Chapter 4

The development of new regulations

Predictable and systematic procedures for making regulations improve the transparency of the regulatory system and the quality of decisions. These include forward planning (the periodic listing of forthcoming regulations), administrative procedures for the management of rule-making, and procedures to secure the legal quality of new regulations (including training and guidance for legal drafting, plain language drafting, and oversight by expert bodies).

Ex ante *impact assessment of new regulations is one of the most important regulatory tools available to governments. Its aim is to assist policy makers in adopting the most efficient and effective regulatory options (including the "no regulation" option), using evidence-based techniques to justify the best option and identify the trade-offs involved when pursuing different policy objectives. The costs of regulations should not exceed their benefits, and alternatives should also be examined. However, the deployment of impact assessment is often resisted or poorly applied, for a variety of reasons, ranging from a political concern that it may substitute for policy making (not true- impact assessment is a tool that helps to ensure a policy which has already been identified and agreed is supported by effective regulations, if they are needed), to the demands that it makes on already hard pressed officials. There is no single remedy to these issues. However experience around the OECD shows that a strong and coherent focal point with adequate resourcing helps to ensure that impact assessment finds an appropriate and timely place in the policy and rule making process, and helps to raise the quality of assessments.*

Effective consultation needs to be an integral part of impact assessment. Impact assessment processes have – or should have – a close link with general consultation processes for the development of new regulations. There is also an important potential link with the measurement of administrative burdens (use of the Standard Cost Model technique can contribute to the benefit-cost analysis for an effective impact assessment).

The use of a wide range of mechanisms, not just traditional "command and control" regulation, for meeting policy goals helps to ensure that the most efficient and effective approaches are used. Experience shows that governments must lead strongly on this to overcome inbuilt inertia and risk aversion. The first response to a problem is often still to regulate. The range of alternative approaches is broad, from voluntary agreements, standardisation, conformity assessment, to self regulation in sectors such as corporate governance, financial markets and professional services such as accounting. At the same time care must be taken when deciding to use "soft" approaches such as self regulation, to ensure that regulatory quality is maintained.

An issue that is attracting increasing attention for the development of new regulations is risk management. Regulation is a fundamental tool for managing the risks present in society and the economy, and can help to reduce the incidence of hazardous events and their severity. A few countries have started to explore how rule-making can better reflect the need to assess and manage risks appropriately.

Assessment and recommendations

Trends in the production of new regulations

Italy is a strong example of a system with deep Napoleonic roots. As a consequence, there is a sort of regulatory presumption in State intervention and the regulatory stock piles up and becomes ever more complex. The decentralisation process and the allocation of competences across levels of government accentuated the problem of regulatory inflation, making the need for regular screening of the necessity, proportionality and consistency of new legislative and regulatory proposals even more pressing.

Ex ante *impact assessment of new regulations*

Italy has intervened on RIA practices of central administrations by introducing a new system in 2008. This signals renewed commitment to mainstream the tool and make it work, compared to the previous years. The system seeks to rationalise, simplify and make more flexible previous approaches. Also thanks to the provision in the 2009 Directive on normative procedures, closer attention is paid to the importance of bridging normative planning and the RIA process. More regular and comprehensive training rounds are organised, helping diffusing basic knowledge and skills both in the Presidency of the Council and across the line ministries. A number of ministries seem to pick up the challenge and are re-organising their structures and procedures to better meet the requirements. An explicit link in the legal acts is made between RIA and *ex post* evaluation, potentially creating structural and procedural integrated mechanisms to carry them out.

The DAGL RIA Unit stands out in its efforts to change the underlying culture within both DAGL itself and the administrations. While the general approach prevailing to date seems to perpetuate a mere formalistic compliance with the obligation of producing a RIA, the critical and constructive evaluation produced by DAGL signals the commitment to progress further.

At the same time, some independent agencies serve as laboratories for carrying out RIA and consultation, and some of the solutions implemented reflect international good practices. Similar considerations can be made on the basis of the experience developed in a few regions and municipalities. Hence, the RIA picture in Italy overall is rather dynamic. The Osservatorio AIR (created in 2009) is one important new actor, for it systematically reviews progress, and critically and constructively proposes improvements. Although focusing on RIA in the independent agencies only, the Osservatorio helps create a debate on RIA in Italy across the PA-stakeholder-academia interface that is very much needed.

Nonetheless, the potential of RIA is still largely unexplored, and many of the recommendations included in the previous OECD assessments have not been implemented. DAGL, as the central co-ordination and oversight body, has correctly identified the most pressing areas for improvement and is currently working on a new regulation governing RIA, VIR and public consultation to address some of these issues. In the context of this forthcoming regulation – whose draft has not been consulted and evaluated as part of this review, this report highlights a number of elements identified by the OECD as critical areas for improvement.

Scope of application: one of the major issues addressed in the first years of the RIA application was the lack of incentives and sanctions for administrations that did not perform impact assessments. The 2008 regulation has made RIA a necessary step to inscribe new draft legislation in the Council of Ministers agenda. This, along with support and training activities carried out by the DAGL, has led to a sharp increase of the production of RIAs. However, more than 150 RIAs per year is an excessive amount, considering the novelty of the tool. This jeopardises the efforts of administrations to produce good quality analyses as well as the task of DAGL to ensure high performance quality check. Italy is still on a learning curve for producing RIAs of good quality that influence decision-making. Experience suggests that to advance on that curve is "to start small but well" – i.e. with fewer but better RIAs.

In light of these challenges, the 2008 RIA regulation does not appear to meet the gaps. It explicitly allows for exempting administration from doing RIAs on urgent / complex proposals – exactly when *ex ante* assessments are most opportune – at a time when central normative action in Italy was mainly promoted through decree-laws, whose rationale is exactly to respond to urgency and emergency situations. While the exemption from RIA for urgent interventions (typically passed through decree-law) may be difficult to avoid because time is of essence to address sudden and unpredictable emergencies, the new RIA regulation envisaged by the DAGL is expected to modify the exemption assumptions to reduce the number of RIA and to cancel the exemption "for more complex issues".

Recommendation:

1. Consider the possibility of introducing a prioritisation mechanism to screen among regulations which ones would require full RIAs (Canada's "triage" mechanism provides an example).

Timing: RIAs tend to be produced very late and to comply with procedural requirements. They are therefore not widely used within the proponent administration, and their impact on policy formulation and decision-making remains modest. RIAs are often used to justify (procedurally) the decisions taken.

Recommendation:

2. Start the RIA process at the earliest stage possible, since good quality RIAs conducted early and allowing the identification of non-regulatory alternatives will help limit the flow of new regulations.

Implementation and capacity building: Besides structural problems related to how the system is conceived, there have been also implementation failures. After two years from the entering into force of the RIA regulation, comprehensive guidelines are still not issued (the current RIA regulation and annex cannot be a proxy for such supporting documentation). In addition, the overall institutional framework to support the production of quality impact assessments has not been significantly upgraded. There are signs that diversified profiles are being hired or trained in some parts of the central administration to better steer the shift towards a more evidence-based approach to decision-making, but RIA seems to remain trapped in rather legalistic, procedural logics.

Recommendations:

3. Issue binding and precise procedural and methodological guidelines to assist with the preparation of RIAs.

4. Consider further investment in staffing and RIA training to enable ministries to conduct the required technical analysis. Take this opportunity to ensure multi-disciplinary backgrounds and skills and initiate a culture of evidence-based approach to decision making within DAGL and the line ministries.

Oversight: RIAs are screened by the DAGL RIA Unit before the proposal is discussed in the (pre-) Council meeting. DAGL requests every administration to apply the necessary modifications in order to make the RIA report consistent with the minimal contents requested by the regulation. In addition, DAGL oversees the final RIA evaluation transmitted to the pre-Council. In August 2011 a new decree was issued reorganising the DAGL. It establishes a Team (*Nucleo*) supporting the activities related to RIA and *ex post* evaluation, which complements the DAGL staff working on RIA.

Recommendations:

5. Publish relevant criteria and modus operandi for DAGL in its function of RIA oversight body.

6. Introduce incentive and sanction mechanisms for administrations to comply with requested changes in impact assessments, for instance by publicly reporting each year information on the relative number of proposals returned to the administration by DAGL on the ground of sub-optimal RIA quality, according to the type of proposal and administration and on the type of problems encountered. A library of examples of good assessments by administrations would help illustrate what is expected from RIA drafters.

Integrated and multi-level analysis: RIA is being increasingly connected to other regulatory tools. For instance, the *Statuto delle imprese* of November 2011 has amended the 2008 RIA Regulation to make the assessment of burdens abolished or introduced by any proposal mandatory. Another example of growing interaction between regulatory tools is the requirement for RIA drafters to include a section on the foreseen *ex post* evaluation aspects. By contrast, more efforts could be made to improve cross-sectoral RIAs produced by teams from more than one department (e.g. on climate change). While not explicitly foreseen or promoted in the 2008 RIA Regulation, the principle is stated in the law.[1] However, RIAs are often carried out by individual ministries and seeking cross-departmental inputs at an early stage is not systematic. Co-ordination is usually organised by DAGL, when the draft bill is already produced. A further area for improvement regards greater and more systematic integration of multi-level dynamics.

Recommendation:

7. Enhance early inter-ministerial co-ordination and information sharing as fundamental elements informing the ex ante assessments.

Comparison of options: The 2008 RIA regulation prescribes that the analysis of costs and benefits be carried out only on the "zero-option" and the preferred option, while the other options can receives less thorough attention. While this "simplified" approach is intended to make the task of RIA drafters easier (and therefore – arguably – to make the tool more attractive and more widely used), it weakens one of the fundamental elements of RIA (the structured comparison of options) and the analysis runs the risk of not going beyond justifications of decisions already taken.

Recommendation

8. Reinforce the requirement to consider alternative forms to regulatory interventions at an early stage in the impact assessment process.

External accountability: Until now, administrations have been able relatively easily to derogate from their legal requirement to carry out consultation during the preparation of the RIA report. They are not subject to authorisation or specific criteria. Their only obligation is to indicate why they chose to do so. There is wide discretion for RIA drafters as to the form and scope of their consultations, which does not provide incentives to strive for comprehensive, transparent and participatory RIAs. Similarly, although publicity and communication of progress are key, they have so far been largely neglected. Final RIA reports are *de facto* public on the Parliament website, because they are attached to the acts transmitted to Parliament by the government. However, their accessibility needs to be improved. Because they are of little relevance to decision-making, RIAs tend to be neglected during the parliamentary phase. Similarly, since they are not easily accessible, it is difficult for the public to evaluate the actual quality of the RIAs. Organisational changes (even if they have not been generalised across central departments) have not been communicated.

Recommendations:

9. Make RIAs systematically available to the public on one single point of access.

10. Seek more systematic dialogue with stakeholders and academia. Consider the Osservatorio AIR as a possible model.

Only time will tell if the current system is structurally better than the previous ones and can deliver lasting changes. Overall, so far the system has not succeeded in creating a community of "RIA stakeholders" (understood here in the broadest sense as desk-officers; top managers; decision-makers; business and other external stakeholders) that have the incentive to and interest in upgrading the system and use RIA as a support of their role in decision-making. As a result, pressure on the central administration to deliver better RIAs has remained limited.

Ex post *evaluation of regulations*

Italy is making efforts to embed *ex post* evaluation of laws. The policy provides for *ex post* evaluation on all normative acts for which an impact assessment has been performed, two years on. To be effective, though, the initial impact assessment needs to be of sufficient quality and to incorporate indicators of success against which the monitoring can be carried out. Efforts to ensure greater interaction between RIAs and *ex post* evaluation are under way. For instance, every RIA has to specify the following information: *i)* the responsible subject of *ex post* evaluation; *ii)* the description of the activities which will be performed to assure proper advertising and information on the new normative intervention; *iii)* the tools which the administration will employ to perform the monitoring and the evaluation, notably the specific aspects concerning VIR. DAGL does not accept the RIAs unless they contain this information and supports through a specific training the ministries in the formulation of appropriate indicators for VIR. The *ex post* evaluation process may produce a long stream of amendments. As in some other countries, it is likely to be sensitive for the ministry/politician concerned.

Recommendations:

11. Consider inserting sunset clauses to avoid instability of the regulatory framework if *ex post* assessments lead systematically to amendments.

12. Consider the bundling of laws for *ex post* evaluation in order to reduce political sensitivities and inconsistencies and better align post-analysis with delivery of results for society, economy and environment.

Background

General context

The structure of regulations

The main written sources of domestic law are: *i)* the Constitution; *ii)* the primary sources of law; and *iii)* regulations. The provisions of the Constitution prevail over all other provisions. These are followed by the primary and secondary sources, as well as custom, in line with the hierarchy set out in Box 4.1. Chapter 8 sets out the situation as regards regulatory powers of the regions and municipalities.

Box 4.1. The structure of regulations in Italy

The *Constitution* is at the apex of Italian law, and it can be amended or added to solely by means of a special procedure, which is highly complex and is laid down in the Constitution itself (Article 138). Some articles of the Constitution may not be changed under any circumstance; this is the case for Italy's status as a republic, which may not be constitutionally revised; in general all points that are essential elements of the constitutional system are also considered to be unchangeable (e.g. the principles of freedom and equality, the parliamentary system, the principle of a fixed Constitution, and constitutional justice).

Generally recognised principles of international law have constitutional status. The *rules of international law, including EU law*, occupy the space between the Constitution and the laws (Art. 117 Constitution). EU law takes precedence over Italian law (as in other EU member states) where the EU has exclusive competence (Costa v Enel, 1964).

The regional statutes are autonomously issued by each region, with the exception of those of the five regions with special status, which are adopted through a constitutional law. The regional statutes determine the form of the regional government, the fundamental principles of its organisation and functioning, the exercise of rights of legislative initiative and referenda, and the procedures for adoption and publication of regional acts.

Constitutional laws modify or complement the Constitution. They are adopted by absolute majority of each of the two chambers, at respective sessions taking place at least three months one after the other. The constitutional law can be put on referendum within three months before its entering into force. The referendum will not take place if the law has been approved by a second vote by each Chamber with a two third majority of its members.

Ordinary laws (*leggi*) are pre-eminent acts, which may be adopted by the State or the regions, according to the Constitution (Art.117). A provision established by a law can be repealed or amended solely by a new law, while an ordinary law may amend or repeal any provision within the legal system, excluding provisions with constitutional status, which may only be repealed or amended by constitutional laws. A conflict between laws passed at different times is resolved using the principle that the subsequent law supersedes that previously in force (*lex posterior derogat prior*).

Box 4.1. The structure of regulations in Italy (*cont.*)

Legislative decrees (decreti legislativi) are issued by the government following prior delegation by parliament through a delegation law (*legge di delega*). Legislative decrees are limited by the guiding principles and criteria set in the delegation law, only for a defined period and for subjects that have been laid down in the delegating law. If legislative decrees exceed the limits of the delegated powers, the issue of unconstitutionality may be raised.

Decree-laws (*decreti legge*) are government acts issued in special cases ((typically as a matter of necessity and urgency). They must be presented on the same day to parliament for conversion into laws; if they are not converted within sixty days of their publication they lose validity retroactively. Parliament may regulate by means of laws any relations that have arisen by virtue of unconverted decrees.

The main secondary regulatory, non-legislative acts are:

- *Government regulations (regolamenti del governo)* are issued through a Decree of the President of the Republic and must be screened by the Council of State and the Court of Audit. Art.17 of Law 400/1988 states several types of regulations: executive, applicative and integrative; independent (concerning subjects where the discipline is not informed by laws according the Constitution to the law itself); organisational and functional types concerning public administrations and law suppressing ones (in the subjects not informed by the Constitution to the law). The law suppressing regulations aim at simplifying the normative system. They undergo the preliminary opinion of the parliamentary committees.
- *Ministeria decrees and Decrees of the President of the Council* are issued by ministers (on matters within their portfolio) or by the Prime Minister in accordance with a law. Ministerial decrees must be communicated to the President of the Council of Ministers before their adoption. The Council of State expresses its own opinion on both types of decrees.

Case law

Case law does not mean the same in Italy's civil law context as it does in a common law context. Case law does not create legal rules because it acts within the framework set by the legislator. If a norm is declared as non-conforming to the Constitution, the norm is repealed with *erga omnes* effects.

"Soft law"

Besides legal acts, the Italian regulatory system (as in most other countries) includes forms of so-called "soft law". Circulars (*circolari*) are not sources of legal norms, but consist of instructions given by a higher administrative authority to a lower administrative authority and therefore presuppose a hierarchical link between the two authorities.

Source: http://ec.europa.eu/civiljustice/legal_order/legal_order_ita_en.htm and Government of Italy (2011).

Trends in the production of new regulations

As reflected in Table 4.1, the production of new ordinary state laws has decreased in absolute terms over the past 10 years. Over the same period, legislative activity of the regions has remained largely stable overall, even though the production of regional laws has reached a low in 2011. Except in 2008 and especially in 2009, production of legislative decrees has also remained relatively stable, at around 70 new decrees per year.

Table 4.1. Production of laws

Year	Ordinary State laws	Legislative decrees	Regional laws
2011	65	63	540
2010	72	82	595
2009	87	24	664
2008	44	41	608
2007	60	74	618
2006	23	73	588
2005	127	77	632
2004	119	62	594
2003	171	79	586
2002	130	37	705

Source: Government of Italy (2011).

Procedures for making new regulations at the central level

The law making process and the role of the central executive

Box 4.2. Drafting a Bill in the Italian government

While not having the monopoly of legislative initiative, in practice the government has the main responsibility for initiating the legislative and regulatory process, which is broadly outlined in a Decree of the Prime Minister of 1993 and, more recently in a Directive of 2009.[1] In order to enter the agenda of the Council of Ministers, a draft bill is subject to a number of tests. Officials put particular attention on:

- The descriptive report *(relazione illustrativa)*, which is obligatory for any regulatory initiative, is arguably the piece of analysis which attracts most attention. It indicates the principle triggering the proposed intervention, describes the problem to be addressed, and outlines how the intervention fits in the overall legal, administrative and policy context. In the case of decree-laws, the illustrative report must highlight the condition of emergency or urgency justifying them. In the case of delegated laws, the delegation and its conditions must be accurately reported;
- The three technical documents are also object of some attention, but arguably more because they are required as mandatory attachments in order for the bill to be considered by the Council of Ministers, than for their actual content. The three documents are a legal analysis (*Analisi Tecnico-Normative*, ATN); Regulatory Impact Assessments (see below), and the Technical-Financial Report, issued in collaboration with the State General Accounting Department (*Ragioneria Generale dello Stato*);[2]
- Whether as a part of the ATN, or of the descriptive report, particular attention is put on outlining the normative competences of various levels of government (EU, State, and regional), especially further to the reform of Title V of the Constitution (de-centralisation process);
- With regard to administrative burdens, the RIA Regulation (Decree 170/2008)[3] requires that the proponent administrations indicate the information obligations introduced (or removed) by the proposal. It did not require that administrative burden calculations be carried out *ex ante*. However, the new Law on the Statute of enterprises approved in November 2011 formally introduces *ex ante* measurement of administrative burdens within RIA.

Upon the submission of the draft bill to DAGL by the proponent ministry, DAGL seeks the inputs of the other administrations involved in the dossier and institutions (*acquisizione dei pareri*). In general, administrations have the discretion as to whom and how to consult, but the DAGL may in some cases play a role in channelling the practice. For some normative acts, specific bodies must be mandatorily consulted (for instance the Council of State, or the Court of Audit).

Box 4.2. Drafting a Bill in the Italian government (*cont.*)

Once the preparatory stages are completed, DAGL screens the draft bill accompanied by related supporting documentation and circulates them electronically to the Cabinets and the legislative offices in the ministries. The 2009 Directive specifies that DAGL can refuse or postpone the inclusion of a draft bill on the agenda of the preparatory meeting of the Council of Ministries (the so-called "pre-council") if one of the previous stages is not completed satisfactorily. In particular, no regulatory proposal can be added to the pre-council agenda, if it is not accompanied by the three reports (ATN, RIA, and financial-technical report).

The draft normative acts are examined at the preparatory meetings of the Council of Ministries. These meetings are chaired by DAGL. All ministries (at the level of the Heads of the Legislative Office or of the Minister's Cabinet) are invited to consider the proposals to be included in the agenda of the Council of Ministers. The appraisal is collegial and it is both procedural and substantial. The draft bills implying financial impacts must first be verified by the Ministry of Economy and Finance (*Ragioneria Generale della Stato*). The preparatory meetings are a critical stage in the process, since here interests are negotiated and potential conflicts settled. The meetings are normally weekly, and they must take place at least two days before the meeting of the Council of Ministries in which the act is discussed.

The Council of Ministers considers the agenda prepared at the pre-council meeting. It proceeds to a first preliminary check, further to which DAGL requests the acquisition of additional evidence from consultation practices and acquisition of compulsory opinions envisaged by the law. Once these are completed, the draft proposals and the revisited supporting documentation is tabled again at a pre-council meeting and eventually submitted to the Council of Minister for the final check. The adopted bill is then either sent to parliament for the legislative adoption or published in the Official Gazette.

1. Direttiva del Presidente del Consiglio dei Ministri, Istruttoria degli atti normative del governo, Gazzetta Ufficiale No. 82, 8 April 2009.
2. *www.rgs.mef.gov.it.*
3. Decreto del Presidente del Consiglio dei Ministri, Regolamento recante disciplina attuativa dell'analisi dell'impatto della regolamentazione (AIR), ai sensi dell'articolo 14, comma 5, della legge 28 novembre 2005, No. 246, 11 September 2008, No. 170, *www.governo.it/Presidenza/AIR/normativa/decreto_11settembre2008.pdf.*

The law-making process and the parliament

Box 4.3. Stages in the law-making process

The Italian Constitution provides that the legislative function is exercised collectively by both Houses (Art. 70). This means that in order to become law, a bill must be approved by the Chamber of Deputies and the Senate in identical terms. Each of them, separately and successively, considers and approves the bills. The process of formation of the law (the so-called *iter*) consists of the following stages:

Presentation of the draft bill (legislative initiative)

The legislative *iter* can be initiated by the government, through parliamentary initiatives (by individual senators and representatives, in the House to which they belong) and popular initiatives (signed by at least 50 000 voters), as well as by the National Council of Economy and Labour or the Regional Councils. The texts presented by the government are called bills (*disegni di legge*), while all others are called legislative proposals (*proposte di legge*).

Consideration

The bill is first discussed and approved by the chamber to which it was originally presented. The bill is assigned to the parliamentary committee (*commissione*) responsible by subject-matter (there are 14 standing committees in each chamber). The committee sits in this case in its reporting capacity (*commissione in sede referente*). It carries out an examination (*istruttoria*) and prepares a text and an accompanying report to be submitted to the plenary. The committee may decide to consider two or more bills jointly but submit a single report and a single text.

Box 4.3. Stages in the law-making process (*cont.*)

During the examination, the committee takes account of the views of other committees, which meet in an advisory capacity to comment and make suggestions on that part of their responsibility. The committee acquires opinions and information as needed and appropriate, including through hearings. The government participates in the preliminary stages and processing of the text.

The Committee drafts bill sections, decides on amendments, which can be proposed by all members of the chamber, by the rapporteur and by the Government, and finally appoints the *rapporteur (relatore)* in charge to prepare the report for the plenary. Minority reports can also be presented. In view to the plenary debate (in the Chamber of deputies only) a small committee of nine MPs (*Comitato dei nove*) is set up, including the *rapporteur* and representatives of the groups which carried out the examination in the parliamentary committee.

In the plenary, the government representative intervenes after the *rapporteur*. The groups then express their opinions. The *Rapporteur* and also the so-called Committee of Nine provide guidance during the debate and express their advice on each amendment together with the competent representative of government. Each individual article of the draft – as well as its amendments – has to be separately discussed and voted. A final vote on the entire bill closes the session.

Transmission of the text to the other House

The text of the bill adopted in the first reading is then sent to the other chamber either in the same wording or with modifications. The discussion and adoption of the bill follows the same procedure as for the first reading. If amendments are adopted in the second reading, the bill moves from one chamber to the other, until it is approved by both in the identical formulation (this is the so-called "shuttle").

Fast-track procedures (*procedimenti abbreviati*)

In addition to the ordinary procedure (which must be followed for some types of legislation indicated by the Constitution and the Rules of Procedures of both Houses), two abbreviated methods can be used:

- *the review and approval of the bill in committee*. Committees have direct legislative competences (*commissione in sede legilsativa*), unless the government or one tenth of the deputies / senators and one-fifth of the committee object. In that case, the draft is put back to the plenary; and
- *examination by the Commission in drafting capacity* (*in sede redigente*). In this case, the committee is specifically empowered by the chamber to prepare a text of the bill and to submit it to the plenary. The latter votes the individual articles and the entire bill, but cannot amend the text adopted by the committee.

Enactment

The adopted bill is promulgated by the President of the Republic within a month of adoption. The President of the Republic may, by sending a reasoned memorandum to parliament, request a new debate, but if the law is once again adopted by the Chambers, it must be promulgated. Once promulgated, the law is published in the Official Gazette before entering into force fifteen days after publication (unless the law itself prescribes a longer or shorter term).

Popular referenda

Concerning national laws, there are two kinds of referendum:

- "abrogative" referenda: these can be called in order to totally or partially repeal a law, but only at the request of 500 000 electors or five regional councils. Financial laws, laws relating to pardons or laws ratifying international treaties may not be put to a referendum; if the majority of the electorate votes, the result of the referendum is considered valid; and

Box 4.3. Stages in the law-making process (*cont.*)

- "constitutional" referenda: these can be called in order to approve constitutional amendments or other constitutional laws, but only at the request of 500 000 electors, five regional councils or a fifth of the members of one of the two Houses of Parliament. The law submitted to a referendum shall not be promulgated unless approved by a majority of valid votes. Referendums shall not be held if the law has been approved in the second voting by each of the houses by a majority of two thirds.

Regional referenda may be envisaged by the regional statutes (and have a binding or non-binding character) and be optional, notably to approve the regional statute itself. At municipal level, binding and non-binding referenda can be held on issues related to local policies.

Source: www.camera.it/716 and G.M. Salerno (2005), "I referendum in Italia: fortune e debolezze di uno strumento multifunzionale", in *Diritto Pubblico Comparato Europeo*, Fascicolo 3.

Forward planning

Individual ministries and departments have large discretion in setting their legislative and regulatory agendas. Nonetheless, the government has launched a series of initiatives to make legislative and regulatory planning more rationale and systematic. Based on the government rules of procedures of 1993,[2] the 2009 Directive of the Prime Minister regulating the preparatory stages of rule-making[3] requires administrations to communicate the initiatives that they intend to present to the Council of Ministers in the following trimester to DAGL. The administrations formally notify DAGL also about the start-up of RIAs. Within the programming framework, DAGL informs the administrations about the outcome of its monitoring on the "delegated laws" and about the acts to be submitted to the final approval of the Council of Ministers. On that basis, DAGL defines the agenda of the Council of Ministers (*agenda dei provvedimenti normativi*).

The government adopted a political and programmatic document listing all the commitments – the "Programme Tree" (*Albero del programma*) – managed by the specifically created Department for the implementation of the programme.[4] The government now proceeds to a systematic monitoring of the programme implementation throughout the legislature, registering and summarising both the proposals that are still to be adopted by the Council of Ministers and the ones that have gone through the parliamentary debates. Such registration and examination concern also the government's legislative decrees (such as those implementing delegated laws, or transposing EU directives).

Administrative procedures

Law 241/1990 has served as a sort of "Administrative Procedure Act", providing for timing of procedures, accountability, motivation of the acts, participation, transparency and right of access. The Prime Minister Directive of February 2009 updates and summarises the procedure to be followed by administrations in the preparation and adoption of normative acts by the government.[5] The Directive indicates the sequence and the timing with which administration must submit the draft bill and the accompanying documentation to DAGL (see Box 4.2). It seeks to rationalise and standardise the normative activity of the government. In this respect, the Directive calls upon administrations to ensure their adequate organisation, notably by setting up and equipping units for the preparation of RIAs and *ex post* evaluations. The Directive also foresees the consultation phase (without, however, providing detailed standards, since the practice will be disciplined by a separate directive on public consultation to be issued.

Because of their independent and neutral status, regulatory authorities are not subject to the provisions of Law 241/1990.[6]

Legal quality

The responsibility for drafting quality lies with DAGL. Since 2000, Italy has acquired experience in performing Legal Technical Analysis (*Analisi tecnico-legislativa*, ATN) to evaluate the quality of legal texts. The timing and methodology to carry out ATNs were revised in September 2008 by a Directive of the Presidency of the Council.[7] This includes assessing the implications for the legal order, in the light of the jurisprudence, and presenting this jointly with the technical-financial analysis and the RIA. Emphasis is put on the analysis of the national and international legal context (conformity check); on the quality of drafting; on the legal consistency of the legislative proposal; and on the compliance with pre-existent de-regulation measures. The directive also fosters collaboration between the legal offices of the administrations.

Over the years, both the government and the legislature have issued circulars and guidelines on legal drafting. In 2001, the Presidents of the Chamber, the Senate, and the Council of Ministers jointly adopted new circulars on technical drafting of legal acts. In 2002, the Ministry for Public Administration issued a circular letter on simplifying the language of administrative acts. More recently, the USQR and the DAGL have worked towards establishing a national “Chart for Regulatory Quality”. An internal software introduced in 2005 allowing standardised and consistent legal drafting is available to the DAGL and the ministries. The software ensures compatibility with the drafting processes at the regional level.

Ex ante *impact assessment of new regulations at the central level*

Policy on Impact Assessment

Early approaches

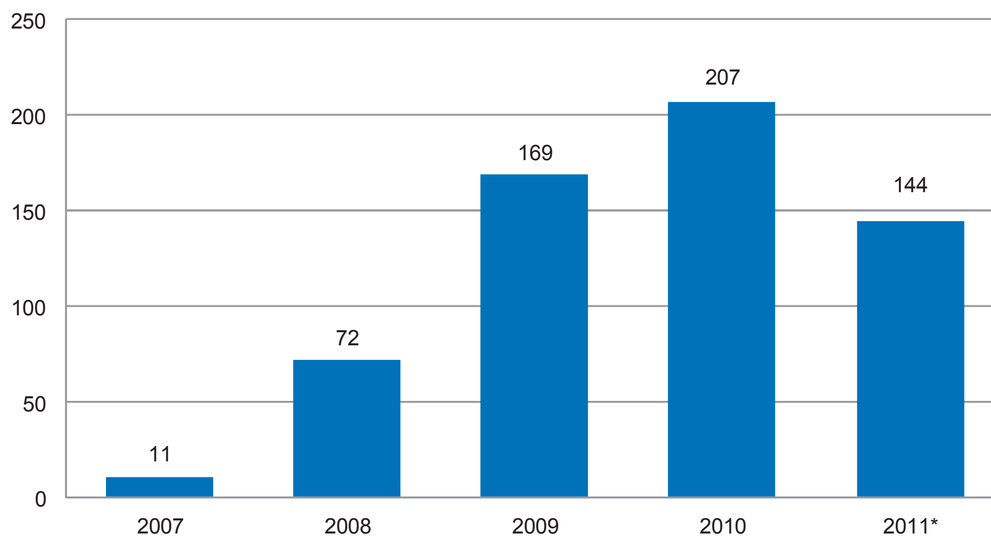
RIA was formally introduced in 1999-2000, as a pilot project, by a directive of the Prime minister and fairly detailed guidelines. As originally designed, RIA consisted of a two-tiered process. A standardised “preliminary assessment” first identified the problem to be addressed, the objectives of the intervention, and the stakeholders. They were also to analyse likely budgetary, economic and social constraints, including impacts, provide a general assessment of alternatives, including the “no action-option”, and, finally describe the appropriate level of the regulation proposed. At a second stage, a more comprehensive RIA was to accompany the final draft proposal. The final RIA was to be supported by a consultation phase. This first experimental phase produced five full RIAs.

Renewed political impetus was given to RIA with Law 246/2005, further to which the scope of application of RIA was extended to cover both primary and secondary regulations, including on acts transposing EU directives. Responsibilities for carrying out RIAs were decentralised, and the methodology “simplified” in order to ensure the widest recourse possible to RIA by administrations.

Recent developments

In 2008, a RIA regulation (DPCM 170/2008) was adopted. The principal goal of the revised approach was to diffuse and embed the instrument into the working methods of each central administration. At the same time, the regulation sought to extend the application of the tool.[8] Under the current system, RIA is one of the three mandatory reports that must accompany any proposal for normative acts submitted to the Council of Ministers. Exceptions still exist, and are listed in the 2005 Law (see below). In addition, the Council of Ministers may always decide and motivate exemptions. In any case, the regulatory memorandum accompanying the act (*relazione illustrativa*) has to report on the motivations for eventual exemptions. Central administrations have carried out more than 670 RIAs since 2007, with an increasing trend in annual production (with the exception of 2008, in which anticipated parliamentary elections took place) (see Figure 4.1.).

Figure 4.1. RIAs carried out by central administrations



*. 1 January – 6 December 2011.

Source: DAGL, 2011.

Institutional framework

As in most OECD countries, operational responsibility to carry out RIAs lies with the ministries. Their legal offices provide a first screening of the quality of the analysis, before RIAs are submitted to DAGL. Administrations are upgrading their legislative offices with a view to better co-ordinate and assist with the production of RIAs – for instance by setting up a RIA unit within its legislative office, or by establishing a network of internal and external experts.

According to the 2008 RIA Regulation, central administrations are expected to inform DAGL when they start the RIA process. The Regulation however does not specify when such communication shall take place. This gap is compensated by the requirement in the 2009 Directive on the organisation of the rule-making process, which calls upon the administration to indicate their planning to DAGL quarterly. In practice, communication of the planning is still unsystematic or partial. Since in principle every government act must be accompanied by a RIA, DAGL is nonetheless informed on the flow of new RIAs beyond the cases of exclusions and of requested exemptions.

Unless the proposal falls under the responsibility of two or more administrations, these are not required to systematically circulate draft RIAs across the government.[9] While they are urged to gather information both from other administrations and from external sources during the preparation of the draft bill, the proponent ministries and departments can choose who and how to proceed. An inter-departmental discussion takes place once the draft bill is submitted to DAGL, and it is organised by the latter in view to setting the agenda of the (pre-)Council meetings.[10]

DAGL serves as the only reference point for both *ex ante* and *ex post* analyses. Its RIA Unit[11] is charged with managing the process and with the control of compliance. The Unit checks the appropriateness and the completeness of the analysis and verifies the exclusions and exemptions from RIA:

- RIA is not requested for constitutional bills; regulations dealing with national security; and transposition of international agreements (17 exclusions in 2010; 28 for the period 1st January – 6th December 2011).
- Upon motivated request by the concerned administration, DAGL may exempt it from carrying out a RIA in cases of necessity and urgency, or in the light of the "specific complexity and size of the normative intervention and its likely impacts" (5 exemptions in 2010; 9 for the period 1st January – 6th December 2011).

DAGL may ask the relevant administrations to complement and clarify the RIA report and gives its final opinion on the document before it goes on the agenda of the Council of Ministers. In 2010, DAGL asked for 152 integrations of RIAs (73% of the whole). For the period 1st January – 6th December 2011, DAGL asked for 111 integrations (71% of the whole). [12]

DAGL provides, when necessary, support to the administrations in elaborating the RIA and the other mandatory reports. Its RIA Unit is charged with managing guidelines and with the control of compliance. While not formally foreseen, training is also acknowledged to be a critical element in the strategy to introduce and diffuse the tool. Between 2009 and 2010, two different trainings were organised. In 2009, a course of 6 days overall on RIA, ATN and VIR was provided to 18 officials at the Presidency of the Council of Ministers, covering theoretical aspects and the analysis of case studies. A seminar on RIA and VIR managed by the RIA Unit of the DAGL in collaboration with the *Scuola Superiore della Pubblica Amministrazione* took place twice in 2010. Structured in 15 sessions of 4 hours each, the training was attended by 43 among high officials and civil servants in the central administration. In 2011, DAGL organised a new RIA and VIR training for the staff of the Presidency of the Council, which was attended by 48 administrators.

Since 2010, the Unit has also organised regular meetings with the administrations to provide aggregated feedback, address the main problem they face, and identify priority areas for further action. The aim is to establish a non-formal dialogue between the centre and the periphery, with a view to facilitate the diffusion of the tool through the RIA network.

Methodology and process

The "simplified" approach introduced in 2008 seeks to streamline the procedural steps of the original blueprint (Article 5 of Law 50/1999). The RIA regulation consolidates the previous two circulars of the President of the Council into a single act; and converts the two-tiered approach into a single RIA document. The model relies on seven core sections to be filled as part of the structure of the RIA:

- the issue underpinning the proposed regulation: this includes a description of the "context" of reference; the coherence of the initiative in relation to the government's programmatic objectives; and the information used in the analysis;
- the objectives to be reached;
- the consultation process and its results: where consultation is absent, administrations shall justify why they did not comply with this step;
- the assessment of the "zero" option (no intervention);
- the assessment of alternative options;
- the justification of the chosen regulatory option, with the methods and comparisons (with particular emphasis on the assessment of the likely administrative burdens implied by the chosen option); and
- the modalities for implementing the regulatory intervention.

With regard to the methodologies, administrations have to cover:

- the assumptions underlying each alternative;
- the main advantages and disadvantages of the alternatives considered with a special emphasis on the preferred option (the cost-benefit analysis is indicated as one of the possible techniques available);
- the information obligations (and related administrative costs) introduced on businesses and citizens;
- the impact on well functioning markets and on the competitiveness of the country; and
- the impact on liberalisation processes.

Law 180/2011 on the Statute of enterprises approved in November 2011 includes significant specifications on enhanced attention to be put on the regulatory impacts – including administrative burdens – on SMEs. Consultations aspects are also strengthened (see Chapter 3).[13] This reflects and integrates the thrust to foster SMEs environment in Europe, as outlines in the European Commission's Small Business Act.[14] The DAGL is currently upgrading the regulation on RIA, VIR and public consultation, which will be complemented by to a guidance material also with a view to integrate such elements.

The 2008 RIA Regulation expressly mentions competition effects as one of the impacts that administration should analyse and consider when elaborating the preferred option. A (rather superficial) note is published also on the DAGL website.[15] As a result, RIA reports usually include a (mostly qualitative) brief assessment. Between 2006 and 2008, Italy promoted, together with the UK, a twining project with the Government of Romania on enhancing pro-competition policies and reforms, also through the means of RIA.[16] Because not a regulatory agency, the national Antitrust Authority (*Autorità Garante della Concorrenza e del Mercato*, AGCM) is not subject to the legal requirements of Law 246/2005 and it has not developed a system for systematic RIA.[17] Nonetheless, the AGCM has carried out *ad hoc* advisory analyses for regions (e.g. Tuscany) and to publish studies on the anti-competitive behaviour of firms.[18]

Besides the RIA report, administrations must produce a Technical-Financial Report, which lists the quantification of financial requirements and the related sources of coverage. The annual provisions for current expenditures and diminished income are also listed. The Report is joined by a prospectus on the financial impact on the net State balance, on the public administrations balances, and on the net debt of the consolidated account of the public administrations. The Report is updated when the proposed regulation passes from one branch of the Parliament to the other.

Public consultation and communication

The transparency requirements for the simplified RIA have not changed. In accordance with Law 246/2005, each ministry decides autonomously on the form of publicity beyond the minimum requirements set by the law and the allocation of resources. The responsible administration may decide to publish its RIAs also during the preparatory phase. No central administration has so far done so.

Final RIA reports are de facto public, because they are attached to the acts transmitted to Parliament by the government and hence they can be retrieved from the Parliament's website. However, the Parliament website does not provide direct links to the RIA reports, but to the parent act only. It is therefore very difficult to access a RIA report, unless one knows exactly the number of the parent act, and that this latter has already been transmitted to Parliament. It is also unclear if it is possible to request RIAs to the responsible administrations, directly. The new regulation states that the RIAs have to be published and be available on the Government and ministries websites.

DAGL is tasked with the preparation of an annual report to the Parliament on the implementation of both RIA and *ex post* evaluation (VIR, see below). The necessary information underpinning the reports is collected from each administration. In such reports, regional experiences are also listed, as well as those of the independent authorities.[19] Little information is available on the effectiveness of the preliminary quality check by the Legislative Offices of each ministry / department. The Offices are not formally requested to produce general monitoring and evaluation reports.

Appraisal in early 2011 from DAGL of RIAs carried out in the central administrations indicates a number of strong points and weaknesses in the current practice.[20] The strong points can be summarised as follows:

- RIA reports often provide descriptions of the context in which regulatory interventions take place, although mainly in qualitative terms;
- the description and assessment of the problem is accurate, outlining juridical, economic, and social reasons;
- objectives are generally described clearly and appropriately;
- there is always an explicit commitment to carry out the *ex post* evaluation (VIR).

Areas where further improvement is necessary:

- RIAs do not properly consider and compare a variety of options: in many cases, only the "do-nothing" and one alternative are considered;
- generally there is only a qualitative assessment of the preferred option, and estimates of costs and benefits are rare; and
- even when departments carry out consultations, often the results are not included in the RIAs, nor do RIAs indicate the stakeholders consulted.

According to DAGL, the constraints relate to timing, allocation of resources, and availability of expertise. RIAs are often prepared too late, when there is no concrete possibility of considering different alternatives. Time spent on preparing RIAs is residual, which gives little chance to officials in charge of preparing the RIA document to improve the content (e.g. by searching for new data). Finally, RIA drafters are often located in the legislative offices of the department. They normally have a juridical background and no technical expertise on the issues covered by the proposal.

DAGL has committed to address these challenges in the forthcoming new regulation, notably by:

- *intervening on the forward planning and streamlining the scope*. RIA should be more closely connected to the normative agenda, so as to identify the most relevant acts earlier in the process and allocate resources where RIA is necessary. At the same time, DAGL intends to provide enhanced specific technical advice to the ministries;
- *enhancing the interface with public consultation*. To this end, DAGL is planning to introduce an *ad hoc* regulation on consultation and transparency within RIA;
- *informing on the recurrent criticalities when producing RIAs and diffusing best practices*, notably by organizing periodical workshops with the ministries;
- *urging administrations to involve their line general directorates* (and not only the legislative offices) in the RIA process; and
- *enhancing the supporting material for RIA drafters and strengthening training activities*, including through new RIA guidelines, especially for technical directorates.

The role of parliament

In a context where neither the Council of State nor the Court of Audit have so far carried out evaluations of the RIA system and feedback from academia, think tanks and stakeholders associations is not organised, the Parliament plays an important oversight role. According to Law 246/2005, the government is responsible for drafting and proposing RIAs. They are then forwarded to parliament for consideration. Parliament is committed to examine the whole set of information and explanations accompanying proposed legislation.

The Service for the quality of legislation of the Senate (*Servizio per la qualità degli atti normativi*)[21] published a report in October 2010 of the previous two years of RIA performance in the central administrations.[22] This report complements the "annual" screening by the DAGL. Besides listing the normative acts for which no RIA was prepared, the Service comes to the conclusion that the RIA documents do not substantially deviate from the descriptive reports.

The Legislation Committee of the Chamber of Representatives (*Comitato per la legislazione*)[23] made a mere quantitative evaluation, noting that out of the 20 acts screened by the Committee between March 2009 and January 2010, for which a RIA and a legal analysis (ATN) would have been required, only 8 actually attached such documents (representing nonetheless an increase from 27.5% to 40% compared to the period May 2008-March 2009).[24]

RIA and the regulatory agencies

Regulatory agencies are compelled by law to perform impact assessment on regulation since 2003. However, as independent authorities, they are not bound by the 2008 RIA Regulation. In their discretion on how to implement the legal requirement to carry out RIAs, some agencies have developed a RIA system that meets international good standards.[25] The energy regulator (*Autorità per l'energia elettrica ed il gas*, AEEG) is a point in case and it is often described as the agency with the most advanced experience with RIA in Italy. AEEG was the first among the regulatory agencies to establish internal RIA procedures, launching a pilot phase in 2005. In 2008, the AEEG system reached cruising speed and internal guidelines were adopted (*Guida per l'analisi di impatto della regolazione*). A RIA unit (*Nucleo AIR*) co-ordinating the RIA process and dedicated office a (*Ufficio per l'impatto regolatorio*) were set up. The AEEG has produced more than 20 analyses. Specific features of the AEEG system are the close linkages with the agenda and the consultation procedure and the flexibility in the analysis of the various regulatory options.

The Bank of Italy has also developed advanced RIA practices. Carrying out three trial RIAs since 2009, the Bank published its RIA guidelines in March 2010. They foresee two types of RIAs: simplified RIAs differ from fully-fledged RIAs in terms of both content and organisation (the latter case implying stronger centralisation). Simplified RIAs may indicate the opportunity to proceed to more in-depth analyses. The procedure follows to a large extent the classic analytical steps, while the methodologies tend to promote rather qualitative assessments and multi-criteria analyses.

Further experiences with RIA are being made by other agencies. The communication regulator (AGCOM), in particular, has completed some 17 RIAs since 2006. However, it lacks a procedural discipline and its RIAs tend to be market analysis and focus on competitive impacts only rather than being comprehensive regulatory impact analysis. In the last few years, the Authority has not published the RIA reports but included the market analysis in the regulatory decision directly. The Italian securities market regulator (CONSOB) has so far published only a few RIAs, but it has, in the last few years, invested more and more on this tool. However, proper RIA regulation for the sector has not been adopted yet even if two drafts were subject to consultation in 2007 and 2010. The Italian insurance regulator (ISVAP) published a draft RIA regulation in 2008 but it has not realised any yet. Similar situations can be found for the supervisory authority of pension funds (COVIP) and the authority of public contracts (AVCP), which both published regulations concerning RIA and the public consultation procedures in 2011. These agencies are upgrading their systems and they have launched pilot projects.

No systematic training has yet taken place within the independent agencies. The AEEG has organised a few informative seminars.

Each independent regulatory agency decides on the publication of its RIA reports. In general, all the agencies that have developed RIA practices also publish their RIAs. While in some cases the RIA reports are included as an annex in the act (as the Bank of Italy and CONSOB do), in other cases they are easily identifiable online because they have individual links.[26] Law 229/2003 also required the authorities to forward their RIA reports to the parliament. This constituted a relative novelty among OECD countries. However, agencies have complied with these provisions to various extents, in a context where no sanction is envisaged in case of non compliance.

To report on these developments, and to monitor in general the evolution of RIA systems in the independent agencies in Italy, a dedicated independent Observatory was established by academic institutes in 2009 (see Box 4.4).

Box 4.4. Monitoring RIA in regulatory agencies: The Osservatorio AIR

The Observatory on Italian Independent Regulators' RIA, was founded in 2009 following an agreement between the Department of Legal Sciences of the *University of Tusci* (*Viterbo*) and the Faculty of Law of the *Parthenope University of Naples*. The Observatory is funded by the Institute for Research on Public Administration and consists of political scientists, economists, jurists and communication experts. Its main purpose is to constantly monitor the application of Regulatory Impact Analysis (RIA) methodology by the eight Italian Independent Regulators with regulatory and surveillance powers in the economic sector. It also produces analyses, papers and case studies as well as investigations and comparisons with the most significant international experiences.

Source: www.osservatorioair.it.

Ex post *evaluation of regulations*

Ex post evaluation of regulations has been formally foreseen since the Prime Minister Directive of September 2001. Parliament put renewed emphasis on regulatory review through two important provisions included in the Simplification Act for 2005 (Law 246/2005): the *ex post* evaluation of regulation (*Verifica dell'impatto della regolamentazione*, VIR), and the cutting-laws mechanisms (see Chapter 5).

The law establishes that the responsibility for carrying out the VIR lies with the administration that originally performed the RIA or, in case no RIA was originally performed, with the administration "competent by subject". However, the instrument has not been fully implemented, yet.[27]

In November 2009, a Prime Minister Decree was issued[28] to regulate the tool in more detail. As provided for in the law, the Decree indicates that the VIR should be carried out two years after the entering into force of the legal act, and be regularly updated every two years. A VIR should be undertaken on the acts for which a RIA was produced, on all legislative decrees and laws converting legislative decrees into law, and upon request of the parliamentary committee and the Council of Ministers. The generic formulation of the Decree gives the possibility to derogate from these requirements only in those cases where the DAGL allows a RIA exemption. While a template for the VIR report is provided, further guidelines supporting *ex post* analysis still need to be outlined. An Annex[29] attached to the enabling regulation provides some basic indications on how to perform the analysis. As for RIA, each administration is responsible for the VIR evaluation and decides on the type and form of its publication.

In principle, Law 246/2005 extends the requirement to carry out *ex post* evaluation to the regulatory acts adopted by the independent agencies. While no concrete implementation of such requirement has been registered so far, some agencies have undertaken initiatives that link *ex post* evaluation to other practices. This is the case notably of the Bank of Italy, CONSOB, ISVAP and COVIP, which are also subject to Law 262/2005 requiring a review of the impacts at least every three years after entering into force. The CONSOB, for instance, complemented its guidelines on impact assessment in 2010 with a provision on consultation, insisting on the "maintenance" of its existing regulation through monitoring and evaluation. The AEEG has emphasised the importance of assessing the baseline option when doing a RIA, in order to include *ex post* evaluation elements.[30] In accordance to Law 262/2005, ISVAP, AVCP, CONSOB, Bank of Italy and COVIP have proceeded in the last few years to updating pieces of regulation.

Regional involvement in central impact assessment

Conscious of the need to better integrate the EU, national and sub-national RIA processes for the development of new regulations, Italian authorities signed an agreement in 2007 on simplifying and improving the quality of regulation.[31] The agreement reiterates for each level of government the principles of regulatory quality shared in Europe: necessity, proportionality, subsidiarity, transparency, accountability, accessibility and simplicity of the rules. The agreement is expected to identify shared methodologies and principles, with the aim to extend to the entire regulatory process the main analysis tools such as technical standards (ATN), RIA and consultation, *ex post* evaluation (VIR), regulatory simplification, and the measurement and reduction of administrative burdens. It also provides for the establishment of adequate support structures or other centres of responsibility for the drafting of legislation and for the carrying out of RIAs.

Alternatives to regulation

Italy has developed self-regulation practices in a variety of sectors. As in many other OECD countries, environmental policy is one of the main fields in which such an approach has been followed. Since the end-1990s, the Ministry for Environment has promoted voluntary agreements in a variety of economic sectors, including in the framework of the implementation of the Kyoto Protocol. Initiatives have ranged from the use of bio-fuels in the transport sector, the so-called "car-sharing initiative", and the diffusion of methane in automotive vehicles, to the creation of protected natural reserves.

However, the use of alternatives to regulation has remained limited, despite the fact that the 2001 Italian RIA Guidelines explicitly required administrations to consider and evaluate alternatives to the regulatory option when carrying out RIAs. Under the current RIA regime, while the "zero option" is clearly pointed out as the baseline for measurement of the effects of the proposal, the simplified RIA approach allows for a less detailed analysis of options other than the chosen one. To get through this crucial phase, the new RIA regulation under development envisages deeper analysis of all the options.

Risk-based approaches

Forms of risk management are applied to a number of policies and sectors, including regulatory activity. Some examples include hydro-geological and seismic risks as well as technological risks related to public health and the environment. Scientific and technical support on environmental policies is provided by the National Environmental Protection Agency (APAT – renamed ISPRA in 2008). Further to the Environmental Code of 2006, the ISPRA has acquired an autonomous status in terms of internal organisation, management and budget, as well as technical and scientific advice and regulatory powers. Since 2001, ISPRA is integrated into a network, the Environmental Agency System, which includes 21 Regional (ARPA) and Provincial (APPA) Agencies established by special regional laws to perform inspection and enforcement.

Risk-related issues may also be addressed as part of the environmental impact assessment. The *Valutazione dell'impatto ambientale* (VIA) assesses potential impacts of projects, while the *Valutazione Ambientale Strategica* (VAS) seeks to integrated environmental considerations in the design and implementation of policy programmes and strategies as mandated by EU requirements.[32]

In the field of health, the *Consiglio Superiore di Sanità* is the technical consultative organ supporting the Ministry of Public Health. The *Istituto Superiore di Sanità* (ISS) is the leading technical and scientific public body of the Italian National Health Service. The National Committee for Food Safety (CNSA) became operational in February 2008. It serves as a technical advisory body participating in the network of the European Food Safety Authority (EFSA). As such, the CNSA provides scientific opinions to the relevant ministerial administrations as well as to the regions and Autonomous provinces.

Notes

1. Art. 3 of Law 246/2005.
2. Decree by the Presidency of the Council of Ministers, Internal Rules of Procedure of the Council of Ministers, 10 November 1993.
3. Directive by the Presidency of the Council of Ministers, Investigation of government regulations, Official Gazette No. 82, April 8, 2009, *www.governo.it/Presidenza/AIR/normativa/direttiva_pcm_260409.pdf*.
4. *www.attuazione.it*.
5. Directive by the Presidency of the Council of Ministers, Investigation of government regulations, Official Gazette No. 82, April 8, 2009.
6. On the matter, see Mattarella, G.B. (2010), and Cocconi, M. (2011).
7. Directive by the Presidency of the Council of Ministers, timing and modalities in carrying out legal technical analyses, 10 September 2008.
8. In 2006, draft regulatory instruments submitted by administrations to the President of the Council accompanied by RIA reports accounted for only 50% of all draft regulatory instruments examined (source: *First Progress Report to the Parliament on the Implementation of the Regulatory Impact Analysis* (RIA), of 13 July 2007, pursuant Art.14, par.10, of Law 246/2005.
9. Art.3(2) of the 2008 RIA Regulation.
10. Directive by the Presidency of the Council of Ministers, Investigation of government regulations, Official Gazette No. 82, April 8, 2009, *www.governo.it/Presidenza/AIR/normativa/direttiva_pcm_260409.pdf*.
11. *www.governo.it/Presidenza/AIR/index.html*.
12. Information provided by DAGL to the review team, January 2011.
13. See in particular Art. 6 of AS 2626 of 20 October 2011, at *www.senato.it/leg/16/BGT/Schede/Ddliter/36585.htm*.
14. *http://ec.europa.eu/enterprise/policies/sme/small-business-act*.
15. *www.governo.it/Presidenza/AIR/impatto_concorrenziale.pdf*.
16. *www.governo.it/Presidenza/AIR/cooperazione_AIR_Romania.pdf*.

17. On the matter, see Cavallo (2010), p.10ff.
18. *www.agcm.it/studi-e-ricerche/5412-2-analisi-di-impatto-della-regolazione-sulla-concorrenza-linee-guida-e-applicazione-al-caso-della-regione-toscana.html*.
19. Decree of the President of the Council of Ministers 170/2008.
20. Information provided by DAGL to the review team, January 2011.
21. *www.senato.it/leggiedocumenti/152388/152432/152434/genpagspalla.htm*.
22. *www.senato.it/documenti/repository/dossier/drafting/2010/Dossier%2037.pdf*.
23. *www.camera.it/803*.
24. *www.camera.it/application/xmanager/projects/camera/file/documenti/Rapporto_Duilio_sintetico_2.pdf; www.governo.it/Presidenza/AIR/rassegna_stampa/sole24ore_15_2_2010.pdf*.
25. The Osservatorio AIR collects documentation on the main Italian agencies and publishes it on its website www.osservatorioair.it/?page_id=406. Detailed information can be retrieved there (in Italian).
26. For an example of the latter approach, see *www.autorita.energia.it/it/_pagine_informative_/air.htm*.
27. *www.osservatorioair.it/wp-content/uploads/2010/10/Paper_Cacciatore_AI-VIR_sett2010.pdf*.
28. Decree by the President of the Council of Ministers, 19 November 2009 No. 212, Regulations on carrying out *ex post* analyses (VIR), pursuant to Article 14, Clause 5, of the Law of 28 November 2005, No. 246.
29. *www.governo.it/Presidenza/AIR/normativa_vir/Allegato_A.pdf*.
30. *www.osservatorioair.it/wp-content/uploads/2010/10/Paper_Cacciatore_AI-VIR_sett2010.pdf*, pp. 26-28.
31. Accordo Stato-Regioni-Autonomie locali in materia di semplificazione e analisi di impatto della regolazione of 29 March 2007, signed by the State, the Regions and Autonomous Provinces of Trento and Bolzano, provinces, municipalities and mountain communities.
32. EC Directive 97/11, and EC Directive 2001/42, respectively. Besides the VIA and VAS, so-called “super-VIAs” can be performed on projects with high strategic priority. The super-VIA is a simplified and accelerated environmental impact assessment that facilitated the fast adoption of a piece of legislation.

From:
Better Regulation in Europe: Italy 2012
Revised edition, June 2013

Access the complete publication at:
https://doi.org/10.1787/9789264204454-en

Please cite this chapter as:

OECD (2013), “The development of new regulations”, in *Better Regulation in Europe: Italy 2012: Revised edition, June 2013*, OECD Publishing, Paris.

DOI: https://doi.org/10.1787/9789264204454-10-en

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