Chapter I
Better regulation in the Commission

1.   INTRODUCTION

European policies and legislation impact the lives of the Union's 500 million inhabitants and its millions of companies. A substantial body of legislation now exists and this legislation must continue to keep pace with evolving political, societal and technological developments. The European Commission has a key role in this regard given its right to initiate new legislation and its responsibility to ensure the correct application of Union law. EU action must lead to a simple, clear, stable and predictable regulatory framework for businesses, workers and citizens that continue to add value as problems evolve, new solutions emerge and political priorities change.

The European Commission is determined, therefore, to ensure that its proposals meet policy goals at minimum cost and deliver maximum benefits to citizens, businesses and workers while avoiding all unnecessary regulatory burdens. This is key to support growth and job creation – allowing the EU to ensure its competitiveness in the global economy - while maintaining social and environmental sustainability.

Determining when and how EU action should be undertaken, reviewed or repealed is ultimately a political choice. The quality of these choices, however, can be improved if better regulation principles and practices are followed when preparing, implementing and evaluating policies, measures and financial programmes.

Box 1. How to apply these Guidelines

- The Guidelines and associated better regulation "Toolbox" should be applied in a proportionate manner using common sense. The aim is not to respect procedural requirements per se but to ensure that the Commission is equipped with relevant and timely information on which to base its decisions. Similarly, the depth of analysis should reflect the significance of the impacts or effects of the initiative or intervention.

- The main Guidelines set out the mandatory requirements and obligations for each step in the policy cycle while the Toolbox provides additional guidance and advice which is not binding unless expressly stated to be so. Exceptions to these requirements are possible but must validated and justified externally.

- There may be cases where it is not possible or appropriate to follow each step in the Guidelines. For example, a special regime applies to the Commission's proposals for a Council decision to implement social partners' agreements under Article 155 TFEU due to the role and autonomy entrusted by the Treaty to the social partners. In other cases, there may be a political imperative to move ahead quickly, an emergency that requires a rapid response, a need to adhere to specific deadlines in legislation which cannot be respected on the basis of a normal planning or a need to protect security-related or confidential information.

- For major initiatives, exceptions from the Guidelines can be requested at the time the initiative undergoes political validation (via D*e*cide). For other initiatives (and for cases arising after validation), requests for exceptions should be sent to the Director responsible for smart regulation in the Secretariat-General who will decide in consultation with the First Vice-President. The following functional mailbox should be used for such requests: SG-BETTER-REGULATION-EXCEPTIONS@ec.europa.eu

- Whenever relevant, the agreed approach should be externally communicated together with a justification and an explanation of the efforts made to respect the spirit of the Guidelines (typically through the final roadmap or inception impact assessment). The Toolbox provides more information on exceptions.

- Questions about their interpretation or application can be obtained from the responisble units in the Secretariat-General using the functional mailboxes below:

Aspects of better regulation	Functional mailbox
Planning	SG-PLANNING@ec.europa.eu
Evaluation & fitness checks	SG-EVALUATION-AND-SIMPLIFICATION@ec.europa.eu
Impact assessment	SG-IMPACT-ASSESSMENT-GUIDELINES@ec.europa.eu
Stakeholder consultation	SG-STAKEHOLDER-CONSULTATION@ec.europa.eu
Feedback mechanisms	SG-STAKEHOLDER-FEEDBACK@ec.europa.eu

- To avoid undue delays and to maximise the quality of outputs, the efficient application of these guidelines requires a constructive and timely collaboration between the lead service, the Secretariat-General and those services included in interservice groups.

- The Secretariat-General will continuously monitor the impact of the better regulation Guidelines and propose, if needed, ways to eliminate any source of administrative burden or undue procedural delay based on experience. Any such review will not endanger the respect of the better regulation principles identified in these Guidelines and in the Commission Communication 'Better regulation for better results – An EU agenda'.[1]

These Guidelines explain what better regulation is and how it should be applied in the day to day practices of Commission officials preparing new initiatives and proposals or managing existing policies and legislation. The Guidelines should be read by all officials involved in regulatory activities and managers who are responsible for quality control and the allocation of resources within Commission departments. Better regulation cannot be implemented without dedicated financial and human resources; DGs must ensure that appropriate centres of expertise (or functions) and training are available to support the proper implemention of the various aspects of better regulation.

2. WHAT IS BETTER REGULATION?

"Better regulation" means designing EU policies and laws so that they achieve their objectives at minimum cost. Better regulation is not about regulating or deregulating. It is a way of working to ensure that political decisions are prepared in an open, transparent manner, informed by the best available evidence[2] and backed by the comprehensive involvement of stakeholders. This is necessary to ensure that the Union's interventions respect the overarching principles of subsidiarity and proportionality i.e. acting only where necessary at EU level and in a way that does not go beyond what is needed to

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[1] COM(2015)215

[2] The Commission has a policy on data, information and knowledge management which helps support policymaking by maximising the use of data (SWD(2016) 333). In this context, the EU Open Data Portal is important as a source and repository of open data.

resolve the problem. Better regulation also provides the means to mainstream sustainable development into the Union's policies.

Better regulation applies to new and to existing initiatives. Through evaluations and other means, the Commission is constantly collecting and analysing information about the performance of the Union's policies. The aim is to ensure that objectives continue to be met without imposing unnecessary costs on society. As such, any proposal to revise existing legislation must look at whether there is potential to simplify and to reduce regulatory costs but without undermining the aims or benefits of the legislation. Where no simplification or cost reduction is possible, this must also be reported. The Commission's Regulatory Fitness programme (REFIT) provides a framework for this work.

Better regulation covers the whole policy cycle – policy design and preparation, adoption, implementation (transposition, complementary non-regulatory actions), application (including monitoring and enforcement), evaluation and revision. For each phase of the policy cycle, there are a number of better regulation principles, objectives, tools and procedures to make sure that the EU has the best policy possible. These relate to planning, impact assessment, stakeholder consultation, implementation and evaluation.

Figure 1. The EU Policy cycle
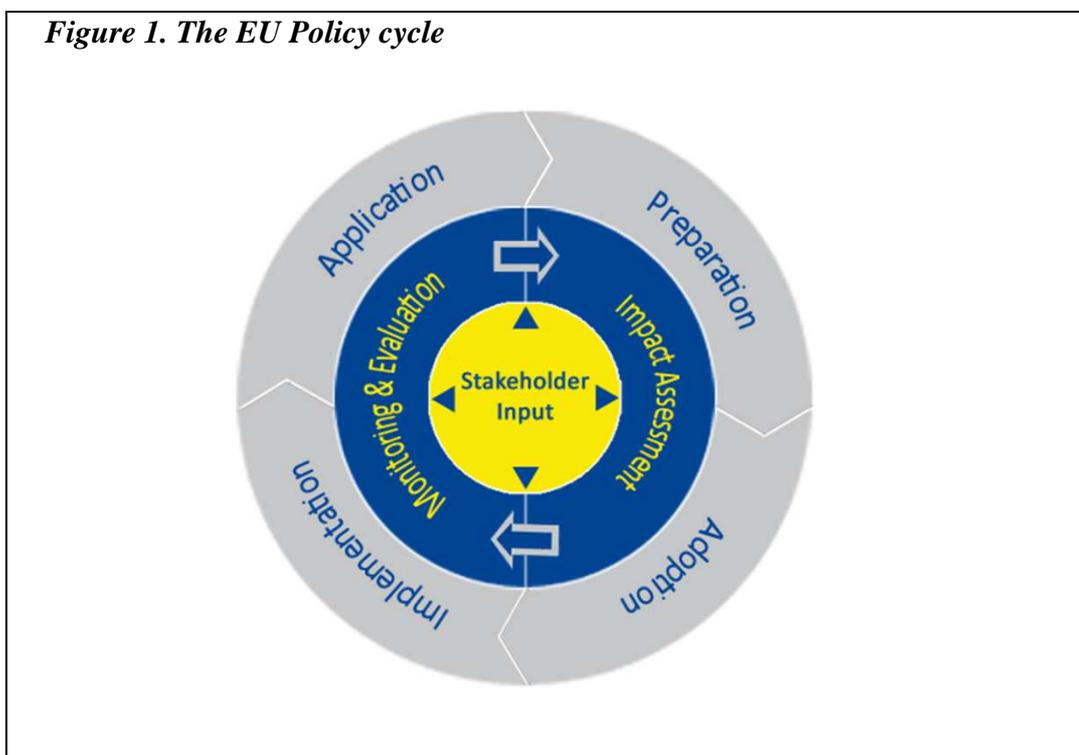
The different phases are closely interrelated and to recognise better the connections and to ensure greater coherence, the previously separate guidance documents have been brought together into a single streamlined and integrated better regulation guide. These Guidelines replace the previous standalone guidelines which addressed separately impact assessment, evaluation, implementation and also include new guidance on planning and stakeholder consultation[3].

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[3] These guidelines confirm and further define the general rules on how Commission services should consult set out in the 2002 Commission Communication *Towards a reinforced culture of consultation and dialogue - General principles and minimum standards for consultation of interested parties by the*

Better regulation is a shared commitment of all of the EU institutions. An Interinstitutional Agreement on Better Law-Making[4] was signed by the European Parliament, the Council and the Commission on 13 April 2016. It replaces the previous agreement from 2003 and the interinstitutional accord on impact assessment from 2005. The agreement addresses annual and multi-annual programming as well as all aspects of the policy cycle. The agreement sets out the various commitments of the three institutions to deliver high-quality Union legislation which is efficient, effective, simple, clear and which avoids overregulation and administrative burdens for citizens, public authorities and businesses, especially SMEs. More detailed information has been prepared to guide its implementation in the Commission.[5]

3.   HOW TO REGULATE BETTER? - THE ESSENTIALS

3.1.   Forward planning and political validation

Good regulation starts with good planning. Work should focus on the Commission's priorities as reflected in the President's political guidelines[6] and the Commission's annual work programmes[7]. Good planning covers the initial consideration of an initiative within the Commission and the organisation of the supporting processes – the evaluation of policies already in place, the assessment of problems and alternative solutions, the active engagement with stakeholders and the preparation of initiatives including translation[8]. These activities take time, need resources to deliver timely results and require a level of political validation proportionate to the nature of the initiative under consideration.

The first step in the planning process is therefore to define the scope of the planned initiative and seek the appropriate level of political validation to develop the idea further. D*e*cide is the main planning tool used in this process[9]. The details on which initiatives must be uploaded in D*e*cide, and on which validations are required, are provided in the instructions of the Secretary-General[10] which complement the Working Methods of the European Commission 2014-2019.[11] They are outlined in detail in Chapter II on Planning and in the associated Toolbox.

Commission COM(2002) 704 final, complemented by COM(2012) 746 and accompanying SWD(2012) 422 and by COM(2014) 368.

[4]   OJ L 123, 12.5.2016, p.1.; http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2016:123:TOC

[5]   https://myintracomm.ec.europa.eu/sg/better_regulation/Pages/IIABL.aspx

[6]   http://ec.europa.eu/priorities/docs/pg_en.pdf

[7]   http://ec.europa.eu/atwork/key-documents/index_en.htm

[8]   Communication (2016) 2000 describes the role of translation in the Commission's decision-making process including the limits on document length and translation deadlines.

[9]   D*e*cide is the Commission's IT platform for managing the preparation of initiatives.

[10]   https://myintracomm.ec.europa.eu/sg/comcab/pages/methods.aspx

[11]   C(2014)9004; http://ec.europa.eu/transparency/regdoc/rep/3/2014/EN/3-2014-9004-EN-F1-1.Pdf

Box 2. Scoping, political validation and interservice work

- **Political validation** is required to move beyond the informal consideration of a possible initiative and to start the substantive prepatory work including engagement with stakeholders.

- The level of political validation depends on the nature and importance of the inititiave. **"Major initiatives"** should, in principle, be entered into D*e*cide at least 12 months prior to adoption by the College. They must be validated by the lead Commissioner, relevant Vice-President and the First Vice-President before being accepted to be included into the Commissions' planning. "Other initiatives" should be validated by the lead Commissioner or by the Director-General of the lead DG as appropriate.

- Political validation must be understood as giving the green light to start the substantive preparatory work. It should not be interpreted as a decision on a particular initiative or course of action that prejudges the outcome of any impact assessment process, stakeholder consultation or later political discussion in the College.

- For major initiatives and for evaluations (including fitness checks), once political validation is granted, **roadmaps** or **inception impact assessments** must be finalised and published as quickly as possible. They explain to external stakeholders what the Commission is considering and allow them to provide early feedback.

- **Roadmaps** are used for initiatives which do not require an impact assessment. The reasons justifying the absence of an impact assessment will be included.

- **Inception impact assessments** are used for initiatives subject to an impact assessment. These set out in greater detail the description of the problem, issues related to subsidiarity, the policy objectives and options as well as the likely impacts of each option.

- A roadmap is prepared for each **evaluation or fitness check**. This specifies the context, scope and purpose of the evaluation and outlines the proposed approach.

- All roadmaps (including for evaluations and fitness checks) and inception impact assessments are published by the Secretariat-General on the Commission's website[12] so that citizens and stakeholders are informed and can provide initial feedback (including data and information they may possess) on all aspects of the intended initiative and where applicable its impact assessment.

- Evaluations, impact assessments, stakeholder consultations, policy proposals and implementation plans must be discussed collectively by the services[13] within **an interservice group**. It is important that all services with an interest participate actively in the interservice work from the outset, particularly those DGs with specific expertise (e.g. competitiveness and innovation, SME impacts, economic, social impacts, environmental impacts and scientific/analytical methods).

- The launch of the interservice consultation must be agreed politically (in a similar way to the validation of new initiatives). In addition, where an initiative is supported by an

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[12] http://ec.europa.eu/info/law/better-regulation/initiatives

[13] See also art 23 of the Rules of Procedures of the Commission *Cooperation and coordination between departments*: http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1427880050708&uri=URISERV:o10004

impact assessment, a positive opinion of the Regulatory Scrutiny Board is required in order for the initiative to be presented to the Commission for decision.

3.2. Stakeholder consultation

Stakeholder consultation is an essential element of policy preparation and review. Good policy development is built on openness. Stakeholder inputs provide feedback and evidence to support evaluations, impact assessments, the preparation of initiatives and political decisions. It is good practice to plan stakeholder consultations using a simple, concise consultation strategy that identifies and targets relevant stakeholders with a range of conultation activities in order to gather all relevant evidence comprising data/information and views.

It is important to consult as early and as widely as possible in order to maximise the usefulness of the consultation and to secure an inclusive approach where all interested parties have the opportunity to contribute to the timely development of effective policies. Consultation activities should allow reasonable time for respondents in order to encourage informed and effective contributions from all relevant stakeholders. Feedback should be given to respondents about how their information and views were used. Public consultation is an essential element of all impact assessments, evaluations and fitness checks.

3.3. Evaluation/fitness checks

Policy preparation should be supported by both evaluations and impact assessments. Both look at how a problem is, or should be, addressed (and its underlying causes) to achieve the desired objectives taking account of costs and benefits. Both are based on an integrated approach that addresses impacts across the environmental, social and economic pillars of sustainable development and so contribute to the mainstreaming of sustainability in policymaking at the Union level.

Evaluations gather evidence to assess how a specific intervention has performed (or is working), taking account of earlier predictions made in the context of an impact assessment and whether there were unintended/unexpected effects which were not anticipated by the impact assessment or the act agreed by the Legislator. An evaluation also draws conclusions on whether the EU intervention continues to be justified or should be modified to improve its effectiveness, relevance and coherence and/or to eliminate excessive burdens or inconsistencies or simply be repealed.

A fitness check is a comprehensive evaluation of a policy area that usually addresses how several related legislative acts have contributed (or otherwise) to the attainment of policy objectives. Fitness checks are particularly well-suited to identify overlaps, inconsistencies, synergies and the cumulative impacts of regulation.

It is important to monitor the impacts flowing from the implementation and application of the legislation in order to allow both Member States and the Commission to undertake a meaningful evaluation of the intervention at a future point in time. If there is no useful monitoring information, it will be difficult to evaluate the intervention appropriately and to rectify any problems or improve the delivery of the desired results.

3.4. Impact assessment

Impact assessments collect evidence (including results from evaluations) to assess if future legislative or non-legislative EU action is justified and how such action can best be

designed to achieve desired policy objectives. An impact assessment must identify and describe the problem to be tackled, establish objectives, formulate policy options, assess the impacts of these options and describe how the expected results will be monitored. The Commission's impact assessment system follows an integrated approach that assesses the environmental, social and economic impacts of a range of policy options thereby mainstreaming sustainability into Union policymaking.

3.5. Quality control

Staff working documents (SWD) are required to present the results of all impact assessments and evaluations/fitness checks.

The quality of these staff working documents is checked by the Regulatory Scrutiny Board (RSB) who will assess all impact assessments and fitness checks and selected evaluations. The Board issues opinions based on the requirements of these Guidelines. DGs are expected to modify their reports to reflect the Board's opinion. For initiatives supported by impact assessments, the Commission's working methods stipulate that a positive opinion is needed from the Board before an interservice consultation can be launched. The interservice consultation should check how the Board's comments have been integrated and should also check the quality of the drafting of the initiative/legal proposal (see Chapter IV).

3.6. Implementation support and monitoring

The full benefits of an EU intervention will only be delivered if the policy is implemented and applied appropriately. Similarly, burdens for business may be increased beyond what is foreseen by the legislation if the Member States impose additional obligations (so-called "gold-plating") or implement the legislation inefficiently. That is why it is essential to take into account implementation and enforcement issues when designing an EU intervention including the impact assessment process and associated stakeholder consultation. It is also important to identify ways to assist Member States in the transposition phase (aligning national legislation with EU legislation) by preparing 'implementation plans' (in the form of a SWD) which should also be subject to interservice consultation together with the impact assessment and the proposed intervention. Checks on transposition and assessments of compliance are also key tools used to monitor the correct application of EU legislation.

4. THE STRUCTURE OF THE GUIDELINES

The better regulation Guidelines are structured into separate chapters which cover

- Chapter II: Planning

- Chapter III: Impact assessment;

- Chapter IV: Implementation;

- Chapter V: Monitoring;

- Chapter VI: Evaluation and fitness checks;

- Chapter VII: Stakeholder consultation.

The Secretariat-General is responsible for the preparation of the better regulation Guidelines. Individual DGs and services with particular expertise in the field of better regulation may also make additional materials available to those preparing evaluations, fitness checks, impact assessments and stakeholder consultations via their respective web sites.