discussed in Kamkhaji, J., P. Ladegaard and P. Lundkvist, 2019, *Risks When Reforming: Challenges and Sustainability of RIA Systems: Results of the First Systematic Study on RIA Reforms in Developing Countries*. European Journal of Risk Regulation 10, pp. 187-200.

²⁴ Kirkpatrick, C., 2017, *Developing Countries* in C.A. Dunlop and C.M. Radaelli. Op. Cit.

²⁵ Kamkhaji, J., et al., 2019, Op. Cit.

²⁶ World Bank, 2010, *Making it Work: RIA light for developing countries*. World Bank Group, Washington (Investment Climate Advisory Services).

bar too high for developing countries.²⁷ Pilot programmes, training programmes and the subsequent emergence of communities of practice have more traction than adopting guidance that exists just on paper. The RIA programmes introduced in Year 1 will inevitably need adaptation: to monitor, evaluate and learn how to change and improve over time is the best approach. Socialisation is an important aspect of such gradual scaling-up of capacities. Several countries have launched more or less formalised networks and “communities of practice” to address common problems, share good practices, and facilitate learning.

Road maps and inception RIAs in developing countries can stimulate stakeholders’ engagement and citizen’s participation at three levels: the emergence of a structured platform for dialogue; the consideration of different categories of costs and, more generally, effects that are not easily known to governments with limited capacity for data gathering; and the emergence of a demand for robust impact assessment in multi-stakeholder environments. Without demand from outside public administration, there is no external pressure to improve. Engagement should start at an early stage: instead of waiting until the analyses and data converge towards an option, regulators should embrace regulatory humility²⁸ and seek views on what evidence is available, from what sources and where, how the problem is perceived, and what intervention logistics are feasible. It has also been suggested that during consultation the wider public should be given access to a ‘reply to comment’ feature on the consultation portal – essentially giving the public the ability to expand or add to a comment made by a stakeholder.²⁹

In short, developing countries must manage domestic expectations and the expectations of foreign investors and international donors. RIAs won’t change every policy decision, but they can gradually change how governments ‘think’ about making policy.³⁰ Most crucially, RIAs can avoid dramatically wrong choices and limit policy disasters, which often turn into political disasters for the government. Expectations are easier to manage if a RIA is nested within a vision and specific mission that can mobilize the efforts of stakeholders. The SDGs are the perfect set of goals to connect RIAs and outcome-driven decision-making.

²⁷ Carrigan, C. and S. Shapiro, 2017, *What's Wrong with the Back of the Envelope? A Call for Simple (and Timely) Benefit–Cost Analysis*. Regulation & Governance 11, pp. 203-12.

²⁸ Humility about their cognitive bias and the limited capacity to control for unintended consequences. This point is fundamental also for training officers on regulation and RIA specifically. See Dunlop, C. and C. M. Radaelli, 2016, *Teaching Regulatory Humility: Experimenting with students practitioners*. Politics. 36(1): 79-94.

²⁹ Dudley, S., 2021, *Advice for the Biden-Harris Administration: Embrace Regulatory Humility*. Washington DC, George Washington University Regulatory Studies Center. <https://regulatorystudies.columbian.gwu.edu/advice-biden-harris-administration>

³⁰ Adelle, C., D. Macrae, A. Marusic and F. Naru, 2015, *New Development: Regulatory Impact Assessment in Developing Countries—Tales from the Road to Good Governance*. Public Money & Management 35, pp. 233-38.

Institution building should accompany the roll out of RIA as a reform process. Experience suggests embedding RIA in cabinet decision-making. Several countries have embarked on RIA with a purpose-built scrutiny institution, also known as an oversight body.³¹ Cross-country experiences over the last several decades have led to a closer integration of (ex-post) evaluation with (ex-ante) RIA. After all, RIAs are contingent on hypotheses about how an intervention will produce effects. It is necessary to test these hypotheses against real-world facts, controlling for the unintended consequences of the intervention. This is the Regulatory Governance Cycle vision or managing the whole life cycle of regulation. There are institutional attempts to connect evaluation and impact assessment – for example, by entrusting regulatory oversight bodies with functions of coordination and quality control across the whole Regulatory Governance Cycle.³²

Another example is to require regulators to evaluate first. Before work on a proposal and its RIA starts, officers have to provide an evaluation of the existing rules and their effects (this is a principle endorsed by the European Commission). Another example of institutional change is to alter the default condition of new rules: instead of assuming they will stay in the statute book indefinitely, “review clauses” stipulate that rules will be terminated unless positively evaluated.³³

Developing countries should also blend calculations of costs and benefits (which are by definition subject to margins of uncertainty when administrative capacity is limited) with design-thinking, which means giving priority to a user-centred approach and considering prototypes when designing new regulations. In other words, the capacity to analyse has to be accompanied with the capacity to listen and reflect on the concerns of society and stakeholders, which often point to unintended consequences.³⁴

Communication, or the lack thereof, is another implementation issue (see Text box 1). Complex analyses fail to be communicated efficiently to decision makers, legislators and stakeholders. For those reasons, some countries adopted one-page summary sheets with all necessary information that were signed by the chief economist (or officer with similar authority) to confirm that data generation and data analysis satisfy professional standards (see Figure 1). The summary page informs decision makers on the key steps and findings, reports

³¹ For example, when in 2003-2004 Serbia introduced RIA in the process of drafting legislation, it also activated a Council for Regulatory Reform to scrutinize regulatory impact analysis.

³² OECD, 2014, Op. Cit. Also: OECD, 2020, *Reviewing the Stock of Regulation*. Paris, OECD Publishing.

³³ Ranchordás, S., 2014, *Constitutional Sunsets and Experimental Legislation: A Comparative Perspective*. Cheltenham: Elgar.

³⁴ Allio, L., 2014, Op. Cit. On capacities see Dunlop, C., and C. M. Radaelli, 2016, "Policy Learning and Organizational Capacity" in Ongaro, E. and S. van Thiel (Eds.) *The Palgrave Handbook of Public Administration and Public Management in Europe*. Palgrave.

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on the impact on small business, sets a date for review and is signed off by the responsible government official. Good practice also requires the timely posting of RIAs on unified web portals, along with the draft measures they refer to, for the public to easily retrieve and comment upon.³⁵

Figure 1. Example of a one-page summary of an impact assessment

Title: The Future of UK Carbon Pricing Impact Assessment IA No: BEIS019(F)-19-HET RPC Reference No: N/A Lead department or agency: BEIS Other departments or agencies: HMT, DfT, DAs		Impact Assessment (IA) Date: 29/05/2020 Stage: Final Source of intervention: Domestic Type of measure: Secondary Legislation Contact for enquiries: emissions.trading@beis.gov.uk	
Summary: Intervention and Options		RPC Opinion: N/A	
Cost of Preferred (or more likely) Option (in 2019 prices)			
Total Net Present Social Value £66 to 92m	Business Net Present Value £-29 to -63m	Net cost to business per year £5 to 11m	Business Impact Target Status Not a qualifying provision
What is the problem under consideration? Why is government intervention necessary? The impact of greenhouse gases on climate change is a negative externality that arises from the market's failure to account for the wider cost to society and the environment when producing goods and services associated with these emissions. In the Climate Change Act 2008 (2050 Target Amendment Order 2019), the UK set a legally binding target of net zero emissions by 2050, to mitigate the negative impacts of climate change. The EU Emissions Trading System (ETS) is a key policy for reducing emissions in the power sector, energy intensive industries, and the aviation sector (the 'traded sectors'). Government intervention is necessary to ensure that emissions from sectors currently covered by the EU ETS continue to be covered by a carbon pricing policy following UK withdrawal from the EU.			
What are the policy objectives and the intended effects? The objective of the policy is to incentivise cost-effective emissions reductions for sectors currently in scope of the EU ETS, while balancing this ambition with the competitiveness of UK industry. As set out in the Clean Growth Strategy, our future approach will be at least as ambitious as the current EU ETS and will provide a smooth transition for all relevant sectors.			
What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base). Policy option: We assess the design of the UK ETS set out in the accompanying government response document, in its initial years of operation (from 2021 to 2024). This system is intended to fulfil the policy objectives outlined above as a standalone system, while also providing a platform to negotiate a linked system with the EU ETS, if it is in the best interests of both parties. Long-term ETS policy, including a linking agreement, is subject to ongoing negotiations with the EU and so quantitative analysis of this is not within scope of this IA. Counterfactual: The policy option is compared against a counterfactual of continued UK participation in the EU ETS in Phase IV of the system. This represents the main policy that would have covered greenhouse gas emissions in the traded sectors if the UK were to have remained part of the EU.			
Will the policy be reviewed? It will be reviewed. If applicable, set review date: Multiple dates from 2021.			
Does implementation go beyond minimum EU requirements?		N/A	
Is this measure likely to impact on international trade and investment?		Yes	
Are any of these organisations in scope?		Micro Yes	Small Yes
		Medium Yes	Large Yes
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)		Traded -2 to -3	Non-traded 0
<i>I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.</i>			
Signed by the responsible Minister, Kwasi Kwarteng: _____		Date: 7 December 2020	

³⁵ Malaysia: <https://upc.mpc.gov.my/>; Uzbekistan: <https://regulation.gov.uz/uz/>; and Jordan: <http://www.lob.jo>.

Methods of implementation

Although impact assessments vary by structure and depth, depending on the country and the likely effects of the intervention, international practice has consolidated around the steps portrayed in Text box 2.³⁶ In real-world practice, the steps are not strictly linear and sequential. The whole RIA process is an iterative analytical process. It is appropriate to step back to earlier stages with the insights gained from subsequent steps.

Text box 2. Regulatory impact assessment building blocks

1. Problem definition
2. Baseline measurement
3. Objectives and options
4. Decision-making criteria and intervention logic
5. Consultation
6. Data-gathering
7. Analysis and comparison of different options
8. Choice of an option
9. Limitations and uncertainty
10. Monitoring and evaluation

Early steps

RIA starts off with a dynamic situation analysis. Problem definition consists of the identification and definition of the problem, typically a market failure or the failure of previous regulatory interventions (such as compliance and enforcement problems). Baseline measurement quantifies the status quo and how the baseline may evolve in the future, absent any regulatory intervention or change. Objectives should be specific, measurable, achievable, realistic and timely.

The elaboration of feasible alternative options (including the option of not intervening, also known as the ‘do nothing option’) to achieve the objective brings about comparative thinking and limits tunnel vision. Consultation is both a data and information-gathering step and a component of open and transparent governance. As mentioned, this is the stage where decision makers can exploit the potential of RIA as a communication tool, and stakeholders

³⁶ OECD, 2012, *Recommendation of the Council on Regulatory Policy and Governance*, Paris, OECD Publications. On the analytical steps, see various official guides to RIA produced by government and multilateral institutions and Naundorf, S. and C. M. Radaelli, 2017, "Regulatory Evaluation Ex Ante and Ex Post: Best Practice, Guidance and Methods" in Karpen, U. and H. Xanthaki (Eds.) *Legislation in Europe: A Comprehensive Guide for Scholars and Practitioners*. Oxford: Hart.

can exploit its potential for accountability. Consultation is mostly beneficial when carried out at the early stage, when the minds of regulators are not set on a particular intervention option – the suggestion is to use advance notices of rulemaking and the possibility to comment on the evidence, models and data before the preferred regulatory option has been chosen.

Techniques

Data-gathering and analysis revolve around the choice of technique and decision-making criteria. Typically, costs are easier to characterize and quantify than benefits. Compliance cost assessment is a widely diffused technique. The Standard Cost Model is used for the identification and measurement of administrative burdens and direct compliance costs.

An important part of RIA is the comparison of options with each other and against the baseline scenario. Comparative methodologies include:

- Cost-effectiveness analysis. When the benefit is known or the target is fixed by the government or by an international organization, this technique identifies the most cost-effective way to reach an objective. To illustrate, the level of reduction of a chemical compound in water is often fixed by European Union regulations, and Member States have to find the most cost-effective way to achieve this reduction.
- Benefit-cost analysis. This is based on key performance indicators in monetary values that rank the options in terms of net benefits across economic sectors. In its most ambitious form, this technique takes into account dynamic effects and the impacts of productivity, innovation and trade.
- Multicriteria analysis. This is useful when options must be ranked according to different criteria.

Multicriteria analysis can assist countries on their SDG path, for example, by showing how two different options fare in terms of productivity, CO₂ reduction, impact on jobs, and gender. In a multicriteria context, decision makers can take the final step of choosing according to a criterion that is judged to be the most relevant, given the stage of development, needs and values of a country, effectively weighting a desired outcome or a combination of outcomes more than others.

No one methodology is superior *per se*. The choice of which methodology to apply depends on several factors, such as the purpose of the RIA and the availability of reliable data, expertise and time. Whatever the choice of technique may be, the analysis should always include information on uncertainty and estimated levels of compliance – too many RIAs work with the implicit (and unrealistic) assumption of 100 per cent compliance. In the response to the COVID-19 pandemic, many countries have launched ambitious recovery plans. In these cases, the analysis should pay particular attention to the impact on growth and innovation (beyond direct compliance costs affecting a given industry).

RIA in support of the SDGs

The SDGs can be operationalized in RIAs by embracing and integrating sustainability and environmental appraisals, poverty impact assessments, health impact assessments, social impact assessments, and gender appraisals.³⁷ Further, there are methodologies on how to integrate gender,³⁸ social effects,³⁹ energy,⁴⁰ agriculture⁴¹ and health⁴² in a single RIA template, although practice has not yet caught up with these methods. There is also evidence on how to enhance the participatory dimension of RIA by drawing on interpretive policy analysis, with the aim of reaching out to the whole of society.⁴³

Concretely, this may take shape in all steps. During the problem definition phase, SDG considerations should prompt RIA drafters to consider trends, trade-offs and synergies among the economic, social and environmental dimensions. Policy objectives should be set out by referring to SDG indicators and targets. When it comes to identifying and assessing the impacts of the various options, regulators should consider distributional effects (not just net benefits) – to achieve the goal of compassionate and equitable policies⁴⁴ where no one is left behind.⁴⁵ The unintended consequences on the SDGs should be taken into consideration when appraising options.

³⁷ The Edward Elgar Series on Research Handbooks on Impact Assessment edited by Frank Vanclay accompanies the Handbook on RIA to specialised Handbooks on: Sustainability Assessment, Biodiversity and Ecosystem Services; Human Rights; Strategic Environmental Assessment; and Cumulative Impact Assessment. <https://www.e-elgar.com/shop/gbp/book-series/economics-and-finance/research-handbooks-on-impact-assessment-series.html>

³⁸ On gender see Gains, F., 2017, “*Gender and RIA*” in Dunlop, C. and C. M. Radaelli, Eds. Handbook of Regulatory Impact Assessment. Staronova, K., et al., 2017, “*Making regulatory impact assessment gender sensitive: The case of the Czech Republic and Slovakia.*” *Transylvanian Review of Administrative Sciences* 51, pp. 89-105.

³⁹ Schrefler, L., 2017, “*Social Impact Assessment*” in Dunlop, C. and C. M. Radaelli, Op. Cit. Vanclay, F., 2003, “*International principles for social impact assessment*” in *Impact Assessment and Policy Appraisal*. 21(1), pp. 5-12. Vanclay, F., 2020, “*Reflections on social impact assessment in the 21st century*” in *Impact Assessment and Project Appraisal*. 38(2), pp. 126-131.

⁴⁰ Torriti, J., 2017, “*Energy*” in Dunlop, C. and C. M. Radaelli, Op. Cit.

⁴¹ Russel, D., 2017, “*Agriculture*” in Dunlop, C. and C. M. Radaelli, Op. Cit.

⁴² On health impact assessment and the SDGs see: Green, L., B. Gray and K. Ashton, 2020, “*Using health impact assessments to implement the sustainable development goals in practice: a case study in Wales.*” *Impact Assessment and Project Appraisal*. 38(3), pp. 214–224.

⁴³ Palmer, J., 2017, *Interpretive Analysis and Regulatory Impact Assessment* in Dunlop, C. and C. M. Radaelli, Op. Cit.

⁴⁴ Dudley, S., 2021, Op.Cit.

⁴⁵ In the United States, Executive Order 13563 asks federal executive agencies to consider equity, human dignity, fairness and distributive impacts, even if these dimensions cannot be described in monetary terms. <https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review>

Making RIAs smarter

Artificial intelligence and big data can overcome some classic limitations of data generation and make RIAs smarter. They can be deployed to avoid classic command-and-control regulation and instead nudge citizens and firms towards the desired outcomes.⁴⁶ However, this potential comes with caveats in terms of privacy and regulatory paternalism. Big data also find many possible correlations in wide data sets, but large data sets typically show correlations that are misleading.

Another way to overcome data problems is to build a repository of data that has been gathered over time by previous impact assessments. Existing RIAs often contain a mix of consultation-generated data and data gathered by departments and/or independent regulators with a stated purpose (that is, to carry out a specific RIA), but this data should be recycled. In fact, repositories of RIA data could be recycled to generate confidence intervals and approximations in future RIAs. For example, the compliance costs of a new regulation affecting a particular sector may be approximated via existing compliance costs data gathered in previous RIAs on sectors that are somewhat comparable to the target sector.

Criteria

Decision-making criteria range from basic minimization of administrative costs to more complex criteria such as a higher net present value among the chosen options. Good practice suggests maximum transparency on the limitations and uncertainty of the analysis. RIAs may give a false sense of certainty when it is publicly known that the data available to governments are far from high standards or reliability. One way to test for the robustness of the conclusions is a sensitivity analysis – a leading author has published freely accessible detailed guidance [here](#).

Monitoring and evaluation

A robust RIA should show how the preferred option will be monitored and evaluated – the review clauses mentioned above are cases in point. Lacking precise information about how the regulation will be monitored, it is impossible to close the policy cycle.⁴⁷ Several countries

⁴⁶ On nudging and RIA, see the examples in Sunstein, C. R., 2013, *Simpler: The Future of Government*. Simon and Schuster. Dunlop, C. and C. M. Radaelli, 2015, "Overcoming Illusions of Control: How to Nudge and Teach Regulatory Humility" in *Nudging and the Law What Can EU Law Learn from Behavioural Sciences?*, eds. A. Alemanno and A.L. Sibony. London: Hart, pp. 139-57. Dudley, S. E. and Z. Xie, 2020, Op. Cit.

⁴⁷ Regulatory Policy Committee, 2020, *Impact Assessments: Room for Improvement?* London, Regulatory Policy Committee: <https://www.gov.uk/government/publications/impact-assessments-room-for-improvement>
OECD, 2020. *Reviewing the Stock of Regulation*. Paris: OECD Publishing.

have embedded RIA within an overall plan for the retrospective review of existing regulations. Finally, many governments have committed to an overall, multi-year, regulatory cost target.⁴⁸

Case studies

Launched in 2017, the World Bank's [Global RIA Awards](#) initiative is a transnational platform open to 45 of the World Bank's 154 developing and transitional client countries that currently use RIA. The 2017 edition produced a shortlist of 21 entries. The Awards include three categories: 'influential RIAs', won by Armenia; 'data innovation in RIA', won by Brazil; and 'regulatory alternatives', won by Bosnia and Herzegovina.

A good case to learn from is the Brazilian award-winning RIA carried out by the National Institute of Metrology, Quality and Technology (INMETRO). Whenever a technical regulation sets out a conformity assessment procedure for a product, the manufacturers of that product must follow that procedure and gain a certification by a laboratory. The labs must be accredited by INMETRO. The product then carries the safety certification and can be sold. In the case examined by the award-winning RIA (cycling helmets), the issue was the lack of compulsion for the labs to gain accreditation from INMETRO for new conformity assessment procedures.

There are four main lessons in this case. First, RIA-as-process challenged the initial assumptions and beliefs about the need to intervene with classic regulation in the case of cycling helmets. The process led INMETRO to choose an information campaign instead of binding rules (because the delivery chain would not have supported mandatory rules). This shows the potential of RIA to draw attention to non-regulatory interventions that still achieve the desired objectives by changing the information available. Second, gathering evidence was extended to include data from outside the public administration. Inputs were sought and received from companies, testing laboratories, university researchers and stakeholders. INMETRO gathered data on consumers' perceptions of risk through a survey. Third, although the process was already at the stage of policy formulation, regulators had to address questions of delivery, monitoring and compliance. Key to the INMETRO case were the following questions: How will a binding regulation be delivered? What are the hypotheses about compliance? Does the delivery chain appear robust enough to achieve the objectives? Are there enough laboratories to provide accreditation for the manufacturers?⁴⁹ Thinking

⁴⁸ Trnka, D. and Y. Thuerer, 2019, "One-in, X-Out: Regulatory Offsetting in Selected OECD Countries." In *Secondary One-in, X-Out: Regulatory Offsetting in Selected OECD Countries*. OECD Regulatory Policy Working Papers, No. 11, Paris: OECD Publishing.

⁴⁹ The RIA is mentioned in Adelle, C., et al., 2015, Op. Cit.

about compliance and delivery at the stage of policy formulation is not an auxiliary step, it is fundamental.⁵⁰ Fourth, with regard to communication, the RIA contained visualizations and cartoons that were easy to read and understand.

Dunlop and Radaelli's Handbook of Regulatory Impact Assessment (2017) provides chapters on Australia, the European Union, Latin America, New Zealand, South Korea and the United States, and chapters on cross-national diffusion and implementation. The [OECD regulatory reviews](#) are essentially single-country studies of how governments have designed and managed RIA systems (as opposed to case studies of individual RIAs). These OECD reviews cover Argentina (2019), Brazil (2008), Chile (2016), Colombia (2013), Kazakhstan (2014), Indonesia (2012) and Peru (2016).⁵¹ The [World Bank](#) has shared original information and field observations on RIA implementation in Botswana (2013-2014), Cambodia (2008-ongoing), Kenya (2009-2013) and Uganda (2004-2007), as well as providing cross-cutting lessons.

Georgia is in the process of implementing RIAs. It illustrates how to make RIA 'stick' by combining it with capacity building, communities of practice, and detailed guidance. In Georgia, the strategy is to connect RIA explicitly to the achievement of the SDGs.⁵² RIA has therefore been adapted to meet the requirements of the 2030 Agenda.⁵³

Peer-to-peer learning and research

Networks

In contrast to the networks and professional communities developed around policy evaluation, RIA communities are less organized, with the [International Association for Impact Assessment](#) being the exception. This organization provides videos, publications and training material on every type of appraisal, be it project appraisal or RIA. Although less developed than in the field of policy evaluation, there is an international market offering training, including Masters' courses.⁵⁴ Evaluation societies (national as well as regional, such as the [European Evaluation Society](#)) occasionally deal with RIA although their main focus is on the evaluation of existing interventions.

⁵⁰ Macrae, D., 2017, "Compliance and Delivery Analysis" in C.A. Dunlop and C.M. Radaelli, Op.Cit.

⁵¹ On RIA specifically, see OECD, 2017, Chile Evaluation Report: Regulatory Impact Assessment. Paris: OECD Publications. <http://www.oecd.org/gov/regulatory-policy/Chile-Evaluation-Full-Report-web.pdf>

⁵² Federal Ministry for Economic Cooperation and Development, 2019, *A sustainable path to the future*. Available [here](#). See p.16.

⁵³ The project involves the whole region of South Caucasus: <https://www.giz.de/en/worldwide/20313.html>

⁵⁴ Allio, L., 2016, "Implementing in the classroom: Teaching regulatory impact assessment" in Handbook of Regulatory Impact Assessment, eds. C. A. Dunlop and C. M. Radaelli. Cheltenham: Elgar.

Advocacy

Among the most visible advocacy organizations with a critical view of better regulation are the [Corporate Europe Observatory](#) and the [Center for Progressive Reform](#), in particular see the page on [regulation](#).

Policy institutes and academic research

- Centre for Analysis of Risk and Regulation ([CARR](#)) provides interdisciplinary research on all aspects of regulatory policy.
- Centre for European Policy Studies ([CEPS](#)) is a European think tank with a division on Regulatory Affairs.
- Standing Group on Regulation & Governance ([ECPR](#)) has a mailing list with thousands of researchers and practitioners that debate issues of regulatory analysis (inclusive but not limited to RIA).
- The European Regulation and Innovation Forum ([ERIF](#)) has defined the [innovation principle](#) and its application to RIA. The Forum publishes briefing notes on risk regulation.
- The George Washington University's [Regulatory Studies Center](#) provides research and news on regulatory policy in the United States.
- The [International Association of Legislation](#) covers all features of good legislative practice, including drafting, consultation and impact assessment.
- [Penn Program on Regulation](#) is a hub for research on regulation. It publishes the [Regulatory Review](#).
- School of Regulation and Global Governance ([RegNet](#)) of the Australian National University publishes research on regulation in diverse fields such as climate, energy, safety, health, trade, investment, intellectual property and human rights.
- The United Nations Environment Programme developed a methodology to measure progress towards SDG 17 that covers mechanisms of policy coherence. Among these mechanisms are consultations, benefit-cost analysis of policy impacts across sectors, and impact appraisals.⁵⁵
- Researchers have surveyed comprehensively the methods to appraise individual RIAs, such as the scorecards developed in the Handbook of Regulatory Impact Assessment.⁵⁶

⁵⁵ United Nations Environment Programme, *Methodology for SDG Indicator 17.14.1: Mechanisms in place to enhance policy coherence for sustainable development*. New York, United Nations.

⁵⁶ Fritsch, O. and J. C. Kamkhaji, 2016, "Implementing in the Laboratory: Scorecards for Appraising Regulatory Impact Assessments" in Handbook of Regulatory Impact Assessment, eds. C. A. Dunlop and C. M. Radaelli. Cheltenham: Elgar.

International development cooperation

The World Bank organizes training and capacity-building programmes throughout the world and assists governments in the review of their rule-making processes. Several RIA guides that are available in developing countries have been prepared with the assistance of the World Bank and its consultants.

The [Better Regulation Toolbox](#) of the European Commission contains 65 tools that range from the impacts on small and medium enterprises (Tool 22) to the impact of European Union policies on developing countries (Tool 34) and the standard cost model (Tool 60). Together with other institutions, the European Commission offers support for regulatory reforms to countries aiming to joining the European Union (see [DG Reform](#) and [SIGMA](#)).

Multilateral organizations, such as the Inter-American Development Bank, the Asian Development Bank and the OECD, are increasingly engaged in better regulation and RIA capacity building.

The OECD Council has endorsed RIA in its Recommendations on Regulatory Policy and Governance.⁵⁷ The Paris-based organization is a main producer of research and advice on RIA and its institutional dimension, as well as the previously mentioned regulatory reviews. The OECD Regulatory Policy Committee has been active since 2009. With the assistance of a dedicated Secretariat, this OECD body has helped to collate and disseminate RIA good practices. The OECD has also published guidance on specific RIA techniques – an example is the [Toolkit for Behavioural Insights](#). The OECD [Network of Economic Regulators](#) is a forum for dialogue and sharing of best practices across countries and sectors.

Among the departments for international cooperation and development, the [German Ministry for Economic Cooperation and Development](#) offers programmes to integrate the SDGs in the development of legislation. Its work on SDG-oriented impact assessment is **valuable** for other neighbouring countries. Several countries (for example the [United Kingdom](#)) and the [European Commission](#) have published extensive guidance material (see the United States' influential [Circular A4](#)) and repositories of existing RIAs. The opinions on individual RIAs of the regulatory oversight bodies, when public, are rich in detail about how to improve on the evidence base for new proposals. In the case of the European Union, the oversight body published opinions on RIA and [retrospective evaluations](#) of regulations. All United States' executive orders and “good practices” are available on the site of the [Office for Information and Regulatory Affairs](#). The standard cost model network has made available its handbook on how to calculate administrative burdens, which is hosted on the [OECD portal](#). The Australian

⁵⁷ OECD, 2012. *Recommendations of the Council on Regulatory Policy and Governance*. Paris: OECD Publications.

Government's [Productivity Commission](#) promotes integrated thinking for regulatory policy, innovation and growth. Eight oversight bodies gather in [RegWatch Europe](#) and publish opinions on the scrutiny of RIA and the methods available.

As mentioned above, regulatory performance indicators are published by the [World Bank](#) and the [OECD](#). OECD indicators allow for comparison across time because they have been collected in different waves over the years. They also cover a selection of [Latin American countries](#).

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