



REPORT 1.2.1: RECOMMENDATIONS FOR A NEW INSTITUTIONAL AND LEGAL SYSTEM OF RIA IN ROMANIA*

Report prepared in the framework of the World Bank Project “**Strengthening the Regulatory Impact Assessment Framework in Romania**”

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EXECUTIVE SUMMARY

I. **This report follows up with the diagnosis of the weaknesses and gaps of the current system for regulatory impacts in the Government of Romania (GoR), as presented by the Report 1.1.1 “Current Gaps of the RIA System in Romania”.**

II. **The report builds upon two main assumptions. The first one is that RIA has a double nature.** While it finds expression in an analytical report that supports decision-makers, the notion of RIA should be understood more widely as an integral part of the regulatory reform program, embracing an institutional, organizational and procedural dimension. RIA is very much a process of evidence-based decision-making.

III. **The second assumption is that Copernican revolutions are not necessarily a panacea when it comes to regulatory and administrative reform.** In the framework of the project especially, there is clear merit in considering a longer term perspective that also builds on existing positive features. A system of evidence-based decision-making is already in place within the Romanian Government, with routinized procedural practices whose dismantlement and substitution would probably be more costly than proceeding to targeted incremental improvement. The recommendations formulated in this report seek moreover to capitalize on past initiatives and to increase the scope of synergies and economies of scale.

IV. **Against this backdrop, the report contains elements which should help design a framework that the GoR may consider when designing a comprehensive reform strategy for enhanced Substantiation Note (SN) practices.** The overarching goal of such a reform strategy should be to enhance predictability; transparency and accountability; consistency and rationalization; as well as effectiveness and proportionality.

V. **Two specific lines of action are presented:** the revision of the organization and process for SN in the central public administration; and the upgrading the analytical capacity for SN.

Designing a new Substantiation Note system in Romania

VI. **The revision of the current organization and the process that underpins and governs the production of the SNs are the first main line of action of the reform.** The recommended changes follow a five-fold rationale:

- **To bring the evidence-based reasoning back to the center of Government action;**
- **To make the SN process feasible and manageable** by introducing a proportionate scope of application;
- **To enhance public consultation and publication practices** to ensure richer evidence collection and validation and incentivize continued quality improvements;
- **To reinforce the central steering and oversight function on SNs;** and
- **Mainstreaming internal coordination and consultation,** notably in cases of “high impact” proposals so as to create ownership within government for relevant decisions.

VII. **Accordingly, the GoR may consider structuring the new SN system along the following stages:**

- **Grounding SN to the Government Annual Work Plan (GAWP),** to increase systematicity, predictability and rational allocation of resources;

- **Applying exclusion and exemption criteria to first filter Government initiatives, which will not be subject to an impact analysis.** The exclusion criteria should be exhaustively specified in relevant legal bases, while the decision to exempt an initiative from a SN should pertain to the Prime Minister upon proposal of the responsible line minister;
- **Determining the magnitude of the impacts by applying the “triage” mechanism.** As a result, items will be classified into “low impact”, “medium impact” and “high impact” initiatives. The responsibility for carrying out the triage lies with the ministry(-ies) responsible for the initiative, following established, public criteria. In all cases, an impact analysis must be produced in accordance to the guidelines and the template established by the new legal base.

VIII. **A new process of producing the analysis, differentiating three approaches according to the magnitude of impacts is outlined.** Following the principle of proportionality, the administrative procedures and requirements are lighter for lower impact and more complex for high impact initiatives. The main differences include:

- **SN study.** A more comprehensive SN study (instead of merely filling the SN template) will have to be produced for high impact initiatives;
- **SN Working Group.** This shall be convened by the SN initiator for those high impact initiatives, which the Inter-Ministerial Committee for coordination of elaboration and implementation of GAWP determines as having cross-portfolio implications;
- **Internal and public consultation on the SN.** Unlike in the case of low impact initiatives, the initiating line ministry must organize both internal consultation and a public consultation exclusively focused on the draft SN; and
- **The central quality appraisal also varies.** While no specific new feature is introduced for low impact initiatives, a procedural and a substantial screening by DCPD is required for medium and high impact initiatives, respectively. After having performed the central scrutiny, DCPD will issue an opinion addressed to the department drafting the analysis for revision.

IX. **In the case of medium and high impact initiatives, ministries start drafting the acts to be submitted to Government for formal adoption only after considering the opinion on the SN or SN study issued by the DCPD.** This will ensure that proportionality is better applied and quality control can properly be exerted.

X. **Irrespective of the type of initiatives under preparation, once the draft legal act is produced, the process basically follows the same requirements and stages, as it is currently the case.** In the new system, publication will include keeping record of the SN process in a single portal administered by DCPD.

XI. **The report identifies a number of amendments to existing legal provisions that appear to be necessary, should the proposed innovative elements be applied.** The amendments are summarized in Table 1.

Enhancing the quality of the analyses

XII. **The second line of action in the reform strategy for improved SN pertains to increase the quality of the analyses produced.** To that end, the report envisages three levels of intervention:

- **The simplification of the SN template.** The SN Template is the document that needs to be filled in when preparing any initiative that is expected to be adopted by Government (except in cases of exclusion or exemption). For high impact initiatives, as resulted from applying the triage filter, the SN Template will constitute the Executive Summary to be attached to the more comprehensive SN Study. The current model provided for by Government Decision 1361/2006 is not wrong *per se*, but it may not be the most instrumental tool to assist the SN drafter. Annex 2 to this report provides a possible streamlined format.
- **The rationalization and upgrade of the underlying a SN Guidelines.** At present, several guidance documents exist that pertain to the preparation of SN in the decision-making process. The legal and operational nature of each individual guidance document is not clear. Ministries have de facto relative discretion in considering whether and when to use one source of support as opposed to others. It is therefore recommended that everybody be on the same page, taking account of both the new SN system and the new SN Template. The Guidelines reported in Annex 3 are specifically meant to assist SN drafter when they have to fill in the SN Template.
- **The development of a systemic capacity-building program.** Capacity building through training is a necessary element of the reform. In this respect, there is a wide tank of resources from initiatives over the past years that need to be capitalized upon. A capacity-building program, however, goes beyond training classes. It also relies on awareness campaigns addressed to policy-makers and encompasses an intensified dialogue with the business community and stakeholders. As the main reference body managing the new SN system, DCPD appears to be best placed to take over the organization of the capacity-building initiatives aimed at strengthening the in-house expertise; raising awareness among policy-makers; and making the interface with external actors porous and constructive.

I. INTRODUCTION

1. **This report follows up with the diagnosis of the weaknesses and gaps of the current system for regulatory impacts in the GoR.** They were identified by a diagnostic report (Report 1.1.1 “Current Gaps of the RIA System in Romania”¹) produced as a part of the current project “Strengthening the Regulatory Impact Assessment Framework in Romania: Improving the Decision Making Process, Capacity Building and Pilot Projects”. While it outlines a number of innovative elements that are expected to enhance the overall performance of the system in the future, the current report is deliberately rooted in the existing organization and procedural contexts.

2. **Copernican revolutions or a change in paradigm are not necessarily a panacea when it comes to regulatory and administrative reform.** Profound crises may justify such shock and radical interventions. However, the WB Team believes, that is not the current scenario in Romania.

3. **A number of considerations justify this standpoint. First, it is important to acknowledge the longer-term perspective.** Achieving a credible, well-performing RIA system is a long-lasting process that inevitably requires adjustments, “learning-by-doing” and “try-and-error” iterations along all three axes of the reform: the politics-bureaucracy interface; the dynamics within the public administration; and the relation between the regulator and the external stakeholders and the public.

4. **Second, it is key to build on existing positive features.** An evidence-based approach to decision-making has been already introduced in the mid-2006 and over the years it has contributed to (incomplete but still significant) changes in the modus operandi of relevant parts of the public administration. Above all, a system is already in place of routinized procedural practices, whose dismantlement and substitution would probably be more costly than proceeding to targeted improvement. Reference is made here for instance to the (non-formalized, but in principle accepted) role played by the Department for Coordination of Public Policies (DCPP) of the Chancellery of the Prime Minister in screening Substantiation Notes (SNs);² the public consultation phase; the internal endorsement process; and the role played by the Ministry of Finance and the Competition Council in reviewing parts of the SNs.

5. **Third, it is important to capitalize on past reform inputs.** Over the past years, the GoR has benefitted from several projects aimed at boosting evidence-based decision-making. Own initiatives as well as international partners have contributed to designing such reforms both from a comprehensive and more targeted perspective. Projects by the World Bank Group,³ in particular, have regularly provided refined inputs to the reform. All these contributions constitute an invaluable asset upon which the Government should capitalize both in terms of ideas and good international practices; and, indirectly, as know-how and experience mainstreamed across the public administration.

¹ Cfr. the *Report on the current gaps of the RIA system in Romania*, Final Draft of July 8, 2014.

² This report will use the term “Substantiation Note”. It designs the tool used for regulatory impact assessment currently in use in the Romanian Government, which is the most closely related to the international notion and practice of RIA. The Project recommends maintaining the same terminology in order to avoid confusion among the future users of the new system and their impression it is an additional bureaucratic requirement.

³ For instance, Functional Reviews of the Center of the Government and of the Ministry of Economy, Commerce and Business Environment, published in 2011, have provided input about the RIA system.

6. **Fourth, it is key to seek for synergies and economies of scale.** On-going at the very moment of drafting this report are further prominent initiatives that clearly impact on – and can in turn be informed by – this Project. First to mind comes the elaboration of the new “Better Regulation Strategy: 2014-2010”. Another key project in this regard is the one aimed at re-engineering government procedures and introducing ICT tools - software and interfaces for decision-making (including rule-making). There is, moreover, the recently introduced Government Annual Work Plan (GAWP) tool. This is a potentially very powerful instrument to rationalize the flow of new Government decisions on the basis of strategic prioritization against budgetary constraints. 2014 has been the first year of implementation of the GAWP and it appears both logical and desirable to link the introduction of the new SN system to the refinement of the GAWP procedures. These are but three paramount illustrations of the fundamental need to work jointly towards a synergetic strategic vision of the Government’s regulatory function in the next few years. To achieve such vision, no single initiative or project should result in disjointed “Copernican revolutions”, if individual recommendations are to be not only meaningful and desirable but also workable.

7. **Far from signaling lack of ambition in the desired outcomes, starting from what is currently in place is therefore a pre-condition for maximizing the likely impacts of the recommended reforms.** As a result, the proposed recommendations for change seek to ensure the smoothest and incremental reform possible by critically elaborating on the current system, instead of disrupting it fully.

8. **By the same token, the envisaged new SN system will apply only to those initiatives that are going to be adopted by Government.** Excluded from the system are hence ministerial decrees and other decisions that are not included in the agenda of Government meetings or do not require a formal endorsement at Government level. Government will on the other hand be entitled to require the production of a SN for such initiatives at its discretion.

9. **On the basis of this assumption, this report contains elements that should help design a framework that the GoR may consider when designing a comprehensive reform strategy for enhanced SN practices.**

10. **The strategy should be set to achieve a number of overarching goals, including predictability, transparency and accountability; consistency and rationalization; and, effectiveness and proportionality**

- **Predictability.** Public decision-making in general, and normative interventions in particular, must guarantee not only full legal clarity and the complete respect of administrative procedures, but also a degree of legitimate predictability for all public and private stakeholders about the resulting policy decisions. This is for instance essential for business to (re-)allocate current resources and planning future investments in a timely and efficient manner. In this respect, predictability refers not only to the legal aspects but also to the capacity by decision-makers to identify and estimate with a reasonable degree of certainty – and, in any case, in a transparent manner – the likely impacts of the decisions.
- **Transparency and accountability.** Decision-making must be grounded on the principle of transparency and accountability of the underlying processes, so as to avoid arbitrariness and capture; and to ensure equity and proportionality.
- **Consistency and rationalization.** Public policy decisions must respect fundamental principles and freedoms (as enshrined in the Constitution and in major international agreements). They also must be consistent with each other, avoiding duplications,

overlap, legal vacuum and contradictions. Decision-making must strive to rationalizing the production of new regulation; avoiding regulatory inflation, and reducing unnecessary administrative and regulatory costs.

- ***Effectiveness and proportionality.*** Decisions must be aimed at maximizing societal welfare by meeting the needs and expectations of citizens, economic operators and stakeholders in the most cost-effective manner, while keeping the impact of unexpected and/or unintended consequences to an accepted minimum.

11. By setting these general goals for the coming years, the GoR could significantly strengthen its commitment to promote sustained inclusive economic growth in line with the EU 2020 targets and the conditions of the new EU Cohesion Policy. A well-designed and functioning SN system can assist the Government's efforts to reach all the goals mentioned above.

12. This report is accordingly structured along two specific "lines of action": the revision of the organization and process for SN in the central public administration; and upgrading the analytical capacity for SN. After outlining the main rationale for introducing RIA as a tool for modern decision-making (Section II), Section III will thus discuss the possible revision of the scope of application of the future SN system and the actors, roles and responsibilities at play. It will also include indications of possible revisions of the legal base affecting SN. Section IV by contrast will cover instruments such as guidelines, templates and capacity-building schemes. Section V concludes.

13. In addition, a series of Annexes provide direct inputs that can support the future SN system implementation. Among them, a new set of methodological guidelines and checklists; a revised SN template; and suggestions for functional requirements of the future IT system are incorporated in the reform package.

II. THE NATURE OF RIA IN MODERN DECISION-MAKING

II.1 The notion of evidence-based decision-making

14. **Governments are responsible for making decisions to improve the quality of life of individuals and society; and to create the framework conditions to ensure prosperity, inclusive economic growth and sustainability.** High quality public policy interventions (including regulatory actions) are increasingly needed at a time of economic crisis where public authorities are subject to tight fiscal constraints, and where governments are called upon to respond to pressing demands for action while enjoying low levels of public trust. High quality government decisions are likely to result from institutional and procedural regimes that apply the core principles of necessity, proportionality, subsidiarity, transparency, accountability, accessibility and simplicity.

15. **Evidence-based decision-making is an integral part of the approaches to enhance predictability, improve effectiveness, minimize unintended consequences and, ultimately, increase legitimacy.** It refers to an approach for making decisions that ideally is grounded in the best available research and informed by experimental data evidence from the field and relevant contextual evidence. When evidence is not used as a basis for decision-making, or the evidence that is used is poor, partial and incomplete, the risks of regulatory failures increase because of potential unjustified political and administrative discretion; capture; value judgments and biases.

16. **If implemented well, evidence-based decision-making is likely to yield a number of benefits.** These include:

- ensuring that policies are responding to the real needs of the community, which in turn, can lead to better outcomes for the population in the long term;
- highlighting the urgency of an issue or problem which requires immediate attention;
- enabling information sharing amongst other members of the public sector, in regard to what policies have or have not worked;
- reducing government expenditure which may otherwise be directed into ineffective policies or programs which could be costly and time consuming;
- producing an acceptable return on the financial investment that is allocated toward public programs by improving service delivery and outcomes; and
- ensuring that decisions are made in a way that is consistent with democratic and political processes in respect of the transparency and accountability principles.

II.2 Towards a definition of Regulatory Impact Assessment

17. **Since the mid of the 1990s Regulatory Impact Analysis (RIA) has become the most widely diffused tool to implement efforts to improve evidence-based decision-making.** Admittedly, its diffusion across both developed and developing countries conceals a variety of interpretations – not everything labeled RIA defines the same thing everywhere and different actors may well call the same things in different way. It is hence necessary to define what this project understands with RIA, and what principles should be retained when developing the future SN system in Romania. One way of doing so is to rely on the approach taken by the Organization for the Economic Cooperation and Development (OECD) over the past 25 years.

18. **The 2012 OECD Recommendation on Regulatory Policy and Governance⁴ calls on countries to:**

- “integrate [RIA] into the early stages of the policy process for the formulation of new regulatory proposals”;
- “clearly identify policy goals, and evaluate if regulation is necessary and how it can be most effective and efficient in achieving those goals”; and
- “consider means other than regulation and identify the trade-offs of the different approaches analyzed to identify the best approach.”

19. **RIA has a double nature: while it finds expression in an analytical report that supports decision-makers, the notion of RIA should be understood more widely as an integral part of the regulatory reform program, embracing an institutional, organizational and procedural dimension.** RIA is very much a process of evidence-based decision-making. Hence,

“RIA aims to be both a tool and a decision process for informing political decision makers on whether and how to regulate to achieve public policy goals. As a tool supporting decision making, RIA systematically examines the potential impacts of government actions by asking questions about the costs and benefits; how effective will the action be achieving its policy goals and; whether there are superior alternative approaches available to governments. As a decision process, RIA is integrated with systems for consultation, policy development and rule making within government in order to communicate information ex ante about the expected effects of regulatory proposals at a time and in a form that can be used by decision makers, and also ex post to assist governments to evaluate existing regulations.”⁵

20. **The European Commission’s definition follows the same approach:**

“Impact assessment is a set of logical steps to be followed when you prepare policy proposals. It is a process that prepares evidence for political decision-makers on the advantages and disadvantages of possible policy options by assessing their potential impacts. The results of this process are summarized and presented in the IA report.”⁶

21. **The worldwide use of RIA may be related to the acknowledgment by governments that well designed and implemented RIA processes help improve the overall quality of decision-making.** The benefits from using RIA can be summarized as follows:

⁴ See <http://www.oecd.org/gov/regulatory-policy/2012recommendation.htm>, p.4. The OECD has been recommending the use of RIA since 1995 with a *Council Recommendation on Improving the Quality of Government Regulation* (OECD, 1995). The 1997 *OECD Report on Regulatory Impact Analysis: Best Practice in OECD Countries* (OECD, 1997) set out a first list of lessons to be drawn from international positive experiences with RIA. The 2005 *Guiding Principles for Regulatory Quality and Performance* (OECD, 2005) reiterated the essential requirement that regulations should be systematically assessed to ensure that they meet their intended objectives efficiently and effectively in a changing and complex world.

⁵ OECD (2009), *Regulatory Impact Analysis. A tool for policy coherence*, OECD Publishing, Paris, p.12.

⁶ European Commission, *Impact Assessment Guidelines*, SEC(2009) 92 of 15 January 2009, at p.4.

- *RIA requires decisions to be taken with much stronger rigor and through a more accountable and transparent process.* The systematic process of questioning at the beginning of the policy cycle facilitates reflection on how to structure the policy-making process; identify cause-effect links and likely impacts; select and compare policy options; and consider unintended consequences. This helps reducing the risk of regulatory failures.
- *RIA allows for an outward-looking, client-oriented decision-making process.* If properly integrated with public consultation and if published in a timely and systematic way, RIAs empower economic operators and citizens and respond to their right to know the reasons for policy and regulatory choices. This contributes to minimize regulatory capture. Three immediate consequences flow from this: a more stable recognition and generalized acceptance of the performance of policy-makers; greater trust in public authorities; and higher compliance rates with regulation.
- *RIA helps shift from a legalistic to a more evidence-based approach to decision-making.* RIA facilitates co-ordination between different public policies, with an aim of highlighting trade-offs and identifying synergies. This helps achieve greater policy coherence; break down sectoral approaches; and promote “horizontal” thinking – contributing thereby to limit regulatory inflation.

22. RIA is meant to assist policy-makers and therefore it does not substitute their decisions. The completion of a RIA report is the result of a rational policy process that should follow a number of stages forming a closed “policy-cycle” (see Box 1).

Box 1: RIA’s typical analytical steps

Typically, fully-fledged RIA analyses should unfold as follows:

- Identification and definition of the problem;
- Spelling out of the desired objective(s);
- Elaboration of the different regulatory and non-regulatory options (including the “no action” option);
- Open and public consultation with external stakeholders and experts;
- Assessment of the likely costs, benefits and distributional effects (wherever possible in quantitative terms);
- Recommendation of the preferred option; and
- Indications on the monitoring, evaluation and reporting requirements.

As a principle, the costs of regulations should not exceed their benefits – or at least be justified by the latter. The assessment may use various methodologies, such as benefit/cost analysis, cost/effectiveness analysis, business impact analysis etc.

23. It is against this background that the Project envisages reforming the current practices for evidence-based decision-making within the Romanian Government. The recommendations formulated in this report take into consideration international good practices, adapted to the realities and capacities of the Romanian administration.

III. DESIGNING A NEW SUBSTANTIATION NOTE SYSTEM IN ROMANIA

24. **The first main line of action proposed by this report refers to the revision of the current organization and the process that underpins and governs the production of the SNs.** This is likely to have direct impact on the structural challenges highlighted in Section III.1 of the Report 1.1.1 (“Current Gaps on the RIA System in Romania). Before describing the various stages of a possible revised system, the following section will briefly illustrate the main rationale for the recommended changes.

25. **SNs are today the closest instrument to RIA in Romania.** Despite the current existence of different instruments to accompany policy and regulatory proposals, Government officials, who have become familiar to their use, commonly prepare SNs. A review of the current SNs system, irrespectively of the type of document to finally be approved, will serve as a basis for improving the preparation of initiatives prepared by the GoR.

III.1. Exploring the rationale for change

26. **In its broadest terms, the recommended revised system seeks to bring the evidence-based reasoning back to the center of government action and reformed SNs will have to be the element around which the regulatory process pivots.** This implies also that the “regulatory bias” is reversed and the first instinct by the regulators is no longer producing a draft legal text *ex novo*. Rather, the regulator will operate in the context of procedures and methodologies that allow for the opportune unfolding of the logical analytical steps constituting SN analyses. Accordingly, the recommended revised system will be based on the following success factors.

27. **Introducing a proportionate scope of application will make the process feasible and manageable.** The current scope of application is general and indiscriminate. In order for a SN to be carried out properly at the earliest possible stages of the regulatory process, it is paramount that time and resources are allocated efficiently to the exercise. The underlying idea should be that more resources and time should be devoted to proposals that are likely to have greater economic, social and environmental impacts, or that are of particular political salience. Given resource constraints, it will be more effective to carry out a few “in-depth” analyses where it matters more, than performing relatively superficial SNs across the board. Accordingly,

- ***The GAWP-SN interface.*** Government has just introduced the Government Annual Work Plan (GAWP) to consolidate all initiatives it expects to adopt; reinforce the ministries’ responsibility towards the Government’s priorities; ensure higher predictability; streamline and prioritize decision-making; and improve strategic planning and budgetary allocation.⁷ Over time, GAWP is expected to become the principal document regulating all policy and regulatory initiatives. It forces ministries

⁷ GWAP was generated by the Decision of the Prime Minister no.414/1.10.2013 on the creation of the Inter-Ministerial Committee for coordination of elaboration and implementation of GAWP, published in the Official Gazette of Romania no.612/2.10.2013. Earlier recommendations for the existence of a strategic plan of the Government were also included in: the Government Decision no.750/14.07.2005 on inter-ministerial committees, published in the Official Gazette of Romania no.676/28.07.2005, as rectified and modified, and the Government Decision no.870/28.06.2006, published in the Official Gazette of Romania no.637/24.07.2006.

to identify and list their planned initiatives for the following year, providing a short description of the rationale for action (problem definition), the envisaged intervention instrument, etc. This activity is very valuable and in its core it constitutes the very same reasoning at the basis of the SN triage, which would be subsequently triggered. In addition, a number of institutional actors are called upon to coordinate the compilation of GAWP: the Chancellery of the Prime Minister, the General Secretariat of the Government (GSG), the Ministry of Public Finance, the Ministry of Foreign Affairs and the Department for Relationship with the Parliament. The GAWP system in other words already embodies the idea of co-operative steering and control across the executive – a feature that the SN oversight functions requires at various stages of the SN process (triage check; central quality control). Besides these “technical” considerations, there are “strategic” considerations that speak in favor of closely linking the new SN system to the GAWP. The GAWP system has already been agreed upon and is reportedly positively considered by Government. Grounding SN in a system for which a “reform battle” was already fought – and won – grants the SN reform legitimacy and higher chances for success.⁸

- ***Accurate and workable selection criteria.*** Specific criteria should be drawn up that clearly define the cases of exclusion and of exemption from carrying out SNs. In the first category (exclusion) will fall all decision items included in the Government agenda for which adoption will by default require no impact assessment of any sort. The second category (exemption) will refer to the cases in which the adoption of an act by Government should in principle be informed by an impact assessment, but reasons of urgency or emergency recommend skipping such requirement. In such cases, a mechanism should be in place to ensure that the impact assessment is carried out within a set deadline after entering into force, failing of which the act will automatically cease effects (review and sunset clauses).
- ***Detailed “triage” system.*** In addition, the proportionate scope of application implies that the intensity of each analysis must be considered carefully depending on the content of the *matter* covered by the decision. It shall be noted here that the intensity of the matter should not be correlated automatically to the type of the envisaged legal act, since different types of acts (e.g. laws, Government decisions, Government ordinances, methodological norms, etc.) may well govern matters of very different importance. International experience shows that countries have approached this selection in different ways – by using quantitative thresholds (like the US); by applying the principle of proportionate analysis (like the European Commission); or by proceeding to a prioritization filter (the so-call “triage system” developed by Canada and Mexico). Through the triage, Government priorities can be better targeted, accurate quantitative assessments may be difficult to obtain, it can offer a flexible approach to profiling that adapts to Romania’s context.

28. The future system shall not only include the development of guidance for the regulator on when and how to apply clear distinguishing criteria to differentiate between minimum and more comprehensive SNs. The current thinking is to envisage three possible types of analysis, corresponding to decision with likely “low impacts”; likely “medium impacts”; and likely “high impacts”. The system shall also foresee distinct procedural patterns and requirements for each of those types of analyses (see chart below).

⁸ There is also scope for seeking synergies between the GAWP and the Legislative Program of the Government (http://www.drp.gov.ro/index.php?prezentare_program), if such as a reform leads to improved planning practices underpinning the SN process.

29. Strengthening public consultation practices also for draft SNs is therefore essential in this new process. The obligation to open so-called “public consultations” is already provided for by law.⁹ However, this in practice results in keeping the consulted documents on the website for passive information, while the actual period open for stakeholders’ inputs is generally limited to 10 days. There are moreover unsystematic efforts by the public administration to reach out to specific groups and categories that, while being directly affected by the regulatory decision under preparation, do not necessarily have easy access to the Internet. The changes recommended here seek to fill these gaps and bring the draft SN / SN study to the core of the public consultation phase. Thus, there shall be a first consultation round entirely and solely devoted to the draft SN / SN study, before the latter is submitted to the DCPD for quality screening.

30. The rationale for such change is threefold. First, richer evidence collection and data validation. Consulting on the draft SN / SN study allows to further check the appropriateness of the initial analyses; seek additional evidence and new data; and inform the potentially affected stakeholders of forthcoming Government initiatives and their likely implications, thereby increasing the chances for smoother implementation.

31. Second, stronger accountability. In addition, from the transparency and accountability perspective, the publicity given to the draft SN / SN study compensates for the opacity of the initial analytical work within the line ministries, as it is reported that current data gathering relies heavily on informal contacts and personal initiatives and, as a result, not all stakeholders may be given equal opportunity to input the SN analyses.

32. Third, stronger incentives to continuous improvement. Finally, international experience suggests that pressure from external stakeholders is a powerful leverage to implement procedural reforms and enhance the quality of SN analyses. By publishing draft SN / SN study and asking for feedback, the ministries and State bodies engage in a more or less explicit benchmarking exercise and they will have to present SNs of increasingly better quality.

33. In addition, a second public consultation round shall take place before the final endorsement, as it is current practice already, and include the draft legal act, the accompanying SN or SN study as well as the opinion issued by the DCPD on the initial draft SN. Both consultation rounds (i.e. the one dedicated solely to the draft SN as well as the latter) must be subject to the same minimum procedural standards.

34. Reinforcing the central steering and oversight function on SNs is also fundamental for the success of the new system. In the future, it will be fundamental to clarify and strengthen the responsibilities and powers of the body tasked with steering, coordinating and controlling the performance of both the SN system as a whole and the quality of individual analyses. This reflects international good practices. The DCPD appears to be currently best placed institutionally to take over such functions – provided that it is equipped with adequate resources. At an initial stage of the system reform, it is neither practicable nor desirable to confer so-called “veto power” to the DCPD – i.e., the authority to require ministries and State bodies to re-submit to its scrutiny any draft SN deemed of insufficient quality until final clearance. That would in fact turn DCPD into a gatekeeper to the agenda of Government able to block decision-making. The DCPD is not ripe and the

⁹ Law no.52/21.01.2003, on transparent decision-making in public administration, republished in the Official Gazette of Romania no.749/3.12.2013; Government Decision no.521/9.06.2005 on the consultation procedure for associative structures of local administration in the drafting of normative acts, published in the Official Gazette of Romania no.529/22.06.2005 (with amendments); Law no.62/10.05.2011 on social dialogue, republished in the Official Gazette of Romania no.625/31.08.2012 (with amendments).

system is politically not ready for such a change. Hence, this Project recommends that the ministries and the State bodies continue being free to include DCP's recommendations in their draft SNs or not. Nonetheless, mechanisms granting some leverage to the DCP's opinions will be designed to guarantee that the quality review is taken seriously. Such mechanisms will particularly relate to the principle of publicity and public scrutiny.

35. Mainstreaming internal coordination and consultation, notably in cases of “high impact” proposals will be an integral part of the efforts to create ownership within government for relevant decisions. Inter-departmental and inter-ministerial consultation is a pre-requisite for richer analyses underpinning the justification of Government interventions and for an overall better informed and responsible decision-making. Consequently, rounds of internal consultations shall take place at the same time when public consultations are organized – this applies to both the final pre-endorsement consultation but also, in case of medium- and high-impact proposals, to the public consultation on the draft SN.

36. This success factor includes two distinct but intertwined additional elements. First, the network of Impact Assessment units in line ministries. International experience suggests that making one single body only responsible for the performance and quality of the whole impact assessment system is not necessarily an efficient solution. The establishment of a network of (small) units in the main ministries and State bodies is likely to provide first-hand and sector-specific assistance to the RIA drafters; contribute to enhancing capacity-building; and possibly provide initial quality screening of the draft RIA reports. Such network, whose member units should benefit from a systematic coordination with the DCP, would also be extremely instrumental in the implementation and communication of the Better Regulation Strategy, ICT and SN reform. Impact Assessment Units shall be granted uniform status within each ministry; enjoy a clearly defined mandate; and be adequately equipped.

37. Second, SN Working Groups. To ensure the highest possible degree of policy integration when designing new Government decision (i.e. identifying synergies, trade-offs and duplications across various policy domains), the new system shall require the establishment of a dedicated SN Working Group responsible for the impact analysis, whenever the triage filter categorizes the proposal as having likely “high impacts”. At present, the setting up of similar inter-ministerial groups and, more generally, recourse to inter-ministerial collaboration is left up to individual initiatives and no specific rules of procedures govern this important aspect of policy formulation. The new system seeks to reduce the variation and discretion in current practices and stimulate holistic approaches at an early stage. For the sake of rationally and proportionally allocating the necessary time and resources, it is recommended that such Working Groups be established only for the most important SNs. However, the new Working Groups should not become a potential platform for non-transparent regulatory capture or corruptive practices. Clear and government-wide terms of references shall therefore be issued.

38. Ensuring greater accountability and publicity of the SN needs to be strengthened. In this regard, quality check functions are best fulfilled if they are structured along an internal and an external component.

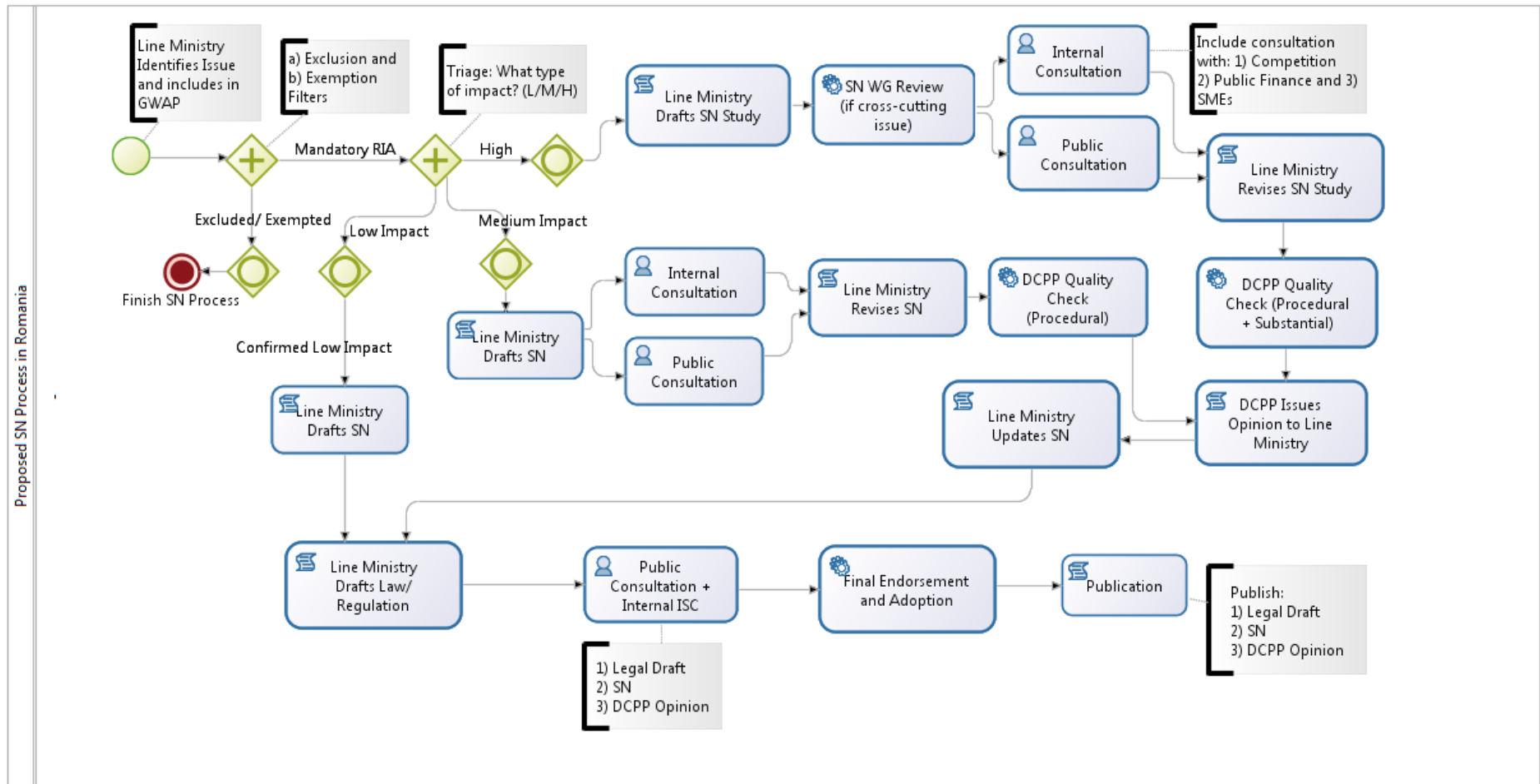
39. The DCP screening and the inter-ministerial consultation and endorsement outlined above account for the internal scrutiny. The certification of SNs and SN studies is a further internal mechanism that helps increase the importance and visibility of SN both in the preparatory phases of decision-making and during the deliberation by Government. Ministerial certification shall continue to be required for all SNs / SN studies, failing which the related initiative cannot be put on the agenda of the Government meeting.

40. The *external quality accountability mechanism* consists of “going public”. This implies that, upon adoption of the act, Government makes publicly available the final legal act together with the final SN / SN study by the ministry or State body responsible for the project, as well as the related opinion of DCP. These documents should preferably be published on a single website (which would serve as a single access point to information on rational for and impacts of Government decisions). As hinted already, the systematic publication of the SN / SN study and of the DCP opinion has two main purposes: first, it would inevitably force the responsible ministry or State body to pay more attention to the issued opinion, since discrepancies between this and the final SN / SN study will eventually go under public scrutiny; and second, the mechanisms would put pressure also onto the DCP itself, because the quality of its opinions would be closely considered. This publication arrangement would therefore enhance the central quality control powers, but also ensure that the latter maintains high working standards for its own credibility and reputation.

III.2. Outlining the new SN system

41. **This section describes in more details the recommended new system for SN.** Based on the process flow chart below, the section outlines the main features responding to the question “who does what and when” throughout the various stages of the preparation of the SN / SN study (see Figure 1). For presentational purposes, the section divides the flow into three phases and ten procedural stages.

Figure 1. Proposed SN process in Romania



PHASE 1 – Consolidating and filtering Government action

42. **This phase is about organizing the annual work program of each ministry in terms of SN production.** To that end, Stage 1 relies on the main instrument available to the ministries that allows to have both a comprehensive overview of the planned initiatives and to structure them according to more or less strategic justifications. Such an instrument is the Government Annual Work Plan (GAWP). The process must then filter and differentiate among the various initiatives on the basis of pre-determined criteria excluding and decision exempting from the obligation to produce a SN (Stage 2). Subsequently, categorizing the initiatives that are subject to SN according to the magnitude of their likely impacts (Stage 3).

Stage 1. Grounding SN to the GAWP

43. **The SN system will be basically grounded in the items listed in the GAWP.** For the time being, the institutional and procedural governance regulating the compilation of the GAWP shall be broadly preserved,¹⁰ with the exception of the filtering criteria.

44. **The GAWP is the primary the basis for the GSG to organize the agenda of Government meetings.** All items listed in the GAWP must undergo the SN filtering Stages 2. and 3 described below. If a ministry launches an initiative for which Government adoption is required without including it in the GAWP,¹¹ the ministry shall proceed to the same stages. Failing to do so will prevent the initiative from being tabled to Government meetings for adoption.

Stage 2. Excluding and exempting ministries from carrying out a SN

45. **The GAWP will be the primary document upon which the SN exclusion criteria (first) and the SN exemption decisions (then) are applied.** Whenever line ministries and State bodies plan to launch an initiative that may require Government adoption, they will have to notify DCPD and apply the exclusion and exemption filter. Two sets of criteria should regulate the two cases (see Box 2).

Box 2. Exclusion and exemption from SN

Exclusion from carrying out a SN is granted to initiatives falling under one of the following cases:

1. Those provided for by art. 6 of GD 561/2009, i.e.:
 - a) acts of individual type that are exclusively aimed at
 - appointments and discharges;
 - establishing some dates;
 - approving technical-economic investment indicators;
 - approving the incomes and expenses budgets of undertakings and of public institutions, the rectification thereof, as well as the expense limits, for the cases provided by law;
 - granting financial and emergency aids;
 - allocating funds from the state budget, from the Budget Reserve Fund available to the Government, from the Intervention Fund available to the Government, as well as from the National Development Fund;
 - approving the finance of projects and actions from the funds for promoting Romania's image abroad;
 - approving the emblems for counties, cities, towns and communes;
 - changing the legal status of some buildings;
 - attesting the public domains of administrative-territorial units;

¹⁰ Following the Guidelines for Elaborating and Implementing the Government's Annual Work Plan.

¹¹ For instance, if the initiative is launched in the course of the year, after the adoption of the GAWP.

- real estate transfers;
 - classifying some roads or road sections in the functional category of county roads; and
 - putting some real estates into free use.
- b) special laws entitling the Government to issue ordinances in areas that are not within the scope of organic laws;
 - c) legislative acts transposing EU legislation or creating the legal framework necessary for the application thereof;
 - d) legislative acts initiated as a result of approval by the Government of the early theses elaborated under art. 26 of Law No. 24/2000, republished, as subsequently amended;
 - e) the legislative acts ratifying, approving, adhering to or accepting an international treaty, in accordance with Law No. 590/2003 on treaties; and
 - f) legislative acts approving the methodological norms provided by law.
2. Financial operations regarding recurrent expenditures under the threshold of 1 million Lei;
 3. New projects for national or foreign public investments under the threshold of 30 million Lei from Law No. 500/2002 updated;
 4. Legislative acts regarding the ratification of international treaties; (records shall be required though for Memorandums approving treaties at state level);
 5. The State budget law and the State social security budget law; and
 6. Notes or other informative documents.

Exemption from carrying out a SN may be granted in instances of urgency and emergency, determined only and directly by the Prime Minister upon proposal by the responsible minister, or in accordance with Art. 115 of the Romanian Constitution. In such cases, the adopted act can have legal force only for a standard limited period of time determined by law (INDICATIVE PROPOSAL: “in any case, not after six months upon the entry into force of the emergency ordinance”). The responsible ministry shall carry out a SN of the same act in accordance with such deadline and justify the continued validity of the act (or a revision thereof), abiding with the general rules for adoption of Government decisions.

46. Responsible for determining whether an item is exempted from SN is the Prime Minister upon proposal by the line minister in charge of the initiative. Justification for the decision shall be given. The decision as to whether to exclude or exempt an item from SN shall be included in the GAWP information whenever possible. DCPD is tasked with checking the appropriateness of the exclusion decision.

47. If an initiative to be adopted by the Government is set to be excluded or exempted from a SN, it falls outside the scope of the rest of the process. The responsible ministries are required to proceed to the subsequent Stage 3 (triage) for all other Government initiatives falling in their portfolio.

Stage 3. Determining the magnitude of the impacts: the “triage” mechanism

48. Initiatives for Government adoption launched by a line ministry or State body, which are not excluded or exempted from a SN, must undergo the “triage” mechanism. Not all initiatives produce the same impacts. Accordingly, not all of them should be impact assessed the same way. This is the rationale for the triage mechanism, which is expected to differentiate initiatives into three categories – low, medium and high impact.

49. The categorization resulting from the triage determines the SN process to be followed (see Stage 4. below). Different routes can be taken, depending on the type of impact (low, medium or high).

50. The responsibility for carrying out the triage lies with the ministry(-ies) responsible for the initiative, following established criteria of classifying low, medium and high impact. The triage questionnaire is a publicly available list of questions designed and managed by DCPD. It should be included in the Guidelines for the production of a SN / SN study. Annex 1 provides a first indicative list of questions.

51. The validity of the triage exercise is checked by the institutional actors responsible for the SN oversight function – i.e. DCPD in the State Chancellery, the Ministry of Public Finance, the Competition Council and the Department for SMEs policy in the Ministry of Economy. This ensures that discretion is reduced to a minimum during the triage exercise and there is compliance with the procedure.

PHASE 2 – Organizing and producing SNs

52. This phase kicks in once ministries have been cleared as to the type of analysis they are expected to carry out in relation to a given initiative. Reflecting the results of the triage mechanism, this phase distinguishes three possible administrative patterns:

- producing SNs for low impact initiatives (Stage 4);
- producing SNs for medium impact initiatives (Stage 5); and
- producing SNs for high impact initiatives (Stage 6).

53. In all cases, the SN or a SN study (for high impact initiatives) must be produced in accordance to the guidelines and the template established by the new legal base. Annex 2 proposes a new template for the preparation of SNs.

Stage 4. Preparing SNs for low impact initiatives

54. If the triage categorizes the initiative as likely to have low impacts and this has been cleared, the responsible line ministry prepares the SN in support to the related act to be adopted by the Government (see Stage 7 below). The process in this case would substantially not be dissimilar to what is current practice at present.

Stage 5. Preparing SNs for medium impact initiatives

55. If the triage categorizes the initiative as likely to have medium impacts and this has been cleared, the responsible line ministry:

- prepares a draft SN;
- organizes both internal consultation and a public consultation exclusively focused on the draft SN; and
- revises the draft SN accordingly, as appropriate.

56. The line ministry thus submits the revised draft SN to DCPD for central quality appraisal. In the case of SN for medium impact initiatives, DCPD will perform only a procedural scrutiny at this stage – i.e. the scrutiny will specifically geared towards ascertaining that all parts of the SN templates are appropriately completed (and if not, that adequate justification is provided).¹²

¹² Procedural screening is what DCPD generally does at present whenever it considers SNs.

57. After having performed its scrutiny, DCPD must issue an opinion addressed to the department drafting the SN. The opinion is mandatory but not binding upon the initiator / co-initiators of the initiative.

58. On the basis of that opinion, the ministry may undertake revisions of the draft SN taking into account the DCPD recommendations fully or in part. It may also decide to revert to DCPD if this is deemed opportune. It will use the resulting SN as the basis to start producing the act to be adopted by the Government (Stage 7).

Stage 6. Preparing SN studies for high impact initiatives

59. From the point of view of the ministry(-ies) responsible for the initiative, two fundamental differences distinguish the high from the medium impact procedures. If the triage categorizes the initiative as likely to have high impacts and this has been cleared, the responsible line ministry in principle proceeds like for medium impact initiatives – i.e. it prepares and revises the draft analysis further to the internal and public consultation. With however two major substantial and procedural differences:

- ***SN study.*** The SN submitted to DCPD and made public can no longer be the complete template as provided for by the SN Guidelines. For high impact initiatives, the responsible ministry will be required to issue a fully-fledged SN study which, while following the same analytical steps foreseen in the template, outlines in details the assumptions made, the methodologies used for data collection, validation and processing, etc. (see Guidelines in Annex 3 for more details).
- ***SN Working Group.*** In order to fully exploit the expertise available in all relevant ministries and State bodies and to ensure adequate policy integration, the SN initiator shall convene and coordinate a SN Working Group, if the Inter-Ministerial Committee for coordination of elaboration and implementation of GAWP (hereinafter the GAWP Committee) determines that the initiative is not only of likely high impact but that it is also cross-portfolio implications.¹³ The membership of the Group is recommended by the GAWP Committee, while DCPD can provide further non-binding advice. DCPD may participate in (part of) the work of the Group upon invitation. Responsibility for the SN study nonetheless remains with the initiator / co-initiators of the initiative.

60. The central quality appraisal also varies in the case of high impact initiatives both with regard to the type and the actors performing the scrutiny. After possible revisions further to the inputs of the SN Working Group, the internal and the public consultation rounds, the SN initiator submits the draft SN study to DCPD for central quality check. This is characterized as follows:

- ***Multi-actor scrutiny.*** As it is also already the case with regard to the final endorsement of draft legal acts to be adopted by Government, a number of institutional actors will be required to provide an in-depth opinion on the quality of the draft SN study. The actors involved *de officio* are the DCPD (for general appraisal); the Ministry of Public Finance (for fiscal and budgetary impacts); the Competition Council (for impacts on competition and State aid); and the Department for SMEs Policy (in charge of the SME Test).¹⁴ The DCPD will be tasked with

¹³ Existing inter-ministerial groups can be used as SN Working Groups, if appropriate.

¹⁴ Law no.346/14.07.2004 on stimulating the creation and development of SMEs, published in the Official Gazette of Romania no.681/29.07.2004 (as modified). The last amendment taken into consideration by this report was provided by Law no.62/30.04.2014, published in the Official Gazette of Romania no.328/6.05.2014.

dispatching the draft SN study and collect the respective opinions into a single opinion.

- ***Procedural and substantial scrutiny.*** Unlike the case of medium impact initiatives, the SN study will have to be reviewed both procedurally and substantially. Each actor intervening in the oversight function will have to rely on own evaluation guidelines to perform this task.

61. After having performed the central scrutiny, DCPD must issue an opinion addressed to the department drafting the SN study. Also in this case, the DCPD opinion is mandatory but not binding upon the initiator / co-initiators of the initiative.

62. On the basis of that opinion, the ministry may undertake revisions of the draft SN study taking into account the DCPD recommendations fully or in part. It may also decide to revert to DCPD if this is deemed opportune. In any event, it must consult the SN Working Group. The resulting revised SN study will then be used as the basis to start producing the act to be adopted by the Government (Stage 7).

PHASE 3 – Preparing acts for Government decisions

63. Only at this stage of the decision-making process do ministries start drafting the acts to be submitted to Government for formal adoption. This part of the process basically leaves the current rules of procedures of the Government unchanged, although amendments are recommended notably in relation to the organization of the internal and public consultation minimum standards as well as the publication requirements. Accordingly, the phase is divided along the following stages:

- drafting of the Government act (Stage 7);
- internal and public consultation (Stage 8);
- final endorsement and adoption (Stage 9); and
- promulgation and publication (Stage 10).

64. These stages will have to be undertaken by the ministries, irrespective of whether the triage mechanism classified the initiative as being likely to have low, medium or high impacts. The main innovation in this Phase is the recommendation to increase the days the draft legal proposal is available for consultation with the public, e.g. during 30 days.

Stage 7. Drafting the Government act

65. Presently, initiators of Government acts may be: ministries and other bodies of the central administration, subordinated to the Government as well as autonomous ones, specialized bodies subordinated to the ministries, prefects, county councils, and the General Council of the Bucharest Municipality. The initiator needs to reflect upon the existent national and international legislation and alternative solutions for better formulation.

66. Specialized units of the initiator may use specific norms of legislative techniques¹⁵ in order to produce a legal draft. In doing so, they may demand the assistance

The Methodology for the elaboration and application of the SMEs test was approved by Order of the Ministry of Economy no.698/4.06.2014, published in the Official Gazette of Romania no.438/16.06.2014.

¹⁵ Law no. 24/27.03.2000, published in the Official Gazette of Romania no.139/31.03.2000, as modified. The last amendment considered by this report was made by Law no.29/11.03.2011, published in the Official Gazette of Romania no.182/15.03.2011.

of the Legislative Council, or search for the jurisprudence of the Romanian Constitutional Court of that of the European Court on Human Rights.

67. At this stage, the DCPD and the GSG may only serve as possible counterparts in the drafting of the act or as informal consultants on the solutions in hand. No additional impact on the existent legislation is foreseen, as this stage aims at consolidating current practices and clarifying the terminological confusion between regulatory and normative actions.

Stage 8. Internal and public consultation

68. According to provisions currently in force, the initiator is responsible for sending two copies of the finalized initial draft to the GSG (in electronic and written format) in view of registration and publication on the Government website. Concomitantly, it ensures the publication of the draft on its own webpage and sets up the framework for internal and public consultation. The novelty to be introduced here is that aside the draft act, the initiator will be responsible for the publication of the SN draft / study as well. That will strengthen the predictability of the RIA process and increase public awareness. Increasing the number of days for consultation of the draft legal instrument, e.g. 30 days in the website to receive feedback and comments, is also a suggestion that intends to bring consultation practices in Romania up to international standards.

69. At this stage, the Direction for Relations with the Parliament, Ministry of Justice, Ministry of Public Finance need to provide an opinion on the act only if considered necessary.

Stage 9. Final adoption and endorsement

70. All documentation pertaining to the new SN system will be circulated between different endorsers (Legislative Council, Direction for Relations with the Parliament, Ministry of Justice, Ministry of Public Finance, Competition Council, Supreme Council for State Defense, Social and Economic Council, Court of Auditors, Supreme Council of Magistrates and the Group for Evaluating the Economic impact on SMEs). There could be three types of reactions from opinion drafters: 1) favorable opinion; 2) favorable opinion with objections or proposals; and 3) negative opinion. The Initiator could only motivate its responses in the cases of: favorable opinions with objections and negative opinions.

Stage 10. Signature and publication

71. Upon reaching the final stage, the act receives the signature of the Prime Minister and that of the initiator and is subject to publication by the GSG. In the new system, publication will include keeping record of the SN process in a single portal administered by DCPD.

III.3. Identifying necessary amendments

72. On the basis of the features of the new SN system envisaged above, a number of amendments to the current legal base are likely to be required. The following table schematically outlines the main provisions that require consideration for possible amendment by Government in relation to each of the innovative elements brought about by the new system.

Table 1: Recommended amendments to current legal bases

Phase of the new system	Stage of the new system	Current legal base potentially to be changed	Article(s) proposed for revision	Scope of revision (specific innovative element)
1 - Consolidating and filtering Government action	1. Grounding SN to the GAWP	Decision of the Prime Minister no.414/2013	article 2.2 - establishing the coordination role of the Committee over the SN, and linking it to GAWP; new article: introducing GAWP Guidelines for triage	Linking SN to GAWP
		Government Decision no.750/2005	article 2 - establishing the coordination role for SN	Introducing SN to inter-ministerial committees
		Government Decision no.561/2009	articles 27, 32 - presenting the rules of agenda setting for Government meeting; Chapter VII - on the statute, composition, organization and meetings of the Government preparatory meetings, articles 34, 35, 37 and 38	Correlation with GAWP and the DCPD role's of coordination
		Law no.24/2000	Articles 6 and 7, and Section 4 (Articles 30-34) on the motivation of legal drafts	Linking SN to the legal draft, explaining the rationale of the new SN system and clearing the misinterpretations on normative versus regulatory
		Government Decision no.775/2005	all articles	Introducing the SN and the new SN system
	2. Excluding and exempting ministries from carrying out a SN	Government Decision no.561/2009	article 6 - on the cases of exclusion	Reframing it to accommodate exclusions and exemption from SN
	3. Determining the magnitude of the impacts: the "triage" mechanism	Government Decision no.561/2009	new article(s)	Introducing the triage mechanism
2 - Organising and producing SNs	4. Preparing SNs for low impact initiatives	Government Decision no.561/2009	reformulation of articles (Chapter III, IV, and V)	Clarifying the scope and applicability of SN and the new flow chart for SN
		Law no.346/2004 (as revised in 2014) and Methodological norms	reframing of the SME Test	Correlating the SME Test with the SN (so to be included in the templates)
	5. Preparing SNs for medium impact initiatives	Government Decision no.561/2009	reformulation of articles (Chapter III, IV, and V)	Clarifying the scope and applicability of SN and the new flow chart for SN
		Government Decision no.775/2005	new Annex	Introducing the new SN template
	6. Preparing SN studies	Government Decision no.775/2005	new Annex	Introducing the new SN study

Phase of the new system	Stage of the new system	Current legal base potentially to be changed	Article(s) proposed for revision	Scope of revision (specific innovative element)
	for high impact initiatives	Government Decision no.561/2009	reformulation of articles (Chapter III, IV, and V)	Clarifying the scope and applicability of SN and the new flow chart for SN
		Decision of the Prime Minister no.414/2013	new article: introducing the WG on SN	Creating a SN Working Group
		Government Decision no.561/2009	new article: correlating the role of the WG on SN, with the rest of the actors	Consolidating the SN Working Group
		Law no.346/2004 and Order of the Ministry of Economy no.698/4.06.2014	new article: to correlate the new SN system with the SME Test	Correlation of the SME Test with the new SN process
3 - Preparing acts for Government decisions	7. Drafting the Government act	Government Decision no.561/2009	clarification of articles 1-14	Clarifying the terminological confusion between regulatory and normative acts
	8. Internal and public consultation	Government Decision no.561/2009	Chapter IV and article 17.2 on the template of the notification address	Introducing the SN draft for public consultation
		Law no.52/2003	Article 2 on general principles; Article 3.j; Article 7	Introducing SN in the list of documents open to public consultation and the new timeline for consultation (e.g. 30 days for consultation)
		Law 62/2011	Articles 68, 83, 121 on the scope of consultation	Introducing SN in the list of documents open to public consultation and correlation to the new provisions on the schedule of consultation
		Government Decision no.521/2005	Article 2 et seq.	Introducing SN in the list of documents open to public consultation and correlation to the new provisions on the schedule of consultation
	9. Final adoption and endorsement	Government Decision no.561/2009	Articles 23-30	Making the new SN system compatible with the existent framework
10. Promulgation and publication	Government Decision no.561/2009	Articles 23-30	Making the new SN system compatible with the existent framework	

IV. ENHANCING THE QUALITY OF THE ANALYSES

73. **The second line of action in the reform strategy for improved SN pertains to increase the quality of the analyses produced.** The diagnosis carried out in the framework of this project has revealed that officials intervening in the SN process are generally insufficiently prepared to master the analytical steps and methodologies. This is partly due to the lack or the inefficient allocation of expertise in the line ministries; to problems related to collecting, validating and processing relevant and comparable data; to silos approaches and missed cross-fertilization of information and experiences; and to the failure to consider the whole policy cycle when designing Government decisions.

74. **To overcome these challenges, it is recommended to operate along three levels of intervention:**

- the simplification of the SN template;
- the rationalization and upgrade of the underlying a SN Guidelines; and
- the development of a systemic capacity-building program.

IV.1 A simple SN template

75. **The current model provided for by Government Decision 1361/2006 is not wrong per se, but it may not be the most instrumental tool to assist the SN drafter.** It combines both elements typical of a template (i.e. standardized format) that obliges SN drafters to fill all required fields with elements that should rather pertain to more comprehensive guidance documentation. The model appears moreover to put uneven balance on the various sections for analysis.

76. **For these reasons, it is recommended to streamline the current model.** The SN Template is the document that needs to be filled when preparing any initiative that is expected to be adopted by Government (except in cases of exclusion or exemption). Annex 2 provides a possible example of such SN Template.

77. **For high impact initiatives, as resulted from applying the triage filter, the SN Template will constitute the Executive Summary to be attached to the more comprehensive SN Study.** The format of the SN Study is not strict. However, it must include all sections provided for in the Template.

IV.2 Upgraded SN Guidelines

78. **At present, several guidance documents exist that pertain to the preparation of SN in the decision-making process.** Some are manuals adopted and endorsed centrally by the GSG, some other are ministerial documents. In addition, some guidance is provided directly by Government Decision 1361/2006.

79. **The legal and operational nature of each individual guidance document is not clear. Ministries have de facto relative discretion in considering whether and when to use one source of support as opposed to others.** Because the manuals have not been checked against their consistency and appropriateness, the risk is to have different

understanding of what the process should be when tackling a SN analysis. Quality standards might also differ significantly.

80. **It is therefore recommended that everybody be on the same page, taking account of both the new SN system and the new SN Template.** The Guidelines reported in Annex 3 are specifically meant to assist SN drafter when they have to fill the SN Template. They are conceived jointly with the template and should support the filling of each one of the sections and steps. The Guidelines also indicate when a step is to be filled in, in relation to the result from the filtering mechanism (triage).

IV.3 Elements for a centralized capacity-building program

81. **A third level of intervention to upgrade the analytical capacity to carry out SNs consists of designing and running a structured, consistent training program.** This is complementary to the introduction of the new Guidelines.

82. **Capacity building through training is a necessary element of the reform. Training should address the rationale for RIA; the main analytical steps; and the various relevant methodologies.** It should be as tailored as possible to the background, skills and needs of the participants, and it should be practical, providing examples and case study exercises. The training strategy of the Government should be designed over a few years and it should not consist of one-off courses. Over time, the RIA Unit staff should be closely involved in the training activities.

83. **There is a wide tank of resources that need to be capitalized upon.** A number of training courses have taken place over the past years under the aegis of various parts of the Government and involving the EU and international partners. Little oversight has nonetheless been applied on the consistency and quality of the inputs provided. There is also unsystematic record on who participated in what type of training. One strand of action planned in this very project, moreover, includes active tailored training modules with a number of officials from selected ministries. Together with the planned pilot projects, this constitutes a further important source for capacity building, as it directly seeks to apply the recommended new system.

84. **A capacity-building program, however, goes beyond training classes. It also relies on awareness campaigns addressed to policy-makers.** The latter are the ones making use of the information provided in SNs. They need therefore to be aware of the role that evidence should play in informing their decisions, and the consequences that political decisions may have upon the economy, society and the environment. By the same token, policy-makers need to understand the procedural requirements regulating a sound SN process so that a climate of trust and respect can emerge between the political and the administrative realm.

85. **Capacity building also encompasses an intensified dialogue with business and stakeholders.** A culture of dialogue should progressively emerge between the public administration and the private sector that avoids confrontational attitudes and minimizes the risks of regulatory capture and corruptive practices. A well-designed SN system is the pivotal element in the reform of public decision-making that can contribute to establishing such culture. Actors external to the Government need also to understand their new roles and bear responsibility in the overall governance of evidence-based decision-making.

86. **As the main reference body managing the new SN system, DCPD appears to be best placed to take over the organization of the capacity-building initiatives aimed at**

strengthening the in-house expertise; raising awareness among policy-makers; and making the interface with external actors porous and constructive. The evolution of capacities within DCPD should also be considered, as they will have a prominent role in ensuring that good regulatory practices are disseminated within the Romanian administration.

V. CONCLUDING REMARKS

87. **This report presented the main features of a new, fully-fledged system for evidence-based (regulatory) decision-making, grounded on the pivotal role of the Substantiation Note.** It is based on a preliminary structured review of the weaknesses and gaps of the current system for regulatory impacts in the Romanian Government,¹⁶ and it is specifically designed to assist the DCPD in the Chancellery with the elaboration of the necessary tools implementing the reform.

88. **Like any other plan for comprehensive reform, the envisaged areas of intervention cover several dimensions which, taken together, form a consistent strategy plan.**

89. **These primarily include, first *the re-organization of the SN process*,** which answers the questions “who does what? When? Why? throughout the SN process”. Among the innovative components proposed by the report are the correlation between the GAWP cycle and the SN process; the introduction of an initial filtering mechanism (triage system): the requirement to carry out public consultations on draft SN for medium and high impact initiatives; and the systematization of the central quality appraisal oversight.

90. **Second, *the rationalization and upgrading of the guidance material supporting SN drafters*,** which answers the question “How shall the SN report be produced?”. Accordingly, the report presented a revised SN Template and a new set of SN Guidelines. The two documents are to be considered jointly, as the latter underpins the preparation of the former.

91. **Third, the report sketched the elements for an implementation strategy** that includes a centralized capacity-building program as well as a communication campaign addressed to both decision-makers and external stakeholders.

92. **Expectations need to be managed, though.** The suggested changes draw from the double assumption that there is already valuable basic elements of evidence-based decision-making practices within the Romanian Government and that reforms are likely to be more successful if conceived incremental progress. Nonetheless, it is important that all actors involved in the renewal of the SN process and affected by it acknowledge that the necessary time horizon is likely to stretch over years and that the introduction of new (legal) instruments is not by itself conducive to immediate positive change. Resistances to the changes will emerge, and institutional learning needs to kick in both within the public administration and among political leaders and stakeholders.

93. **What outlined in this report is therefore to be considered as the initial, necessary but insufficient input to a wider reform endeavor, which will be further consolidated by the other constitutive parts of the project.**

¹⁶ As presented by the Report 1.1.1 “Current Gaps of the RIA System in Romania”, Final Draft of July 8, 2014.

ANNEX 1 – THE TRIAGE FILTER

INTRODUCTION

The purpose of applying a filter such as the triage mechanism is to assist the responsible of any Government initiative with establishing an effective and proportionate allocation of resources in developing the Substantiation Note.

As a result of the triage, initiatives are classified as likely to bear low, medium or high impacts. The SN Guidelines provide information on how to proceed with the completion of the SN Template, for each one of the three impact categories.

The triage mechanism is conceived primarily in conjunction with a supporting centralised IT system, which the Government of Romania is about to procure.

The underlying filter questions are presented below. Once adopted, the questions will have to be published online on the DCPD webpage.

FUNCTIONING OF THE TRIAGE MECHANISM

Initiators must answer all the questions included in the triage form.

- Only one answer is allowed per each question.
- When the IT system will be in place, initiators will have only one chance to submit the form. Once a question is answered, the answer cannot be changed.

There are four possible answers:

- High
- Medium
- Low
- No, or Not applicable (N/A)

If the answer to ONE OR MORE of the triage questions is Medium or High, the initiator has to follow the SN procedure for medium or high impact initiatives.

If all the answers to the questions are Low; or No or N/A, the initiator has to follow the SN procedure for low impact initiatives.

TRIAGE FORM

General information on the initiative				
Reference number				
Title of the initiative				
Responsible department(s)				
Contact person (email, phone nr.)				
Date				
Short problem definition				
Objective(s)				
Legal base				
Impacts	No; N/A	Low	Medium	High
1. Political salience ¹⁾	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Public interest or controversy ²⁾	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Financial impacts				
Periodical (<u>additional annual</u> expenditures or savings)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0 - 1m Lei	1m - 3m Lei	3m - 10m Lei	> 10m Lei
4. Economic impacts				
Nr. of businesses potentially affected	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0 - 50,000	50,000 - 100,000	100,000 - 350,000	> 350,000
Potential economic impact	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0 - 10m Lei	10m - 25m Lei	25m - 50m Lei	> 50m Lei
Nr. of consumers / population potentially affected	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0 - 1m	1 - 5m	5-10 m	> 10 m
5. Social and health impacts				
Well-being of specific selected groups	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Status of human or animal health and safety ³⁾	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Environmental impacts				
Status of plant health, ecosystem quality and natural resources preservation ⁴⁾	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Notes
<p>1) Political salience refers to the degree of political commitment underpinning the initiative or its strategic relevance in the Government program.</p> <p>High - The Prime Minister or a member of the Government has made or is planning to make an important announcement in this regard, being deemed as one of the most important priorities of the Government.</p> <p>Medium - The initiative was publicly announced, it is deemed as an important but not high-priority problem. There is important but not critical commitment within an approved strategy.</p> <p>Low - The initiative is deemed as a minor part of an approved plan/ strategy.</p>
<p>2) Public interest or controversy refers to the extent to which the issue addresses societal interest as a whole, public security or whether positions of relevant stakeholders are particularly conflictual about the issue.</p> <p>High - The initiative is expected to cause significant controversy, is opposed by most stakeholders, or faces large opposition.</p> <p>Medium - The initiative is expected to cause some controversy or is opposed by some key stakeholders.</p> <p>Low - The initiative is expected to cause minimal controversy but is generally supported by all key stakeholder groups, including lobby groups.</p>
<p>3) For this type of impacts, the following classification applies:</p> <p>High - The initiative is expected to have a significant impact, such as mortality, human or animal health or safety.</p> <p>Medium - The initiative is expected to have some impact, such as reducing the delay or the need for medical attention or hospitalization.</p> <p>Low - The initiative is expected to cause very minor impacts.</p>
<p>4) For this type of impacts, the following classification applies:</p> <p>High - The initiative is expected to have a significant impact, such as damaging a sensitive ecosystem or protecting it from severe and irreversible harm or damage.</p> <p>Medium - The initiative is expected to have some severe but reversible harm or damage on the environment.</p> <p>Low - The initiative is expected to trigger marginal and temporary changes in the status of the ecosystem.</p>

ANNEX 2 – THE NEW SUBSTANTIATION NOTE TEMPLATE

Notes: ¹= qualitatively; ²= quantitatively; High impact SN require separate SN study.

Substantiation Note Template	Low	Medium	High
Section 1 – General information on the initiative			
Reference number			
1. Title of the initiative			
2. Responsible department(s)	•	•	•
3. Contact person (Email, phone nr.)			
4. Before / after consultation			
5. Date			
Section 2 – Rationale for launching the initiative			
6. Problem definition			
What problem / issues require Government action?	•	•	•
What are the causes of the problem?			
7. No-action option (baseline scenario)			
Is the problem likely to get better / worse or remain the same (without Government action)?	• ¹	• ²	• ²
What are the likely impacts of the problem (e.g. financial, economic, social /health, environmental)?			
8. Objectives			
State the goals the initiatives is set to achieve, with measurable indications and definite deadlines	•	•	•
9. Other relevant information (optional)			
Indicate any further relevant information.	•	•	•

Section 3 – Preferred option	
10. Description	
Briefly describe the option you recommend for Government to adopt – and the reasons therefor.	
11. Financial impacts	
For the following year	For the next 5 years
12. Economic impacts	
Type of economic BENEFITS	Type of economic COSTS
Beneficiary group(s)	Affected group(s)
Metrics and qualitative / quantitative estimation	Metrics and qualitative / quantitative estimation
Administrative burden measurement (if applicable)	
Impact on competition / state aid (if applicable)	
SME Test results (if applicable)	
13. Social / Health impacts	
Type of social / health BENEFITS	Type of social / health COSTS
Beneficiary group(s)	Affected group(s)
Metrics and qualitative / quantitative estimation	Metrics and qualitative / quantitative estimation

•	•	•
• ¹	• ²	• ²
• ¹	• ²	• ²
• ¹	• ²	• ²

14. Environmental impacts	
Type of environmental BENEFITS	Type of environmental COSTS
Beneficiary group(s)	Affected group(s)
Metrics and qualitative / quantitative estimation	Metrics and qualitative / quantitative estimation
Section 4 – Alternative option	
15. Description	
Briefly describe the option you considered for a comparison with the recommend option, highlighting the differences with the latter.	
16. Financial impacts	
For the following year	For the next 5 years
17. Economic impacts	
Type of economic BENEFITS	Type of economic COSTS
Beneficiary group(s)	Affected group(s)
Metrics and qualitative / quantitative estimation	Metrics and qualitative / quantitative estimation
Administrative burdens measurement (if applicable)	
Impact on competition / state aid (if applicable)	
SME Test results (if applicable)	

• ¹	• ²	• ²
	•	•
	• ¹	• ²
	• ¹	• ²

18. Social / Health impacts	
Type of social / health BENEFITS	Type of social / health COSTS
Beneficiary group(s)	Affected group(s)
Metrics and qualitative / quantitative estimation	Metrics and qualitative / quantitative estimation
19. Environmental impacts	
Type of environmental BENEFITS	Type of environmental COSTS
Beneficiary group(s)	Affected group(s)
Metrics and qualitative / quantitative estimation	Metrics and qualitative / quantitative estimation
Section 5 – Public consultation process (art. 7 of Law 52/2003)	
20. Substantiation Note BEFORE consultation	
Key questions asked to stakeholders and experts	
Envisaged stakeholders / experts to be consulted	
Envisaged public hearing; reason and date thereof	
21. Substantiation Note AFTER consultation	
Method of consultation (hearing, online, etc.) and date	
Participating stakeholders and experts	
Short summary	

	• ¹	• ²
	• ¹	• ²
Section 5 – Public consultation process (art. 7 of Law 52/2003)		
	•	•
	•	•

Section 6 – Post-adoption arrangements (for preferred option only)				
22. Implementation arrangements				
Arrangements / changes for existing public authorities				
Nature of related public funding				
Arrangements / changes for the private sector				
Implementation calendar				
Other information				
23. Monitoring and evaluation activities				
Performance indicators				
Data collection channels				
Actors				
Foreseen timing for monitoring				
Foreseen timing for evaluation				
Foreseen scope of the evaluation				
Section 7 – Information on final endorsement				
Legislative Council				
Supreme Council of National Defense				
Economic and Social Council				
Competition Council				
Court of Accounts				
Section 8 – Accreditation				
Date	Signature			

ANNEX 3 – NEW GUIDELINES SUPPORTING THE SN ANALYSIS

INTRODUCTION

These Guidelines support officials in ministries and State bodies tasked with the preparation of Substantiation Notes (SNs) supporting Government decisions. They are designed so as to particularly assist with the compilation of the SN Template.

The SN Template is the document that needs to be filled when preparing any initiative that is expected to be adopted by Government (except in cases of exclusion or exemption). For HIGH impact initiatives, as resulted from applying the triage filter, the SN Template will constitute the Executive Summary to be attached to the more comprehensive SN Study.

Accordingly, the Guidelines are divided into six sections, which encompass the main analytical steps underpinning the SN exercise. The six sections are:

- (1) General information on the initiative;
- (2) Rationale for launching the initiative;
- (3) Preferred option;
- (4) Alternative option;
- (5) Public consultation process; and
- (6) Post-adoption monitoring and evaluation.

Each section explains the importance of the underlying issues within the whole SN preparation process; provides key definitions and outlines the main methodologies to perform the requested tasks; and indicates possible differences in implementation as a function of the triage results.

These Guidelines consolidate international guidance material and build on existing methodologies developed by the Government of Romania and individual ministries.

SECTION 1 – General information on the initiative

Steps 1-5: Administrative information

A) The importance of this Step

The SN is the result of a logical analytical process, which is unique for each initiative considered to be potentially adopted by the Government, in accordance to XY.¹⁷ For this reason, it is important that accurate information is provided to decision-makers and the stakeholders so that they can situate the initiative at stake; and to identify the administrative office responsible for the production and quality of the SN.

¹⁷ The new legal base for the SN system is to be mentioned here.

B) Filling the SN template

A Reference Number will be given by the system in place, which will allow to track the file and information related to it.

You must fill Steps 1–5 in the SN Template mandatorily – i.e. whether you are preparing a LOW impact, a MEDIUM impact or HIGH impact initiative. In particular,

- Step 1: you must indicate the title of the initiative, possibly as it appears in the GAWP;
- Step 2: you must indicate your institutional affiliation and any possible co-initiating body;
- Step 3: you must provide your contact details;
- Step 4: you must indicate whether the current version of the SN is drafted before or after the public consultation round; and
- Step 5: you must put the date of the day you transmit the SN.

SECTION 2 – Rationale for launching the initiative

Step 6: Problem definition

A) The importance of this Step

Problem definition is arguably the most important step in the process of preparing a SN. The problem must be characterized correctly if you are to solve it. The problem definition is the basis for everything that follows. If the problem is not clearly defined, it is very unlikely that you will develop the right solutions. No analysis – no matter how sophisticated – can compensate for a poor problem definition. It is therefore important that adequate time and resources are dedicated to this step.

B) What does problem definition mean?

It means answering the following questions:

- *What is the issue or mischief that may require Government action?*
- *What are the underlying drivers of the problem?*
- *Why is it a problem?*
- *Who is affected, in what ways, and to what extent?*

AVOID COMMON MISTAKES:

- **Contenting yourself with no definitions or big, vague concepts** (e.g. “*There is no infrastructure.*”) **INSTEAD BE PRECISE:** “*The route from A to B cannot bear heavy trucks.*”
- **Inferring solutions** (e.g. “*There is no funding, hence children do not go to school.*”)

INSTEAD SPELL OUT THE PROBLEM: “*Children do not go to school.*” (the cause might be too high school fees, or other factors, not related to money, e.g. transport issues).

- **Looking for non-existing problems** (e.g. “*There are no NGOs.*”)

INSTEAD CONSIDER THE CONTEXT: “*There is little knowledge of how to run an NGO.*”

- **Formulating value judgments** (e.g. “*Bureaucrats are lazy.*”)

INSTEAD BE OBJECTIVE: “*The government licensing system is not efficient.*”

- **Confusing problem with possible solutions** (e.g. “*There is no law on heating systems.*”)

Writing a law is never a problem, it is part of a possible *solution* to a given problem. There may be other solutions, such as better enforcement, higher sanctions, simplification of the existing legal framework, or education and information campaigns.

C) How to define a problem

The key for a good problem definition is to identify the drivers and establish how those specific particular factors lead to the problem. This helps you tackle the causes rather than the symptoms.

By doing so, you must always hail back to ever more definite causes and find objective causal relationships. The most direct way to achieve this is through the so-called “**problem tree approach**”. This approach helps you:

- differentiate between causes, symptoms and effects;
- investigate cause-effects relationships;
- identify affected groups;
- set a hierarchy of problems; and
- define scope and margins of intervention.

HOW TO BUILD A PROBLEM TREE:

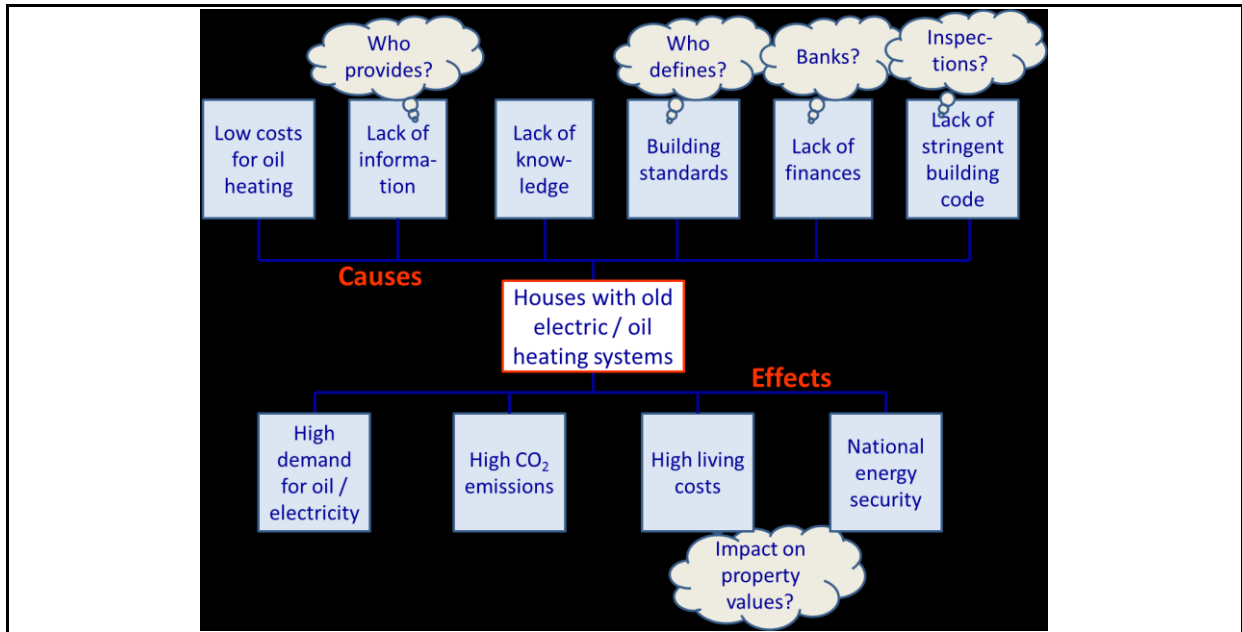
- Write your problem statement in the middle;
- Write all the causes in the compartments above;
- Write all the effects in the compartments below; and
- You can use balloons to add comments.

Your problem definition will have to focus on the upper part of the tree (the “cause’s branches”). These can be as many as they are relevant, and as detailed as necessary. You may have primary and secondary causes. You will identify them by each time asking yourself the question “... and why is it so?”

Which cause(s) to tackle in your SN will depend on the priorities, competences and means at disposal.

Example:¹⁸

¹⁸ Adapted from <http://mechanisms.energychange.info>.



D) Filling the SN template

You must fill Step 6 in the SN Template mandatorily – i.e. whether you are preparing a LOW impact, a MEDIUM impact or HIGH impact initiative.

If you are working on a LOW impact initiative, a qualitative description of the problem is sufficient. For MEDIUM and HIGH impact initiatives, by contrast, you are required to provide quantified evidence.

In the SN study (HIGH impact initiative), you are also required to present the reasoning followed, including the assumptions made and specify the sources from which data was collected.

Step 7: No-action option (baseline scenario)

A) The importance of this step

Your SN is a comparative exercise appraising what will likely happen further to a Government intervention as opposed to what is going to happen if Government does not intervene. Logically, you will recommend Government to take any action only if there is sufficient evidence that that action leads to better scenarios than the *status quo*.

Through this step you collect information on what is specifically wrong with the current situation; and you gather knowledge and analytic capacity that you can later use to balance alternative options.

This step is fundamentally linked to the “Step 1: Problem definition”. Once you have ascertained the nature of the problem, you should clarify whether there is something wrong – or not, which requires Government intervention.

B) What does setting the baseline scenario mean?

The aim of the baseline scenario is to explain how the current situation would evolve without additional public intervention – it is the "no policy change" scenario. It answers the question: *“What would happen if nothing is done?”*.

C) How to set a baseline scenario

When it comes to characterizing the current situation, you need first to **consider the context**:

- NOTE that if there is no specific policy addressing the problem identified, the baseline means the continuation of "no policy". Where there is already a policy, the baseline is the continuation of the current policy without any change, i.e. without any new or additional intervention
- BEWARE that "no policy" includes the expected effects of legislation which has been adopted but not yet implemented;
- TAKE ACCOUNT of any EU or international policies already in place, not only national policies;
- TAKE ALSO ACCOUNT of any initiative launched by non-governmental actors, such as business or civil society associations; and
- CONSIDER relevant case law.

QUESTIONS THAT A BASELINE DESCRIPTION SHOULD ANSWER:

- How serious is the problem?
- Is it about to get solved? When? Why?
- To what extent will it by contrast become more serious? Why?
- What are the probabilities of these scenarios?
- Are there irreversible consequences?

In answering this questions, you need to clarify what assumptions you have made and what data you have used, and why.

A good baseline should have a strong factual basis and, as far as possible, be expressed as much as possible through **quantified evidence**. It should also be set for an **appropriate time horizon** (neither too long nor too short).

D) Filling the SN template

You must fill Step 7 in the SN Template mandatorily – i.e. whether you are preparing a LOW impact, a MEDIUM impact or HIGH impact initiative.

If you are working on a LOW impact initiative, a qualitative description of the current situation is sufficient. For MEDIUM and HIGH impact initiatives, by contrast, you are required to provide quantified evidence.

In the SN study (HIGH impact initiative), you are also required to present the reasoning followed, including the assumptions made and specify the sources from which data was collected.

Step 8: Objectives

A) The importance of this Step

Clearly identifying and defining goals is critical because drive the selection of solutions because they define the main benefits of action. Any intervention must have clear objectives which are directly related to solving the problems identified, because this:

- helps show policy coherence and consistence;
- helps identify prospective courses of action, and assist in comparing policy options;
- makes possible to monitor implementation of the policy and to evaluate achievement or not of desired effects; and
- helps define the performance indicators for assessing whether the major policy objectives are being achieved.

B) What does setting objectives correctly mean?

Potential solutions to the problem should be assessed against so-called **performance goals**. In other words, you should set the objectives to be achieved as measurable performance indicators for the envisaged action (or no action).

Objectives can moreover be **general, specific and operational**.¹⁹ When you define such categorization, make sure you establish clear links both between

- the objectives and the problem and its root causes; and
- the objectives themselves, so that they do not contradict each other.

General objectives	<ul style="list-style-type: none"> • These are Treaty-based goals which the policy aims to contribute to. • They are the link with the existing policy setting. • They should induce policy-makers to take account of the full range of existing policies with the same or similar objectives. • They relate to impact indicators.
Specific objectives	<ul style="list-style-type: none"> • They take account of the envisaged specific domain and particular nature of the policy intervention under consideration. • Their definition is a crucial step in the appraisal as they set out what you want to achieve concretely with the policy intervention. • They correspond to result indicators.
Operational objectives	<ul style="list-style-type: none"> • These are the objectives defined in terms of the deliverables or objects of actions. • These objectives will vary considerably depending on the type of policy examined. • They need to have a close link with output indicators.

¹⁹ The following table is taken from the European Commission Guidelines on Impact Assessment, 2009, p.26.

C) How to set objectives correctly

A useful rule-of-thumb when defining the objectives is to apply the SMART template – i.e., objectives should be:

- **SPECIFIC:** Objectives should be precise and concrete enough not to be open to varying interpretations. They must be understood by all.
- **MEASURABLE:** Objectives should define a desired future state in measurable terms, so that it is possible to verify whether the objective has been achieved or not. Such objectives are either quantified or based on a combination of description and scoring scales.
- **ACHIEVABLE:** If objectives and target levels are to influence behavior, those who are responsible for them must be able to achieve them.
- **RELEVANT:** Objectives and target levels should be ambitious – setting an objective that only reflects the current level of achievement is not useful – but they should also be realistic so that those responsible see them as meaningful.
- **TIME-DEPENDENT:** Objectives and target levels remain vague if they are not related to a fixed date or time period.

SETTING SMART OBJECTIVES: An example

Original policy goal statement: *“To support business start-up in Romania”*

Building the SMART components:

- **SPECIFIC:** *“The Ministry of Economy to fund and organize information sessions for young entrepreneurs...”*
- **MEASURABLE:** *“... three information sessions...”*
- **ACHIEVABLE:** *“...drawing from existing budget lines...”*
- **RELEVANT:** *“... with the target of involving at least 500 young entrepreneurs...”*
- **TIME-DEPENDENT:** *“...each year over the next biennium...”*

Final policy goal statement: *“The Ministry of Economy to fund and organize three information sessions each year over the next biennium, drawing from existing budget lines with the target of involving at least 500 young entrepreneurs.”*

When bridging the “Problem Definition” and “Setting the Objectives” stages, be aware of what you seek to impact. You may tackle **outputs** or **outcomes**, knowing that the extent to which you can control achievement narrows progressively.

FRAMING THE SCOPE OF INTERVENTION²⁰

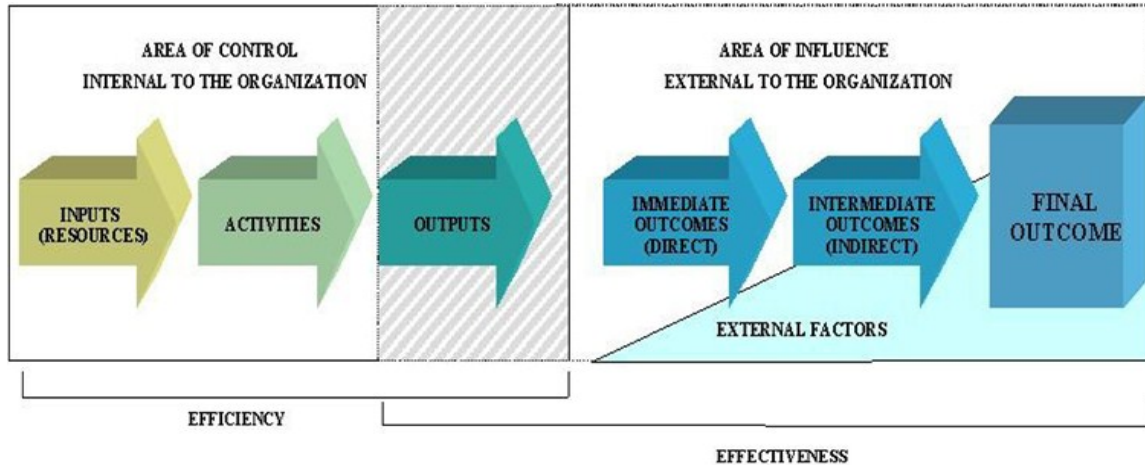
Government intervention must make a difference, and the SN you are producing must realistically show where and how that will be the case. To do so, it is opportune that you understand what your scope of reference is:

- **OUTPUTS** are actions taken in pursuance of policy decisions. They come first and are generally tangible, concrete results of processing resources (inputs).

²⁰ The picture below is adapted from Government of Canada sources.

Example: *the output of recruiting staff is newly appointed employees.*

- OUTCOMES focus on the policy's consequences after implementation. Related to either the process or the outputs, they in any case refer to the level of performance, or the achievement.
Example: *the newly appointed employees may be capable, or incapable of performing their role (Competence vs. Requirements); or too many / too few (Quantity)*



D) Filling the SN template

You must fill Step 8 in the SN Template mandatorily – i.e. whether you are preparing a LOW impact, a MEDIUM impact or HIGH impact initiative.

Step 9: Other relevant information

Filling the SN template

You may fill this Step in the SN Template as appropriate. The information provided is optional.

BE AWARE that it might be more appropriate that you provide additional information when preparing a determined LOW impact initiative than a HIGH impact one.

SECTION 3 – Preferred option

Step 10: Description

A) The importance of this Step

Once you have defined your objectives, you have to identify and explore which options and delivery mechanisms are most likely to achieve them. Reviewing a range of policy options provides greater transparency to the SN exercise. It also grants more robust justification for the chosen course of action, demonstrating to policy-makers and stakeholders that alternative options have been seriously considered but were not pursued for a series of reasons.

B) What may constitute a possible option?

The first thing you have to bear in mind is that any Government action is meant to change behavior of economic and social actors, so that problems are solved. Traditional regulation is but one possible way to change behavior.

POSSIBLE TYPES OF GOVERNMENT INTERVENTIONS

No single solution is correct *a priori*. The main types of options can be situated on a continuum from more intrusive to more respectful of markets and individual choice. They include:

- **COMMAND AND CONTROL REGULATION:** Although *prima facie* it may appear as the easiest and most promising solution (because clear, standardized and predictable), this type of regulation may lead to significant compliance costs; rigidities; opportunistic behaviors (moral hazard).
- **PERFORMANCE-BASED REGULATION:** This type of instrument set standards that specify the required performance of the target population. It does not detail the exact mechanisms by which compliance is obtained, but rather it specifies the criteria to be followed to achieve such compliance. Standards should be flexible allowing aggregation or offsetting between different plants or agents, even regionally or nationally provided this does not unacceptably affect the overall outcome.
- **CO-REGULATION:** This approach implies setting a regulatory framework in which the deadlines and mechanisms for implementation, the methods of monitoring the application of the legislation and any sanctions are set out. The legislative authority also determines to what extent defining and implementing the measures can be left to the concerned parties. The latter must be considered to be representative, organized and accountable. Co-regulation combines the advantages of the binding nature of legislation with a flexible self-regulatory approach to implementation that encourages innovation and draws on the experience of the parties concerned.
- **SELF-REGULATION:** This covers (sectoral) codes of conduct and voluntary agreements, which economic actors and / or civil society players set themselves to regulate and organize their activities. Self-regulation does not involve a legislative act. Self-regulation may provide greater speed, responsiveness and flexibility as it can be established and altered more quickly than legislation. It may therefore be preferable in markets that are changing rapidly. On the other hand, self-regulation techniques require a high degree of trust between government and stakeholders (as well as among the stakeholders). The consensus amongst the various players on the contents and the monitoring of enforcement is crucial for the success of self-regulatory regimes. In addition, self-regulation needs to be an open and transparent process as it may provide an opportunity for collusive arrangements amongst rivals (cartel). In that case, an unintended consequence of self-regulation might be reduced competition.
- **BETTER ENFORCEMENT AND IMPLEMENTATION:** This option should always be considered where legislation is already in place, for instance through improved implementation or inspection guidance.
- **DE-REGULATION AND SIMPLIFICATION:** It is often forgotten that one regulatory policy option is streamlining the stock of existing domestic regulation, at various levels of government.
- **INFORMATION, EDUCATION, CAPACITY-BUILDING CAMPAIGNS** (sponsored by public authorities): Especially if they exploit the self-interest of the target audience, educational instruments may effectively improve compliance and management practices. The government can also “nudge” the targeted group by educating and releasing information on the consequences of unchanged behavior. Apparently small alterations of the information set available to individuals may have large consequences for regulatory results.
- **ECONOMIC AND MARKET-BASED MECHANISMS:** Property rights, creation of new markets, liability provisions, etc. – all these instruments may influence the behavior of market players by providing (negative/positive) monetary incentives or by guaranteeing some basic rules of the game. Taxes, charges and fees are potentially useful policy instrument to influence private behavior towards public objectives. They provide flexibility and cost-effectiveness and can be used to ensure that users pay the social price of their production or consumption.

C) How to identify the options

Policy options must be demonstrably linked both to the **causes** of the problem and to the **objectives**. For each option, you should define the appropriate level of ambition in the light of constraints such as compliance costs or considerations of proportionality. There is also a need to identify appropriate policy instruments (legal acts of Romanian Government, legal acts of EU, self-regulation, co-regulation and economic incentives). These instruments can be combined, if necessary in a package, and/or coordinated with EU action.

NOTE that an option may be differentiated on the basis of **the content** of the intervention (substantial changes), or **the type** of the intervention (form of instrument chosen).

A guiding tool in the identification of the options is the **principle of proportionality**: Any Government action should not go beyond what is necessary to achieve satisfactorily the objectives which have been set. Accordingly, government action should be as simple as possible and leave as much scope for sub-national or private intervention as possible (subsidiarity principle).

STRIVE TO BE PROPORTIONATE²¹

The following questions should be used to examine the proportionality of the options proposed in a SN. They are not designed to be answered on a yes/no basis but rather should be explained and supported with qualitative and quantitative evidence where possible. Examining the proportionality of a range of options will help you to establish a shortlist of feasible options to be analyzed in depth.

In relation to the content of the option:

- Does the option go beyond what is necessary to achieve the objective satisfactorily?
- Is the scope of action limited to those aspects that actors other than Government cannot achieve satisfactorily on their own, and where Government can do better? (boundary test)
- If the initiative creates negative impacts, are such costs minimized and commensurate with the objective(s) to be achieved?
- Will Government action leave as much scope for national decision as possible while achieving satisfactorily the objectives set?
- Is the option in accordance with established international, EU and domestic legal provisions?

In relation to the type of the option:

- Is the choice of instrument as simple as possible, and coherent with satisfactory achievement of the objective and effective enforcement?
- Is there a solid justification for the choice of instrument?

REMEMBER that a good way to make the process of identifying options more systematic is to use the **“problem tree approach”** developed in Step 6. Each “because” statement can lead to a potential solution. Just as a problem might have many drivers or causes, many solutions might be needed to resolve it effectively.

D) Filling the SN template

²¹ Adapted from the European Commission IA Guidelines (2009), p.29.

You must fill Step 10 in the SN Template mandatorily – i.e. whether you are preparing a LOW impact, a MEDIUM impact or HIGH impact initiative.

EXCURSUS 1: What constitutes an impact?

In the following steps of this Section, you are asked to provide information on the **types**, **likelihood** and evidence of the **magnitude** of the impacts that the Government intervention is likely to produce. This serves as the basis for comparing them both against one other and against the baseline scenario developed in Step 7 above.

The identification and estimation of the impacts is not as difficult as it seems. You must proceed step by step, examining the likely results of each option, and identifying those results as negative (costs) or positive (benefits). You will start by describing them qualitatively, and then quantifying the most important impacts.

Any Government intervention produces both **benefits** and **costs**.

IDENTIFY THE IMPACTS

The **benefits** are the reasons for government action. Without clear benefits, the government should not act. Benefits of government action are any major positive outcome of the action, whether the outcome directly intended (as stated in the goals) or a secondary outcome that is also beneficial.

Benefits can take a variety of economic, social, and environmental forms. Common kinds of benefits presented in a SN include:²²

- Benefits to CONSUMERS: a reduction in pain and suffering; increased access to information; lower prices; improved safety of products, workplaces, services etc.;
- Benefits to BUSINESS: reduction in plant or property damage; a reduction in lost production time; reduced compliance costs; less anti-competitive behavior in the market or greater regulatory transparency, certainty and predictability;
- Benefits to GOVERNMENT: streamlined regulatory processes and requirements; reduced monitoring and enforcement costs; higher levels of compliance; and
- Benefits to the COMMUNITY: improved environmental outcomes; safer workplaces; greater access to services or opportunities; more economical use of resources and higher economic growth; and an increase in the standard of living and quality of life.

Whenever possible, and especially for economic benefits, benefits should be stated in monetized terms, such as RON/year. Potential social and environmental benefits may be more easily stated in a standard metric (a metric is simply a way to measure the benefits) so that options can be compared. If you only make general statements, such as “better safety and health” or “safer roads,” it will be impossible to know which option provides more protection. By contrast, try to use metrics such as number (or percentage) lives saved; of mortal accidents prevented; of elderly people rescued from poverty; etc.

Costs are any negative consequence of action or non-action. It is not acceptable to state that Government intervention has benefits, but no costs. Every government policy choice bears costs.

SNs typically consider DIRECT COMPLIANCE COSTS TO BUSINESSES AND CITIZENS. These are the direct additional costs to businesses of performing tasks to comply with government regulation. They can be divided into two categories:

²² Adapted from the Australian Government’s Guide for regulation (1998).

- administrative and other operating costs; and
- capital costs such as buying new equipment.

Costs of government intervention are presented in parallel with the benefits, and are based on the same approach: presentation of major economic costs in RON/year, and presentation of major environmental and social costs in a measurable metric (e.g. tons of CO₂ emitted per year). When no metric is available, the impact should be described as precisely as possible.

In identifying impacts, you should keep the following points in mind:

- think both short-term and long-term – it is often easier to identify short-term impacts;
- make efforts to assess impacts that cannot readily be expressed in quantitative or monetary terms;
- recognize that various factors producing the impacts also interact with one another;
- remember that the impacts of the proposal may be affected by the implementation of other initiatives, particularly if the proposal is part of a ‘package’; and
- assess impacts in context of Romania’s Treaty obligations and the EU’s overall policy goals, e.g. respect for Fundamental Rights, promoting sustainable development, achieving the goals of the Europe2020 Strategy,, etc.

ANNEX 1 to these Guidelines provides a list of possible economic, social and environmental impacts which helps you consider impacts systematically.

EXCURSUS 2: How can I collect data?

Once you know which impacts the option is likely to produce, it is fundamental that you substantiate as much as possible your arguments and reasoning. To that end, you need information and data that is relevant and reliable. This is an essential component of any SN, both for qualitative and quantitative assessments.

Data collection is probably the most time consuming activity in the preparation of a SN. This is particularly the case if you have to prepare a SN Study. Your efforts should therefore be proportionate to the importance of the initiative.

Sources of existing information

Information available at hand may include:

- monitoring or evaluation reports from previous or similar programs and initiatives;
- earlier analyses in your department and consultation documents;
- statistical data from the National Institute of Statistics, Eurostat,²³ and others;
- studies and research by governmental and EU agencies;
- stakeholders sources (e.g. from previous hearings, conferences, press statements);
- national agencies and research institutes, as well as SINAPSE²⁴ (for scientific evidence);

²³ <http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home/>

²⁴ Scientific INformAtion for Policy Support in Europe (SINAPSE) serves as a platform for e-community and as a e-library to promote a better use of expertise in EU policy making and governance. See <http://europa.eu/sinapse/>.

- examples and experiences in other EU Member States, third countries or international organizations (e.g. World Bank, OECD).

If you are not aware of any those, you should seek support as early as possible within your department, in the government, and from external experts.

Data collection methods

When designing the way you will collect data, you can chose among a range of methods. The options suggested below are not exclusive, and may be applied complementarily depending on your needs.

Typical QUANTITATIVE DATA COLLECTION METHODS are:

- Surveys: collects primary data using a questionnaire applied on a representative sample of subjects;
- Descriptive statistics:
 - measures of central tendency: mean, median and mode
 - measures of dispersion: standard deviation and variance
 - measures of association: correlation and regression
- Inferential statistics: go beyond data using samples and populations to test hypotheses

Common QUALITATIVE DATA COLLECTION METHODS include:

- Interviews (structured / unstructured): used in the inception stage of the process to gather information from relevant stakeholders when there is little information available on the wider policy context and issues to be addressed
- Brainstorming / expert methods / DELPHI: used both in defining the problem and the policy options, rely on selecting a group of either external or internal experts and professionals that can deliver in a structured way their opinions; while brainstorming is aimed at merely gathering ideas and criticism is not allowed, DELPHI method uses increasingly precise questionnaires in several rounds, which are statistically processed and significantly different views must be accounted for;
- Focus group: conducted on relatively large numbers of persons divided as per affected groups. It involves a questionnaire with no more that 4-6 questions for each group. Answers must be centralized in a final report highlighting both common and divergent opinions.
- Case study: used to describe the relevant area for the policy proposal, adequate when there is little time to collect quantitative data as it informs on particular issues related to the nature of issues to be addressed;
- SWOT analysis: used during brainstorming sessions for listing out of a wider list of potential strengths, weaknesses, opportunities and threats on a matrix the most important ones;
- Problem-tree method: identifying all major problems which are relevant for the policy area and causal relationships between them, to understand the context and potential impact of implementing a policy;

- Fish-bone diagram: a cause-effect based analysis, aimed at describing both the problems addressed by the policy and the objectives of the policy
- Documentary analysis / desk research; a structured way to collect relevant data using already available reports, studies and statistics.

When using different data collection methods, always keep these key criteria in mind that the data you collect and use after you process it must be:

- reliable (i.e. you get the same results if you repeat the data collection and process exercise); and
- valid (i.e. you are sure that the data reflects what it is supposed to measure).

DETERMINE UNKNOWN FIGURES²⁵

What if I do not possess readily available data?

A number of strategies allows you to get or extrapolate measurement indicators for your impacts. They include

USING REFERENCE SOURCES

- Check the details of how the numbers were derived. Various sources may use different operational definitions.
- Use multiple sources, but ensure that your valuations are consistent.
- Avoid, if you can, sources that don't offer operational definitions.

USING SURVEYS

- Survey systematically interested parties.
- If there is not enough time / resources to conduct an ad hoc survey, look for national / local surveys done on a regular basis by well-known organizations (research centers, leading newspapers ...).

GUESSING

- Use rates that do not vary much from place to place to guess an absolute number (to guess the number of deaths, multiply death rates by a population – instead of compiling actual figures from population registries).
- Look if there are widely accepted rules of thumb.
- Use rates characterizing similar phenomena.
- Use a known variable to guess another when a relationship between the two is known (population growth as a function of time and previous growth rates).
- Set boundaries by reference to another variable (the maximum number of children using diapers cannot be larger than the population between the age of birth to four years).
- Employ triangulation, i.e. using several separate approaches / data sources to estimate a quantity and comparing the results.

USING EXPERTS

- Verify the credentials of the experts.
- Use methods for pooling their estimates and lowering their estimate margin of error (see Delphi method).

²⁵ Adapted from the European Commission IA Guidelines (2009), ANNEX 11.3.

Step 11: Financial impacts

Are public authorities actually involved in or affected by the implementation of the option? This Step refers to the impacts on the general consolidated budget, both on the short term, for the current year, and on the long term (5 years).

A) Types of financial impacts

The Ministry of Public Finance requires information on the following indicators:

Indicators	In thousands of LEI					
	Current year	Next 4 years				5 year average
		3	4	5	6	
1	2	3	4	5	6	7
1. Changes of the budget incomes, plus/minus, of which: a) state budget, of which: (i) tax on profit (ii) tax on income b) local budgets: (i) tax on profit c) state social security budget: (i) social security contributions						
2. Changes of the budget expenses, plus/minus, of which: a) state budget, of which: (i) personnel expenses (ii) goods and services b) local budgets: (i) personnel expenses (ii) goods and services c) state social security budget: (i) personnel expenses (ii) goods and services						
3. Financial impact, plus/minus, of which: a) state budget b) local budgets						
4. Proposals for covering the increased budget expenses						
5. Proposals for compensating the decreased budget incomes						
6. Detailed calculations on substantiation of changes in the budget incomes and/or expenses						
7. Other information						

B) Filling the SN template

You must fill Step 10 in the SN Template mandatorily – i.e. whether you are preparing a LOW impact, a MEDIUM impact or HIGH impact initiative.

If you are working on a LOW impact initiative, a qualitative description of the problem is sufficient. For MEDIUM and HIGH impact initiatives, by contrast, you are required to provide quantified evidence.

In the SN study (HIGH impact initiative), you are also required to present the reasoning followed, including the assumptions made and specify the sources from which data was collected.

Step 12: Economic impacts

A) Determining direct compliance impacts

Direct compliance impacts refer to the sum of all changes associated to compliance process by businesses. Compliance costs are the costs that are incurred by businesses or other parties at whom regulation may be targeted in undertaking actions necessary to comply with the regulatory requirements, as well as the costs to government of regulatory administration and enforcement.

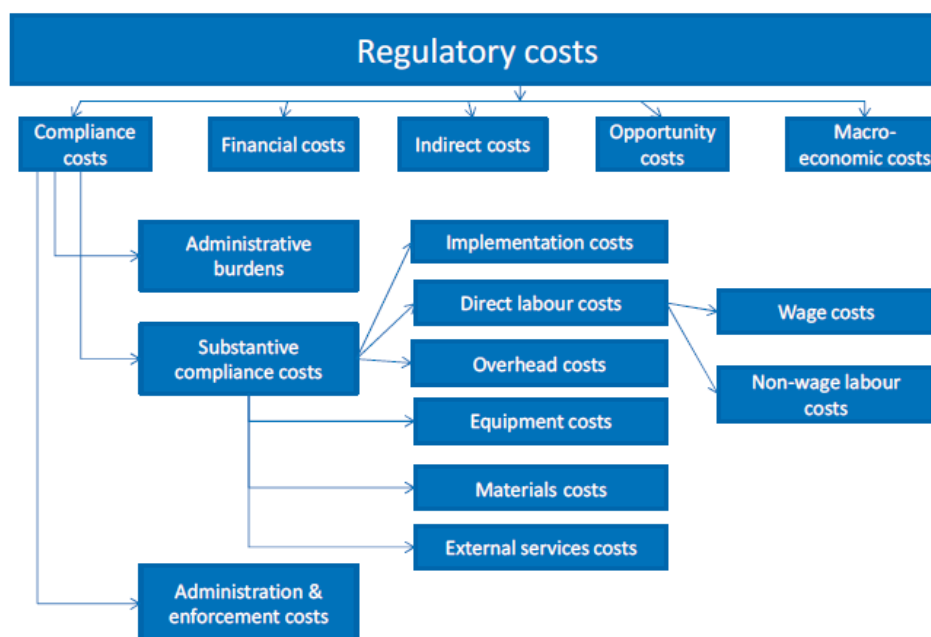
To calculate them:

- estimate cost per each component;
- calculate total compliance costs per business;
- estimate number of business affected; and
- multiply to get the grand total.

WHAT CONSTITUTES A COMPLIANCE COST COMPONENT?²⁶

Substantive compliance costs include only the direct costs borne by those upon whom the regulation imposes compliance obligations.

The following figure illustrates the various types of costs:



²⁶ The figure below stems from the OECD Regulatory Compliance Cost Assessment Guidance, 2014, p.11.

The Australian Government issued an online **BUSINESS COST CALCULATOR**, which can be accessed at <http://www.dpmc.gov.au/deregulation/obpr/bcc/index.cfm>.

HOW TO ESTIMATE THE NUMBER OF AFFECTED FIRMS

Potential sources include:

- government statistical collections;
- industry associations;
- academic research;
- information from other government departments (e.g. where other existing regulations affect a similar group);
- licensing or registration data;
- information from regulators in other, comparable jurisdictions;
- insurance claims data; and
- surveys of potentially affected industry sectors (either existing survey-based data or the results of surveys undertaken as part of the compliance cost assessment process).

B) Measuring administrative burdens

EU conditionalities require you to provide details of the information obligations for businesses that are likely to be added or eliminated if the option were to be implemented. These kinds of costs are quantified because there is an accepted European strategy to reduce them. **Administrative burdens (AB)** are the costs of complying with information obligations stemming from government regulation. Examples of such obligations include:

- gathering information;
- processing information;
- submitting and filing reports;
- external control by accountants;
- general meetings.

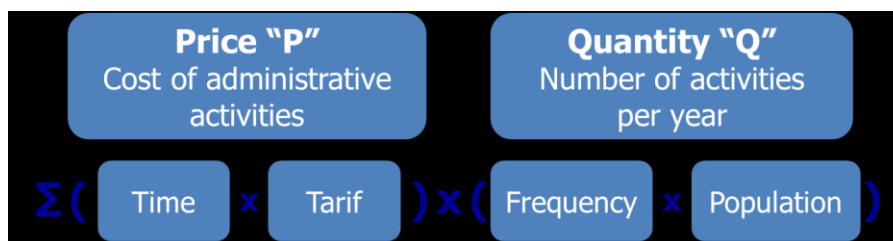
For policy options that entail new information obligations, you should indicate in the SN how this information contributes to the effectiveness of the option in achieving the objectives. You should always consider alternative options that do not lead to additional information obligations. It is important that the analysis of the impacts clarifies the trade-offs between information obligations and the principal objectives of the proposal.

The **Standard Cost Model (SCM)** is the most common formula to express administrative burdens in monetary terms. The SCM multiplies the costs of the activities that have to be carried out to meet information obligations (Price “P”) by the number of activities per year (Quantity “Q”):

- The costs of activities are calculated by multiplying the time spent by a tariff. The latter can be an internal tariff or the hourly cost for external service providers and time.
- The yearly number of activities is calculated by multiplying the frequency by the population.

The sum of all administrative costs of all activities ($\Sigma P*Q$) is the total administrative costs of a regulation (see Figure 1).

Figure 1: The Standard Cost Model formula



Note that more information on the AB measurement and SCM calculations is included in the manual issued by the Government Secretariat General (GSG) in 2010.²⁷

MEASURING ADMINISTRATIVE BURDENS: An example²⁸

If the option would increase the required frequency of reporting to a government agency from quarterly to monthly, the base case incorporates the cost of the currently required quarterly reporting. Thus, the incremental cost is that of preparing and lodging an additional 8 reports annually, rather than the total cost of the 12 reports required.

Thus, if 1 000 firms are affected and the cost per report averages RON 1,500:

Base case costing: RON 1,500 x 1,000 x 4 reports = RON 600,000 per annum

Cost of compliance with new requirement. RON 1,500 x 1 000 x 12 reports = RON 1,800,000 per annum

Incremental cost of the option. RON 1,800,000 – RON 600,000 = RON 1,200,000 per annum.

Thus, the compliance cost assessment should report that the incremental cost of the specific option is equal to RON 1,200,000 per annum

C) Determining impacts on the competition environment and on the state aid area

Because options may have an influence on competition, you should first ascertain whether they include explicit liberalization provisions or measures that are likely to raise or lower the barriers that firms face to enter or leave the market.

The Competition Council provides the following checklist:

- a) direct or indirect limitation of the number of providers in case the draft legislative act:
 - i. ensures a company's exclusive right to provide a product or service;
 - ii. establishes a license, a permit or an authorization as a requirement for carrying out the activity;
 - iii. limits some companies' capacity to participate in public procurements;
 - iv. leads to a significant increase of the market entry or exit costs

²⁷ Berenschot Business Development Group (2010), *Standard Cost Model Manual, Romanian Manual for measuring administrative costs for business*, available online at:

<http://www.sgg.ro/docs/File/UPP/doc/20100617-manual-en.pdf> (last access: 03.07.2014).

²⁸ Adapted from the OECD Regulatory Compliance Cost Assessment Guidance, 2014, p.41.

- v. creates a geographical barrier in relation to the companies' capacity to provide goods or services, to invest capital or to provide workforce
- b) limitation of providers' capacity to compete in case the draft legislative act:
 - i. controls or influences, in a substantial manner, at which price a good or a service is sold;
 - ii. limits the providers' freedom to advertise their own products (beyond the limitation determined by the compliance with copyrights and by the prevention of deceptive advertising);
 - iii. establishes product or service quality standards, which are significantly different from the current practices;
 - iv. leads to a significant increase of the production costs of some providers in relation to the others (especially by the different treatment to be applied to operators newly-entered in the market in relation to the existent ones);
 - c) reduction of the degree of stimulation of providers to effectively compete in case the draft legislative act:
 - i. establishes a self-regulation or co-regulation status;
 - ii. requires or fosters the publication of information on company's production, prices or costs;
 - iii. exonerates the activity in a certain area or a group of undertakings from the application of the rules of competition;
 - d) limits the options and information available to clients in case the draft legislative act:
 - i. limits the clients' options;
 - ii. reduces the clients' mobility against the providers of goods and services by explicitly or implicitly increasing the costs of changing such providers;
 - e) taking a state aid measure in case the draft legislative act establishes a support measure fulfilling the following conditions:
 - i. stems from public funds, regardless of the form (either cash in banks or credits with subsidized interest, or tax exemptions, deferrals or discounts etc.) or are granted by a public institution;
 - ii. is selective;
 - iii. can create an economic advantage for certain undertakings;
 - iv. distorts or can distort competition on the Single Market.

D) Determining the impact on small businesses (SMEs)

Due to their size and scarce resources, Small and Medium-sized Enterprises (SMEs) can be affected by the costs of regulations more than their bigger competitors. At the same time, the benefits of regulations tend to be more evenly distributed over companies of different sizes. SMEs may have limited scope for benefiting from economies of scale. SMEs in general find it more difficult to access capital and as a result the cost of capital for them is often higher than for larger businesses.

The European Commission requires carrying out a dedicated assessment to ensure the effective implementation of the EU Small Business Act and its Review (including the "Think

Small First” principle).²⁹ The Romanian Government adopted a procedure in this regard in May 2014.³⁰

For these reasons, you should consider performing a **SME-Test**. This consists of the following:

- **Establishing whether SMEs are among the affected population, and their characteristics:**
 - number of businesses and their size (micro, small, medium or large enterprises)
 - proportion of the employment concerned in the different categories of enterprises affected
 - weight of the different kind of SMEs in the sector(s) (micro, small and medium ones)
 - links with other sectors and possible effect on subcontracting
- **Measuring the distribution of the potential benefits and costs, differentiating between micro- (0-10 employees); small- (11-50 employees); and medium (51-250 employees) firms.** Typical costs to consider are:
 - Financial costs – created by the obligation to pay fees or duties
 - Substantive costs – created by the obligation to adapt the nature of the product/service and/or production/service delivery process to meet economic, social or environmental standards (e.g. the purchase of new equipment, training of staff, additional investments to be made)
 - Administrative costs – created by the obligation to provide information on the activities or products of the company including one-off and recurring administrative costs (e.g. re-sources to acquire or provide information)
- **Cost and impacts identified for SMEs should be compared with those of large enterprises.** For this purpose, you could for instance compare the overall costs identified to the number of persons employ to obtain the average cost per employee. Alternatively, you could compare the costs identified to the total overhead or turn-over of the company.
- **In addition, it would be useful to consider the following additional elements:**
 - possible loss of competitiveness due to external factors such as the availability of finance, tax regimes, access to resources or skills, etc.
 - possible changes in the behavior of competitors, suppliers or customers
 - possible impacts on barriers to entry, competition in the market and market structure, for example in terms of possibilities for SMEs to enter markets.
 - possible impact on innovation, understood as both technological and non-technological innovation (process, marketing, etc.)
 - benefits, if applicable, coming from the proposal (burden reduction, improved productivity and competitiveness, greater investments or innovation etc.)
- **Assess alternative options and mitigating measures:** if the abovementioned cost/benefit analysis shows that SMEs are disproportionately affected (or disadvantaged compared to large companies), you consider using possible SME specific mitigating measures. A non-exhaustive list of measures to be considered includes:

²⁹ See http://ec.europa.eu/enterprise/policies/sme/small-business-act/index_en.htm.

³⁰ Law 62/2014, published in the Official Gazette of Romania no.328/06.05.2014. The Methodology for the elaboration of the SME Test was adopted by Ministerial Order no.698/04.06.2014, published in the Official Gazette of Romania no.438/16.06.2014.

- complete or partial size-related exemptions for SMEs or micro-businesses (Example: businesses below certain thresholds do not have to comply with certain specific obligations when this does not invalidate the original purpose of the legislation)
 - temporary reduction or exemptions (Example: transition periods during which SMEs are exempted or longer intervals for certain obligations)
 - tax reductions or direct financial aid to compensate costs incurred provided this is compatible with existing legislation (on competition or international trade).
 - reduced fees (Example: when these fees are particularly high and/or represent a fixed cost that would will be felt disproportionately by SMEs)
 - simplified reporting obligations for SMEs (Example: in the area of statistics, explore possible synergies with already existing reporting obligations)
 - specific information campaigns or user guides, training and dedicated help-desks/offices (Example: specific SME help-desks providing tailored information for small businesses)
 - systematically consider general simplification initiatives which can particularly benefit SMEs (Example: possibility to use on-line facilities, simplified inspections)
- When assessing possible mitigating measures for SMEs, you should include the costs that these could produce in your final assessment.

E) Filling the SN template

You must fill Step 11 in the SN Template mandatorily – i.e. whether you are preparing a LOW impact, a MEDIUM impact or HIGH impact initiative.

If you are working on a LOW impact initiative, a qualitative description of the problem is sufficient. For MEDIUM and HIGH impact initiatives, by contrast, you are required to provide quantified evidence.

In the SN study (HIGH impact initiative), you are also required to present the reasoning followed, including the assumptions made and specify the sources from which data was collected.

Step 13: Social and health impacts

A) The importance of this Step

Social impacts include all consequences to human populations, either restricted or taken as a whole. They relate to situations at work; in the education and culture; health; and living in general.

Assessing social impacts correctly is a precondition to ensure effectiveness and efficiency when striving to achieve many policy goals. However, it is also important to facilitate a smooth implementation of the preferred option, for instance by prevent or mitigate resistances by specific groups. Moreover, in the majority of cases, the costs of rectifying adverse social and health impacts are borne by the public sector, so there is a strong incentive to get it right from the outset.

B) Determining social and health impacts

The related table in Annex 1 to these Guidelines lists a number of possible social and health impacts that you should consider at this stage.

These Guidelines draw your attention specifically to three categories that are likely to be among the most relevant for your analysis:

- **DISTRIBUTIONAL IMPACTS:** When addressing different social and economic groups, you need to identify “winners and losers”. You need also to consider any impact on vulnerable groups (e.g. Roma minorities) that the option is likely to trigger. Government action may leave existing inequalities unchanged, aggravate them, or help to reduce them.

For instance, you need to envisage specific supporting action for elderly people as a result of measures introduced to foster electronic access to public services.

This is not a simple matter: for example, differences between male and female lifestyles (e.g. in nutrition habits) may mean that a proposal which appears at first sight to be neutral as regards gender equality will in practice have different impacts on men and women.

Geographical considerations are also relevant in this context – for example with regard to mountain or remote rural areas.

- **HEALTH IMPACTS:**

Often used metrics to express health impacts quantitatively relies on typical indicators such as:

- Healthy life expectancy at birth
- Proportion of population that is disabled or suffers from a given health problem
- Occupational morbidity

In other cases, you may follow the so-called “cost-of-illness approach”. It refers to an estimate of the costs associated to accessing medical treatment – for instance cost of a using a bed for a full day multiplied by the number of hospitalization days.

REFERENCE TO HEALTH IMPACT ASSESSMENT

NOTE that more information on the elaboration of health impact assessment is included in a dedicated manual issued by the Government Secretariat General (GSG) in 2009.³¹

Guidance from the European Commission

For these types of impacts, you may also consider the guidance issued by the European Commission

DG Employment, has issued a useful guide on the matter, which you can download at <http://ec.europa.eu/social/main.jsp?catId=307&langId=en>.

³¹ Romanian version: “Manual și metodologie pentru studii de impact în domeniul sănătății”, accessible online at: <http://www.sgg.ro/docs/File/UPP/doc/manual-metodologie-pentru-studii-de-impact-in-domeniul-sanatatii.pdf> (last access: 03.07.2014).

On Health impact, specifically, you can consult the DG SANCO guide at http://ec.europa.eu/health/ph_projects/2001/monitoring/fp_monitoring_2001_a6_frep_11_en.pdf.

C) Filling the SN Template

You are always required to provide information on the social and health dimension of your proposal.

For LOW impact initiative, such information may remain qualitative (but still objective), while you should provide quantified evidence for MEDIUM and HIGH impact initiatives.

In the SN study (HIGH impact initiative), you are also required to present the reasoning followed, including the assumptions made and specify the sources from which data was collected.

Step 14: Environmental impacts

A) The importance of this Step

Environmental impact assessment is necessary because many economic activities do have repercussions on the quality of the air, soil and waters, as well as on the flora and fauna. As a SN drafter, you can be in the following two situations:

- your initiative is primarily conceived to manage, mitigate or avoid an environmental risk or damage – In this case, your task is to mainly seek to ascertain the type and magnitude of possible environmental benefits from any given option. Alternatively,
- your initiative is not directly triggered by an explicit environmental policy objective – In this case, your task is to identify and assess any possible environmental costs associated to the options you are considering to achieve the set policy objective(s).

B) Determining environmental impacts

The related table in Annex 1 to these Guidelines list a number of possible environmental impacts that you should consider at this stage. Broadly speaking, environmental impacts fall under the following categories:

- climate
- transport / energy
- air / waters / soil quality and resources
- bio-diversity
- land use
- renewable resources
- waste production / management / recycling
- animal welfare
- international env. impacts

As specified above, it is important that you express them AS CLEARLY AS POSSIBLE, possibly with quantified metrics or in monetized terms. This is essential if you want to COMPARE options on an objective basis.

NOTE that environmental impacts are generally easier to quantify than you might initially think. Examples of metrics are:

- tons of CO₂ emitted (or number of estimated trucks on a given road);
- concentration of substance XY in the water;
- value of human life saved; or
- size of population exposed to a given harm.
- Moreover, some costs associated to environmental interventions are usually direct compliance costs (e.g. number and costs of filters or other equipment to apply to factories; reporting costs, etc.).

REFER TO INTERNATIONAL EXPERIENCES AND STUDIES if you have difficulties in identify the appropriate way to express environmental impacts.

C) Filling the SN Template

You are always required to provide information on the environmental dimension of your proposal.

For LOW impact initiative, such information may remain qualitative (but still objective), while you should provide quantified evidence for MEDIUM and HIGH impact initiatives.

In the SN study (HIGH impact initiative), you are also required to present the reasoning followed, including the assumptions made and specify the sources from which data was collected.

SECTION 4 – ALTERNATIVE OPTION

Steps 15-19: Information on the alternative option

Filling the SN Template

You must explore at least a possible alternative option and fill this Section only if you are working on a MEDIUM or HIGH impact initiative. If you are working on a LOW impact initiative, you can skip this Section altogether.

To fill the template, follow the guidance provided for Steps 10–14 above. NOTE that for the MEDIUM impact initiative a qualitative analysis is sufficient. For HIGH impact initiatives, by contrast, you are required to provide quantified evidence.

In the SN study (HIGH impact initiative), you are also required to present the reasoning followed, including the assumptions made and specify the sources from which data was collected.

SECTION 5 – PUBLIC CONSULTATION PROCESS

Step 20: Substantiation Note BEFORE consultation

A) The importance of this Step

Public consultation is integral part and a fundamental component of the SN process. It directly reflects the principle of transparency, of participation and of legitimate expectations from public administration Government action.

The consultation process provides an excellent opportunity for the PPP analysts to collect information held by non-government sources, and at low cost. In particular, consultation serves the following functions:

- bridging the information gap between the regulator and the regulated;
- widening and deepening the empirical basis for decision-making;
- enhancing transparency and accountability;
- reducing the risk of regulatory capture, regulatory failure, and unintended consequences;
- improving implementation by spotting at an early stage what can go wrong with implementation.

REFER TO THE PUBLIC CONSULTATION LEGAL BASE³²

NOTE that public consultation is a mandatory activity forming integral part of the Government decision-making process. You must rely on the following legal bases:

- Law No. 52/2003 on transparent decision-making in public administration;
- Government Decision No. 521/2005 on the procedure for consulting the associative structures of the local public administration authorities in the elaboration of draft legislative acts; and
- Law no.62/2011 on social dialogue.

B) Key questions asked to the stakeholders

You can conceive to focus the consultation round on virtually all aspect of the SN analysis, covering all or only specific steps. The decision on how to craft the consultation document is yours, but you might want to find a balance between standard general questions and more tailor-made enquiries.

The following are possible examples of questions:

- **PROBLEM DEFINITION:** - Is the problem correctly defined and understood? Why not?

³² Eventually the new Guidelines will have to refer to the new provisions (containing the suggested amendments).

- Is the baseline option reasonably projected into the future? Why not?
- PERFORMANCE GOALS: - Are the performance goals appropriate for Romania? Why not?
- OPTIONS: - Are the identified options realistic and reasonable? Why not?
- Should other options be considered? Which ones? Why?
- COSTS AND BENEFITS: - Does the PPP identify all important costs and benefits of the options?
- What other costs and benefits should be considered?
- Can you submit data so as to be more precise about the magnitude of the costs and benefits, and the comparisons of the options?
- OTHER IMPACTS: - Should other impacts, such as distributional impacts, be added to the analysis?

You should always ask stakeholders to provide own data and justify their inputs.

C) Envisaged stakeholders to be consulted

You should identify the main stakeholders who should be involved. This should be broad rather than narrow. When envisaging the type of stakeholders you want to reach out to, you must consider two distinct but equally relevant rationales: first, the consultation exercise is a means for public participation in decision-making, hence it should never exclude anyone with valid interests. Second, the consultation must serve your purpose – i.e. verifying and strengthening your draft SN. Accordingly, you should also think in terms of your specific needs.

- A GOOD consultation process brings in the views of all stakeholders with significant interests, with relevant information, and with a role in implementation.
- A POOR consultation process allows access to only dominant, powerful, or well-connected stakeholders.

Broadly speaking, stakeholders are:

- individuals, groups, or organizations whose interests are affected by the issue or those whose activities strongly affect the issue. Stakeholders might include other levels of government and those from third countries;
- those who possess information, resources and expertise needed for the impact assessment, strategy formulation, and implementation; and
- those who control relevant implementation instruments.

PREPARE A CONSULTATION MATRIX

A consultation matrix is a complete list of stakeholders and their position on the problem or issue you are working on. It should show

- the interests of different stakeholders concerning the identified policy problem

- the resources at their disposal, esp. in relation to what can be brought into the debate on the specific issue
- their capacity to mobilize resources
- official / public position regarding the policy at stake

A possible matrix may look as follows:

Stakeholder	Interest /mission / representativity	Opinion / position	Capacity to mobilize resurces
Stakeholder A			
Stakeholder B			
....			

D) Filling the SN Template

You must fill Step 20 in the SN Template mandatorily – i.e. whether you are preparing a LOW impact, a MEDIUM impact or HIGH impact initiative.

BEAR IN MIND that you have to undergo two rounds of consultations if you are preparing a MEDIUM impact or HIGH impact initiative: the first consultation round pertains only to the draft SN / SN study, while the second round includes also the draft legal act. You must therefore specify which stage of the process you are at when filling this Step.

Step 21: Substantiation Note AFTER consultation

A) The importance of this Step

This Step is based on the previous one and complements the information provided there with the outcomes of the consultation as it took place. It is important for the SN reader to understand how the channels provided for by law have been deployed to reach out stakeholders and experts, and who actually contributed what inputs.

B) Making use of consultation inputs

You are responsible for using the inputs received in an efficient and objective manner. This may not always be as simple as it seems. When carrying out the consultation and using the information it produces, you should be aware of a number of pitfalls that may introduce a bias into the results. In particular,

- **DISTINGUISH EVIDENCE FROM OPINIONS:** When you use a consultation to gather data, you should *verify* carefully that the method you use is correct and appropriate, and try to *validate* the robustness of the results. Peer-reviewing, benchmarking with other studies and sensitivity analysis can significantly enhance the quality of data. You should explore the risks and consequences related to interests groups positions regarding the issue at stake.
- **WEIGHT REPRESENTATIVE INPUTS:** Not all interest groups are equally able to take part in consultations or express their views with the same force. You may need, therefore, to make specific efforts to ensure that all relevant stakeholders are both aware of and able to contribute to the consultation. You should also be careful in drawing

conclusions if there are only a small number of responses and they come from a narrow range of interests. At the same time, you should also give a response its due weight if it represents a large number of citizens or stakeholders.

C) Reporting on the consultation process

You must ensure that as a minimum the following is covered:

- which stakeholders and experts were consulted;
- the reason for having recourse to the chosen consultation channel (especially if it was geared to targeting specific stakeholders or experts); and
- a schematic but comprehensive summary of the main thrust of the comments received, especially those related to the questions asked. In doing so,
 - you must take account of all input received;
 - you should differentiate the arguments outlined, without necessarily naming the source of that position (however, you must keep a precise record of which stakeholder or expert recommended what);
 - very importantly, you must clarify what inputs you decided to retain and which ones you discarded – each time explain why you did so.

D) Filling the SN Template

You must fill Step 21 in the SN Template mandatorily – i.e. whether you are preparing a LOW impact, a MEDIUM impact or HIGH impact initiative.

SECTION 6 – POST-ADOPTION ARRANGEMENTS

Step 22: Implementation arrangements

A) The importance of this Step

Implementation of Government decisions may require substantial changes, the occurrence of which SN readers must be aware of. The costs associated to implementation arrangements must be calculated and taken into consideration when gauging the cost-effectiveness of an option. (As an elementary example, think of nuclear radioactive waste disposal. An environmentally friendly solution would be to store the waste on the moon – but the implementation costs clearly outweigh the benefits.)

B) Implementation arrangements to be considered

One of the primary areas of attention concerns the changes that are likely to occur in the **public sector**. Accordingly, you should indicate (each time by referring to the central and/or the local level):

- possibilities of obtaining the desired outcome by using the existent public institutions (if that is not possible, the reasons shall be specified);
- functions of the existent institutions to be changed (extended or down-sized) or transferred (and to whom);

- public institutions to be established, re-organized or terminated as a consequence of the implementation of the option;
- the nature of the funding associated to these changes, specifying
 - where the funds stem from (e.g. national ordinary budget, extraordinary funds; EU funds, international donors aid, on a fee-for-service basis; etc.); and
 - what the funds will cover (e.g. re-location plans, capacity-building or early retirement programs for affected civil servants, etc.).

Important implementation arrangements may affect the **private sector**, too. These may require specific financial assistance also from public entities.

You must also indicate an **implementation calendar** – i.e. whether the implementation of the Government decision can take place immediately after adoption or whether an additional period and a transition period is granted for implementation.

C) Filling the SN Template

You must provide information in Step 22 on the main arrangements necessary to implement the preferred option **ONLY** if you are working on a MEDIUM or HIGH impact initiative. If you are working on a LOW impact initiative, you can skip this Step.

Step 23: Monitoring and evaluation activities

A) The importance of this Step

To be effective, analysis has to include specific information of compliance, enforcement, and the responses of those who will be most likely be affected by the Government decision. Policy-makers need to have reliable indicators to check if implementation is “on track” and the extent to which the intervention is achieving its objectives. Information on arrangements for monitoring also allow for understanding why the measure is failing to be effective.

DEFINITIONS

“Monitoring” is not the same thing as “evaluation”:

- MONITORING is the continuous and systematic collection of data on specified indicators to provide management and main stakeholders of an ongoing development intervention with the indications of the extent of progress and achievement of objectives;
- EVALUATION is the periodic assessment of the relevance, performance, efficiency, and impact (both expected and unexpected) of an intervention, in relation to the stated objectives.

A detailed outline of the monitoring and evaluation (M&E) activities is normally best designed after the measure is formally adopted. It is obviously useless to provide detailed M&E information on policy options that will not be implemented. In this Step you are asked to sketch the indicators because:

- resources are limited and also M&E activities may be costly. It is important to compute a level of such resources (e.g. number of staff, (outsourced) research, public consultations, etc.) that is proportionate to the scope and potential impact of the proposed measure. As

a general rule, collecting data should not be more costly than the value of the information they provide; and

- the Government decision is part of a policy cycle and it is important to set the bricks that bridge all phases of it – from ex-ante analysis to impact evaluation – so to best prepare the basis possible future interventions.

B) Planning for M&E

When thinking ahead to the M&E activities, you should ask yourself the following questions:

- **NATURE:** - How will this option be measured to see if it is working?
- What are the focus and purpose of M&E activities?
- To what extent do M&E structures already exist? Does new capacity need to be put in place? Is a specific legal basis necessary?
- **TIMING:** - When should findings be produced, and used?
- **DATA:** - Is the information I need to evaluate the policy readily available?
- Is there baseline information to allow for a before vs. after comparison?
- What and where are the data gaps? Can they be addressed now?
- How can I organize end-user feedback?
- **ACTORS:** - Who are the key actors in providing and using such information?
- What will be the roles of these actors? Who is responsible for what?
- **USE:** - How and to whom should the M&E findings be communicated?

C) Developing performance indicators

Performance indicators measure the extent to which the Government decision has been properly implemented and its objectives achieved. Another important factor in designing your indicators is the ease with which data can be collected.

To ensure that performance indicators are properly used, they should:

- be relevant, i.e. closely linked to the objectives;
- be objective, easy to interpret and robust against manipulation;
- be small in number and easy to monitor (data collection should be possible at low cost),
- be accepted (by staff as well as stakeholders); and
- have immediate impact (e.g., naming and shaming, administrative and financial sanctions).

It may be useful to distinguish between input (resources) – output – outcome (end result) – impact indicators. Possible issues covered by a monitoring system include:

- implementation at various levels of government;
- compliance of end-users (e.g. enterprises producing according to certain minimum standards; number of certificates issued, etc.), and their costs;
- number and type of inspections, their results and their costs (enforcement costs);
- number and type of sanctions / penalties;

- attainment of target levels or outcomes specified in the objectives;
- context / macro-economic variables;
- etc.

PERFORMANCE INDICATORS: Some examples

QUANTITATIVE

- number of deaths / road accidents
- percentage of children leaving school with science qualifications / foreign language etc.
- time taken to start-up a business
- percentage of business paying their taxes on time
- change in number of construction companies complying with health and safety legislation

QUALITATIVE

- Levels of satisfaction among citizens / business
- Perceived improvements to quality of life / ease of doing business with government
- Change in media coverage (from negative to positive coverage)

D) Filling the SN Template

You must fill Step 23 in the SN Template ONLY REFERRED TO THE PREFERRED OPTION outlined in Section 3 above, and ONLY if you are working on a HIGH impact initiative.

SECTION 7 – INFORMATION ON FINAL ENDORSEMENT

You are required by law to provide information on both the necessity to get formal endorsement of the draft legislative act and to report any significant objections or comment received which were not included in the finalization of the proposal. The relevant institutions are:

- Legislative Council;
- Supreme Council of National Defense;
- Economic and Social Council;
- Competition Council;
- Court of Accounts.

REFER TO THE FINAL ENDORSEMENT LEGAL BASE

Final endorsement is provided for by GD 561/2009.

Law No. 24/2000 on the legislative technique norms for elaboration of legislative acts, republished, and Government Decision No. 50/2005 approving the Regulation on procedures, at Government level, for the

elaboration, endorsement and presentation of draft legislative acts for adoption, republished, as subsequently amended.

SECTION 8 – ACCREDITATION

Once your SN template is finalized, it must be dated and signed off by your Minister – or a person explicitly delegated by him / her.

An unsigned SN template is not valid.

APPENDIX 1 – POTENTIAL ECONOMIC, SOCIAL AND ENVIRONMENTAL IMPACTS

The tables below provide a list of possible impacts against which to screen your options.³³

Impacturi economice	Întrebări cheie
Funcționarea pieței și concurenței	<ul style="list-style-type: none"> • Ce impact (pozitiv sau negativ) are opțiunea asupra liberei circulații a bunurilor, serviciilor, capitalului și forței de muncă? • Opțiunea va duce la reducerea posibilității de alegere a consumatorilor sau la creșterea prețurilor prin scăderea concurenței, la crearea de bariere pentru noii furnizori, la facilitarea comportamentului anticompetitiv sau la apariția monopolurilor, segmentării pieței, etc.?
Competitivitate, fluxuri comerciale și investiționale	<ul style="list-style-type: none"> • Ce impact are opțiunea asupra poziției competitive a firmelor românești? Are vreun impact asupra productivității? • Ce impact are opțiunea asupra barierelor comerciale? • Are vreun efect asupra fluxurilor investiționale (inclusiv relocarea activităților economice)?
Costuri de funcționare și desfășurarea afacerilor (IMM-uri)	<ul style="list-style-type: none"> • Vor fi impuse costuri suplimentare de ajustare, conformitate sau tranzacție asupra companiilor? • Cum afectează opțiunea costul sau disponibilitatea resurselor esențiale (materie primă, echipamente, forță de muncă, energie, etc.)? • Afectează accesul la finanțare? • Afectează ciclul de investiții? • Presupune retragerea anumitor produse de pe piață? Este limitat sau interzis marketingul anumitor produse? • Sunt introduse reguli mai stricte pentru desfășurarea afacerilor în anumite domenii? • Duce la deschiderea sau închiderea anumitor companii? • Există produse sau companii care sunt tratate diferit de altele într-o situația comparabilă?
Sarcini administrative asupra mediului de afaceri	<ul style="list-style-type: none"> • Opțiunea afectează natura obligațiilor de informare impuse mediului de afaceri (de exemplu, tipul de date solicitate, frecvența de raportare, complexitatea procesului de transmitere a datelor, etc.)? • Care este impactul acestor sarcini asupra IMM-urilor în special?
Autorități publice	<ul style="list-style-type: none"> • Are opțiunea consecințe bugetare pentru autoritățile publice de la diferite niveluri administrative (național, regional, local), atât imediat cât și pe termen lung? • Introduce sarcini administrative suplimentare pentru instituțiile publice? • Este necesară crearea unor autorități noi sau restructurarea celor existente?
Drepturi de proprietate	<ul style="list-style-type: none"> • Sunt afectate drepturile de proprietate (bunuri imobile, bunuri mobile, bunuri tangibile/intangibile)? Este limitată achiziționarea, vânzarea sau utilizarea drepturilor de proprietate? • Există posibilitatea desproprietății?

³³ Translated from the European Commission IA Guidelines (2009), ANNEX p.32-37.

Impacturi economice	Întrebări cheie
Inovare și cercetare	<ul style="list-style-type: none"> • Opțiunea stimulează sau împiedică cercetarea și dezvoltarea? • Facilitează introducerea și diseminarea noilor metode de producție, tehnologii sau produse? • Afectează drepturile de proprietate intelectuală (patente, mărci înregistrate, copyright, alte drepturi)? • Promovează sau limitează cercetarea academică sau industrială? • Promovează creșterea productivității sau utilizarea eficientă a resurselor?
Consumatori și gospodării	<ul style="list-style-type: none"> • Opțiunea afectează prețurile plătite de consumatori? • Are impact asupra calității și/sau disponibilității bunurilor/serviciilor sau asupra încrederii consumatorilor? • Afectează informarea și protecția consumatorilor? • Are consecințe semnificative pentru situația financiară a indivizilor/ gospodăriilor, imediat sau pe termen lung? • Afectează protecția economică a familiei și copilului?
Regiuni sau sectoare specifice	<ul style="list-style-type: none"> • Opțiunea are efecte semnificative asupra anumitor sectoare economice? • Va exista un impact specific asupra anumitor regiuni, de exemplu în ceea ce privește crearea sau pierderea de locuri de muncă? • Există o regiune sau un sector care va fi afectat în mod disproporționat?
Mediul macroeconomic	<ul style="list-style-type: none"> • Are opțiunea consecințe generale pentru creșterea economică și ocuparea forței de muncă? • Cum contribuie opțiunea la îmbunătățirea condițiilor pentru investiții și la buna funcționare a piețelor? • Există un impact direct asupra stabilității macroeconomice?

Impacturi sociale	Întrebări cheie
Ocuparea forței de muncă și piața muncii	<ul style="list-style-type: none"> • Opțiunea facilitează crearea de noi locuri de muncă? • Are efect direct sau indirect asupra pierderii de locuri de muncă? • Are consecințe negative specifice pentru anumite profesii, grupuri de angajați sau liber profesioniști (persoane fizice autorizate să desfășoare activități economice)? • Afectează anumite grupuri de vârstă? • Afectează cererea de forță de muncă? • Are impact asupra funcționării pieței muncii? • Are impact asupra echilibrului între viața privată, familie și viața profesională?
Standarde și drepturi referitoare la calitatea locurilor de muncă	<ul style="list-style-type: none"> • Opțiunea are impact asupra calității locurilor de muncă? • Afectează accesul angajaților sau șomerilor la formare profesională și vocațională? • Afectează sănătatea, siguranța sau demnitatea angajaților? • Există efecte directe sau indirecte asupra drepturilor și obligațiilor existente ale angajaților, în special în ceea ce privește informarea și consultarea și protecția împotriva concedierii? • Afectează protecția tinerilor la locul de muncă? • Afectează direct sau indirect drepturile și obligațiile angajatorilor? • Respectă standardele minime de muncă ale UE? • Opțiunea facilitează sau limitează restructurarea, adaptarea la schimbări și utilizarea inovațiilor tehnologice la locul de muncă?
Incluziunea socială și protecția grupurilor dezavantajate	<ul style="list-style-type: none"> • Opțiunea afectează accesul pe piața muncii sau ieșirea de pe piața muncii? • Conduce direct sau indirect la creșterea egalității sau inegalității? • Afectează accesul egal la bunuri și servicii? • Afectează accesul la servicii la plasare sau servicii de interes economic general? • Contribuie la informarea publicului în legătură cu o anumită problemă? • Are impact mai mare asupra anumitor grupuri sau persoane (de exemplu, persoanele cele mai vulnerabile sau cu risc crescut de sărăcie, copii, femei, bătrâni, persoane cu dizabilități, șomeri, minorități etnice sau religioase, azilanți), companii sau alte organizații (de exemplu biserici) sau localități mai mult decât asupra altora?
Egalitatea de șanse între femei și bărbați, echitate și nediscriminare	<ul style="list-style-type: none"> • Opțiunea afectează principiul nediscriminării, tratamentului și șanselor egale pentru toți? • Are opțiunea un impact diferit asupra femeilor decât asupra bărbaților? • Promovează creșterea egalității de șanse între femei și bărbați? • Implică direct orice diferență de tratament între grupuri sau persoane pe criterii de sex, origine rasială sau etnică, religie, dizabilitate, vârstă sau orientare sexuală? Poate duce la discriminare indirectă?

<p>Indivizi, viața privată și de familie, protecția datelor personale</p>	<ul style="list-style-type: none"> • Opțiunea impune cerințe administrative suplimentare asupra persoanelor sau creșterea complexității administrative? • Afectează intimitatea persoanelor (inclusiv locuința sau comunicațiile)? • Afectează dreptul la libertate al indivizilor? • Afectează viața de familie sau protecția legală, economică sau socială a familiei? • Afectează drepturile copilului? • Opțiunea implică procesarea datelor personale sau accesul persoanelor afectate la datele personale?
<p>Buna guvernare, participare, administrație publică, accesul la justiție, mass media și etică</p>	<ul style="list-style-type: none"> • Opțiunea are efect asupra implicării factorilor afectați în procesele decizionale la nivelul administrației publice? • Sunt toți actorii tratați egal, cu respectarea diversității acestora? Opțiunea are impact asupra diversității culturale sau lingvistice? • Afectează autonomia partenerilor sociali în domeniile de competență ale acestora? De exemplu, afectează dreptul la negociere colectivă sau dreptul de a iniția acțiuni colective? • Implementarea măsurii propuse afectează instituțiile și autoritățile publice, de exemplu prin sporirea responsabilităților acestora? • Afectează accesul persoanelor la justiție? • Prevede dreptul de contestație înainte de a ajunge în instanță? • Contribuie la informarea publicului în legătură cu un anumit aspect? Afectează accesul la informațiile de interes public? • Afectează partidele politice sau organizațiile nonguvernamentale? • Afectează mass media, pluralismul presei sau libertatea de exprimare? • Ridică probleme etice sau bio-etice (clonare, utilizarea corpului uman în scopuri patrimoniale, cercetare/testare genetică, etc.)?
<p>Sănătate și siguranță publică</p>	<ul style="list-style-type: none"> • Opțiunea afectează sănătatea și siguranța persoanelor sau grupurilor, inclusiv speranța de viață, mortalitatea și morbiditatea, prin impactul asupra mediului socio-economic (mediul de lucru, venituri, educație, ocupare, nutriție)? • Opțiunea crește sau reduce probabilitatea riscurilor mortale datorate substanțelor dăunătoare mediului înconjurător? • Afectează sănătatea datorită schimbărilor nivelului zgomotului, calității solului, aerului, apei sau solului? • Va afecta sănătatea datorită schimbărilor în consumul de energie sau în gestionarea deșeurilor? • Afectează factorii de sănătate legați de stilul de viață, cum ar fi dieta, activitatea fizică, fumatul, consumul de alcool sau droguri? • Există efecte specifice asupra unor grupuri de risc (determinate de vârstă, sex, dizabilități, mobilitate, regiune, etc.)?
<p>Infraționalitate, terorism și securitate</p>	<ul style="list-style-type: none"> • Opțiunea are un efect asupra securității, infraționalității, terorismului? • Afectează opțiunea șansele de depistare a infractorilor sau câștigurile potențiale ale acestora din infracțiuni? • Există posibilitatea ca opțiunea să ducă creșterea numărului de infracțiuni? • Afectează capacitatea de asigurare a ordinii și siguranței publice? • Are impact asupra intereselor de securitate? • Are impact asupra dreptului la libertate și siguranță, dreptului la un proces corect și dreptului la apărare? • Afectează drepturile victimelor și ale martorilor?

<p>Accesul și efectele asupra protecției sociale, sănătății și educației</p>	<ul style="list-style-type: none"> • Opțiunea are efecte asupra serviciilor din punct de vedere al calității și accesului egal? • Are efect asupra educației și mobilității lucrătorilor? • Afectează accesul persoanelor la educație publică/privată sau formare vocațională și profesională continuă? • Afectează furnizarea serviciilor transfrontaliere și cooperarea în zonele de frontieră? • Opțiunea are impact asupra finanțării, organizării sau accesului la servicii sociale, de sănătate și îngrijire? • Afectează universitățile și autonomia universitară?
<p>Cultură</p>	<ul style="list-style-type: none"> • Are opțiunea impact asupra conservării patrimoniului cultural? • Afectează diversitatea culturală? • Există efecte asupra participării cetățenilor la manifestări culturale sau asupra accesului lor la resurse culturale?

Impacturi ecologice	Întrebări cheie
Schimbări climatice	<ul style="list-style-type: none"> • Opțiunea afectează emisia în atmosferă a gazelor cu efect de seră (de exemplu dioxid de carbon, metan, etc.)? • Opțiunea afectează emisia de substanțe nocive pentru statul de ozon (CFC, HCFC, etc.)? • Există un impact asupra capacității umane de adaptare la schimbările climatice?
Transport și energie	<ul style="list-style-type: none"> • Opțiunea va determina creșterea/scăderea nevoii/consumului de energie și carburanți? • Afectează intensitatea energetică a activităților economice? • Afectează mixul actual de combustibili (între fosil, gaz, nuclear și regenerabil) utilizat în producția de energie? • Va duce la creșterea sau scăderea cererii pentru transport (de pasageri sau marfă) sau va influența repartizarea modală a transportului? • Generează creșterea sau scăderea emisiilor produse de vehicule?
Calitatea aerului	<ul style="list-style-type: none"> • Opțiunea are efect asupra emisiilor de poluanți acizi, eutrofici, fotochimici sau dăunători care pot afecta sănătatea umană, distruge recolte sau clădiri sau deteriorează mediul (solul, apele)?
Biodiversitate, flora, faună și peisaje	<ul style="list-style-type: none"> • Opțiunea reduce numărul de specii/varietăți/rase (reduce diversitatea biologică) sau crește numărul de specii (promovează conservarea)? • Afectează specii protejate sau amenințate sau habitatele acestora sau regiuni sensibile din punct de vedere ecologic? • Împarte peisajul în zone mai mici sau afectează în alt mod rutele de migrațiune, coridoarele ecologice sau zonele de conservare? • Afectează valoarea turistică a peisajelor protejate?
Calitatea apei și resursele de apă	<ul style="list-style-type: none"> • Opțiunea determină creșterea sau scăderea calității și cantității apei dulci și subterane? • Duce la creșterea sau scăderea calității apei în zonele litorale și marine (de exemplu, deversări de substanțe poluante)? • Afectează resursele de apă potabilă?
Calitatea solului și resursele de sol	<ul style="list-style-type: none"> • Opțiunea afectează acidificarea, contaminarea sau salinitatea solului și rata de eroziune a solului? • Contribuie la pierderea solului disponibil (de exemplu, prin lucrări de construcții) sau la extinderea solului utilizabil (de exemplu, prin decontaminare)?
Utilizarea terenurilor	<ul style="list-style-type: none"> • Opțiunea are efectul de a introduce terenuri noi în utilizare pentru prima dată? • Afectează în vreun mod terenurile desemnate sensibile din punct de vedere ecologic? Duce la vreo schimbare în utilizarea terenurilor (de exemplu, schimbarea împărțirii între rural și urban sau modificarea tipului de agricultură practică)?
Resurse regenerabile sau neregenerabile	<ul style="list-style-type: none"> • Opțiunea afectează utilizarea resurselor regenerabile (de ex, peștele) și conduce la o utilizare mai intensivă decât ritmul de regenerare ? • Reduce sau crește utilizarea resurselor neregenerabile (apă subterană, minerale, etc.)?
Consecințele ecologice ale mediului de afaceri și consumatorilor	<ul style="list-style-type: none"> • Opțiunea determină o producție și un consum mai sustenabil? • Opțiunea schimbă prețurile relative ale produselor ecologice și neecologice? • Promovează sau restricționează bunurile și serviciile ecologice/ neecologice prin schimbări ale regulilor referitoare la investițiile de capital, împrumuturi, asigurări etc.? • Întreprinderile sunt încurajate să devină mai poluante/mai puțin poluante prin schimbări în modul în care funcționează?

Impacturi ecologice	Întrebări cheie
Generarea și reciclarea deșeurilor	<ul style="list-style-type: none"> • Opțiunea afectează producția de deșeuri (solide, urbane, agricole, industriale, miniere, radioactive sau toxice) sau modul de tratare, depozitare sau reciclare a deșeurilor?
Probabilitatea și dimensiunea riscurilor de mediu	<ul style="list-style-type: none"> • Opțiunea afectează probabilitatea prevenirii incendiilor, exploziilor, accidentelor sau emisiilor accidentale? • Afectează riscul diseminării neautorizate sau neintenționate de organisme modificate genetic sau străine?
Protecția animalelor	<ul style="list-style-type: none"> • Există un impact asupra sănătății animalelor? • Opțiunea afectează protecția animalelor (tratamentul uman al animalelor)? • Afectează siguranța alimentelor destinate animalelor?

ANNEX 4 – FUNCTIONALITY REQUIREMENTS FOR THE SN PROCESS IN ROMANIA

Introduction

This annex provides the basis of the technical requirements of the proposed Substantiation Note (SN) workflow system. The definitions below aim to build a process which would allow the creation of new SN initiatives, the interaction by multiple actors in a predetermined sequence, the monitoring and approval steps, the closing and archiving of initiatives, and the evaluation and accessing of closed initiatives. The design is built from an “active user” perspective, in particular the public administration staff and decision makers involved in the process either in preparing, monitoring or using SN for regulatory decision making.

This workflow system can be put in place manually (paper-based) or electronically (workflow software). Even though the electronic option is preferred, the automation of public administration operations is not always feasible in the short or medium term, and therefore a paper-based workflow is the only alternative to advance reforms and test processes before the automation is implemented.

Before the workflow is established, the technical requirements presented below will need to be consulted and refined with all relevant actors involved in the SN process (users of the workflow system). Additionally, before the process is automated further work will be needed, in particular by ICT developers, to translate the functionalities below into detailed technical requirements for software. The functionalities below were drafted based on brief discussions with key public officials mainly at the DCP, the Ministry of Public Finance and three other ministries.

The SN process is understood as part of a broader policy making and legislative process. The functionalities building up the SN workflow need to be therefore imbedded into the policy-making system. The Government of Romania plans to develop a software workflow system for legal drafting and policy making in 2015. This annex is prepared with the objective of contributing to that process by providing information on the SN functionalities, and could be included in the Terms of Reference for the system developers.

The sections below describe the actions available, the actors involved, the interphases for accessibility and a detailed workflow diagram to illustrate the process.

Actions in the Substantiation Note Process

The requirements for the workflow need to facilitate the deployment of the new SN described in section III.2 of this Report. In particular, the following actions will be required:

1. **Initiative creation:** the system will allow the creation of new initiatives, either using an empty initiative form, a previous initiative or some other defined acceptable input.
2. **Input by multiple actors:** several actors will have access to the workflow system to allow them to perform their actions and input data in the SN process.
3. **Monitoring:** the workflow system should allow tracking of active initiatives at all times, access to data fields, dwell time and other information required by users.

4. **Approval:** the system should request approvals to allow technical, quality and management control.
5. **Initiative closing:** Once the process is completed, or if initiatives need to be dropped early in the process, the system should allow closing and archiving initiatives for future access and reference.
6. **Evaluation:** once initiatives are closed, the system should allow random evaluation of initiatives based on pre-established parameters or request specific users to provide evaluation input.
7. **Access to archive and data production:** allow access to information of all initiatives, and easy extraction of statistics and data withheld by the workflow system.

Profiles, Data Fields and Levels of Access to the System

The workflow system should allow a variety of profiles with appropriate responsibilities. Key profiles to be included in the system are listed below in a table, which also includes specific actions that they should perform. The list will need to be finalized in consultation with the different institutions. All profiles should provide input to the process (action 2), be able to monitor initiatives status (action 3), provide input to the evaluation (action 6), and have access to archive and data production (action 7).

Institution	Profile	Main Role	Specific Actions
Line Ministry	Technical Officer	Initiate and complete information needed for SN	<ul style="list-style-type: none"> - Create new SN initiatives (1) - Close Initiatives (5)
Line Ministry	Legal Counsel	Prepare the regulatory text and participate in the SN preparation	<ul style="list-style-type: none"> - Input regulatory text and data fields (2)
Line Ministry	Impact Assessment units officer / Public Manager (PPU)	Link the policy making process to the regulatory making process and monitor quality checks of SN within Ministry	<ul style="list-style-type: none"> - Create new SN initiatives (1) - Monitor quality and technical SN checklist (4)
Line Ministry	Director	Supervise technical team involved in SN preparation	<ul style="list-style-type: none"> - Monitor quality and technical SN checklist (4) and submit to next level of authority
Line Ministry	Minister	Highest authority in line Ministry approves SNs	<ul style="list-style-type: none"> - Approve SN (4) and submit to DCPD and Cabinet
DCPD	Quality Control Official	Check technical quality of SNs	<ul style="list-style-type: none"> - Check quality of SNs (4) - Prepare comments/ feedback to team that prepared SN (2)
DCPD	State Secretary and Government Secretary General	Supervise quality control at DCPD	<ul style="list-style-type: none"> - Approve quality and technical control (4) to send SN back to Line Ministry with comments
Ministry of Public Finance	Ministry Staff	Check fiscal and budgetary impact prepared in SN	<ul style="list-style-type: none"> - Check fiscal and budgetary impact included in SN initiatives (4) - Prepare and input fiscal and budgetary impact in SN process (2)
Ministry of Economy	Ministry Staff	Check economic impact on SMEs prepared in SN	<ul style="list-style-type: none"> - Check economic benefit cost analysis included in SN initiatives (4) - Prepare and input economic analysis in SN process (2)
Competition	Competition Staff	Check impact of the	<ul style="list-style-type: none"> - Prepare and input competition

Council		regulatory measure on competition matters	analysis in SN process (2)
SN Working Groups	Working Group Member	Check impact analysis for high impact initiatives	- Check High Level Impact SN (4)
Legislative Council	Legislative Counsel	Final Endorsement	- Final Endorsement (4)
Supreme Council of National Defense	Council Member	Final Endorsement	- Final Endorsement (4)
Economic and Social Council	Council Member	Final Endorsement	- Final Endorsement (4)
Court of Accounts	Counselor of Accounts	Final Endorsement	- Final Endorsement (4)
External Party	Stakeholder	Participate in Public Consultation	- Access SN initiatives and data open to consultation (3) - Submit feedback on SN initiatives (2) - Send messages to a focal point of contact in the system, for instance to propose new regulatory activity (2)

The workflow system should collect, process and present data fields included in the Triage Form and the Substantiation Note Template, as well as additional operational information. Each data field should have a restriction in number of characters, should allow prepopulated list of answers when needed, and should allow attaching or uploading documents. Additional data fields, which are not included in both predefined forms but need to be considered in the system, include:

- Assigned profiles for each initiative. For instance assigned Legal Drafter, DCPD Officer or other system profiles.
- Initiative Workflow Status.
- Key workflow dates.
- Dwell times.

If the Government considers that some data fields should require different levels of access due to confidentiality, particularly for external parties, each data field should be categorized by level of access. This annex considers that all data fields should be accessible by all stakeholders.

Workflow System Interphase

This workflow system could be implemented before automation. Such a paper-based system must apply the Government of Romania rules for government operations and transmission of files through approval process. The files being transmitted should allow registering profiles assigned to a particular initiative, workflow status, dates and a standard calculation of dwell time. Establishing this paper-based workflow before automation is achieved is recommended in order to fine tune and find ways of improving efficiency and closing information loops.

Ideally, the workflow system should be automated. When a software system is set up, it should provide an interphase adequately adapted to each profile for an efficient

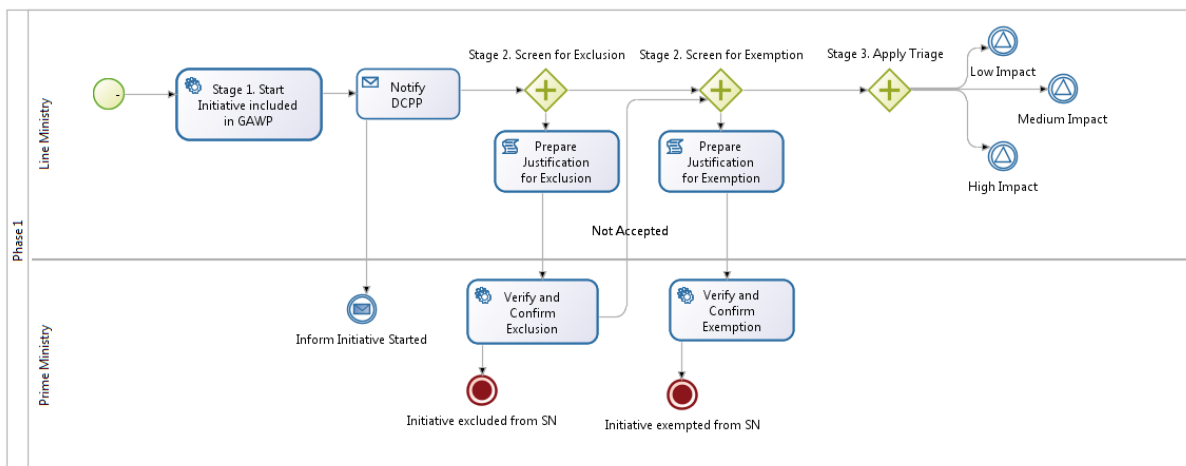
workflow process. The interphase design could benefit from interesting examples in other countries, such as the system in Canada or in Mexico.

Essential elements for the interphase should include:

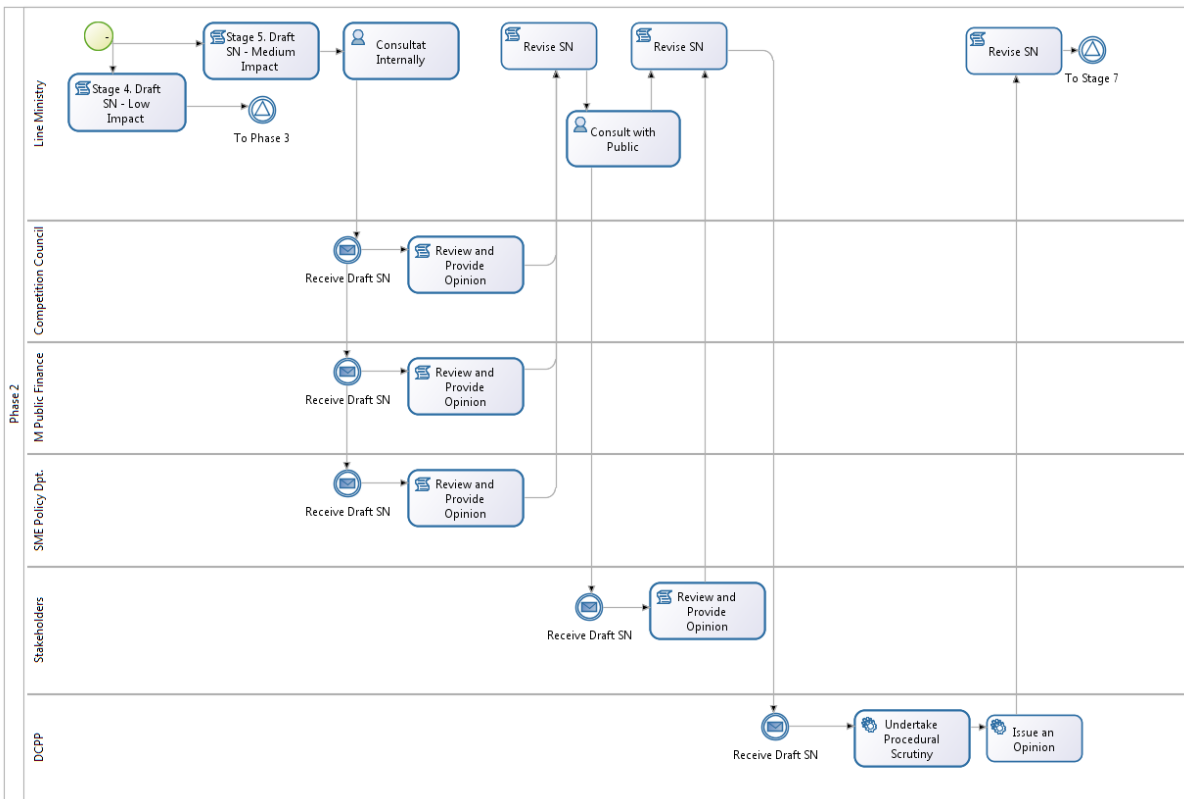
Interphase Elements		Definition
INTRANET	Home Page	Welcome message and access to a menu of options
	Menu Option 1	List of ongoing Initiatives pending action by registered user and allow to take action
	Menu Option 2	List of ongoing Initiatives pending action by other users and (when applicable) allow to close
	Menu Option 3	List of already completed Initiatives
	Menu Option 4	Create new Initiative (when applicable)
	Menu Option 5	System Statistics and Evaluation

A brief workflow process is presented in Figure 1 of this report. A more detailed workflow map for the SN system is provided below. As mentioned, this will need to be consulted in detail with all stakeholders involved and finalized.

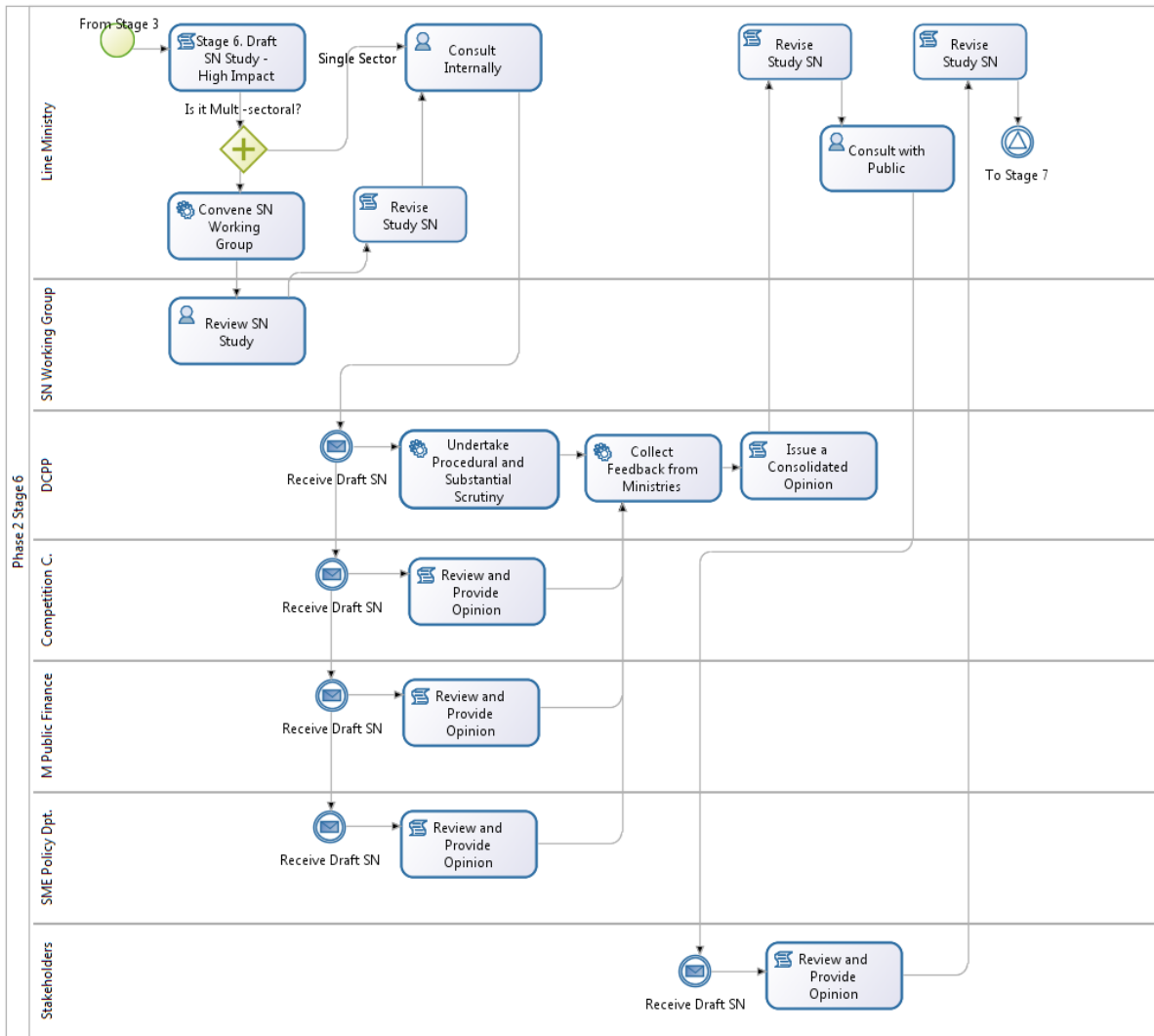
Phase 1. Stages 1, 2 and 3



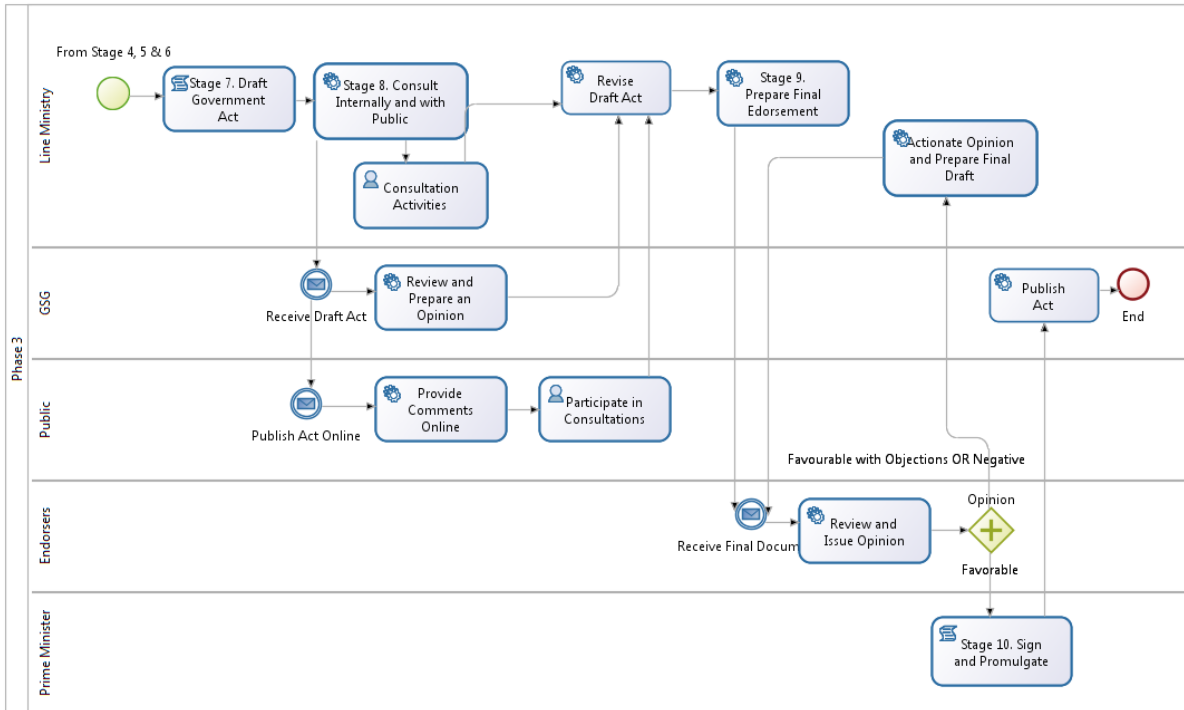
Phase 2. Stages 4 and 5



Phase 2. Stage 6. High Impact SN Study Preparation



Phase 3. Stages 7, 8, 9 and 10



Titlul proiectului: Consolidarea cadrului de evaluare a impactului reglementărilor în România

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