The New Regulation Governing AIR, VIR and Consultation

A Further Step Forward Towards 'Better Regulation' in Italy

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Abstract

This article describes the scope and contents of the newly adopted regulation governing regulatory impact analysis (RIA) and ex post evaluation of regulation (ExPER) in the Italian legal system. The article shows that this regulation has the potential to improve regulatory governance in Italy. Not only does it introduce innovations designed to increase transparency and participation, especially through strengthened consultation and communication mechanisms, but it also aims to improve the quality and effectiveness of regulatory analysis and evaluation activities. How the new regulation will be applied in practice, however, remains to be seen. In the meantime, the new set of rules are a welcome addition to Italy's Better Regulation policy.

Keywords: regulation, RIA, regulatory impact analysis, impact assessment, evaluation, consultation.

A Introduction

On 15 September 2017, the Decree of the President of the Council of Ministers[1] No. 169 'Regulation governing the analysis of the impact of regulation, the evaluation of the impact of regulation and consultation'[2] (hereafter referred to as 'Reg-

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1 In Italy, the President of the Council of Ministers is formally responsible for regulatory quality.

2 *Decreto del Presidente del Consiglio dei Ministri 15 settembre 2017, n. 169 – Regolamento recante disciplina sull'analisi dell'impatto della regolamentazione, la verifica dell'impatto della regolamentazione e la consultazione*, in *Gazzetta Ufficiale* 30 November 2017 No. 280. On the new regulatory framework, *see* Senato della Repubblica (Ufficio Valutazione Impatto), 'La nuova disciplina dell'analisi e della verifica dell'impatto della regolamentazione', April 2018, pp. 1-42.

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ulation') was enacted after a long gestation period leading to a public consultation in 2013, and that had also involved the Council of State in its advisory role.[3]

Prior to the adoption of the Regulation, two separate decrees of the President of the Council of Ministers governed the analysis of the impact of regulation (*Analisi dell'impatto della regolamentazione* – 'AIR') and the evaluation of the impact of regulation (*Verifica dell'impatto della regolamentazione* – 'VIR'), respectively decree 11 September 2008 No. 170 (hereinafter, 'the 2008 AIR Regulation') and decree 19 November 2009 No. 212 (hereinafter, 'the 2009 VIR Regulation'), which have both been repealed.[4] The Regulation, therefore, incorporates into a single normative act all existing provisions concerning ex ante and ex post assessment of the impacts of regulation, with a view to promoting a *systematic* and *comprehensive* approach in which regulatory tools interact and converse with

3 *Consiglio di Stato – Sezione Consultiva per gli Atti Normativi*, opinion No. 807/2017 of 19 June 2017. Besides exercising a judicial function, which involves second-instance jurisdiction on acts of all administrative authorities, the Council of State serves as a legal administrative-consultative body. The Council's consultation is mandatory on draft regulations of the Government or single ministers. In its advisory capacity – and as recently reiterated in its opinion 7 June 2017 No. 807 – the Council of State has consistently recognized the importance of regulatory tools for both end users of regulatory interventions and the policy cycle itself. Recently, it has gone as far as stigmatizing the Ministry of Health's failure to prepare the required AIR report in relation to a draft regulation, by suspending the issuance of its mandatory opinion (*i.e.* opinion 9 February 2017 No. 341). In this respect, *see* G. Dimitrio, 'I recenti interventi del Consiglio di Stato sulle AIR relative agli schemi di regolamento del Ministero della salute e del Ministero dell'ambiente', *Rassegna Trimestrale dell'Osservatorio AIR*, VIII/2, 2017, pp. 1, 12-19. On the growing importance of the Council's role in matters of regulatory quality, *see* M. Benedetti, 'Il Consiglio di Stato e gli strumenti di better regulation', *Rassegna Trimestrale dell'Osservatorio AIR*, VII/4, 2016, pp. 1, 17-25, and M. Cappelletti, 'Il giudice amministrativo e gli strumenti di qualità della regolazione', *in* F. Cacciatore & S. Salvi (Eds.), *L'analisi di impatto e gli altri strumenti per la qualità della regolazione. Annuario 2014*, Rome, Osservatorio AIR, 2014, pp. 1-147. This progressive integration of regulatory quality within the judicial context is, moreover, in line with the current pattern of 'cross-fertilization' between ex ante evaluation and ex post judicial control. The use of RIA by policymakers in the preparation of policy proposals affects more and more the courts when called upon to judge the legality of those initiatives. While RIA is not itself a procedural mechanism for making decisions, it entails – regardless of its formal legal status – substantive, and in some jurisdictions determinative, consequences for the legal system. *See* A. Alemanno, 'Courts and Regulatory Impact Assessment', *in* C.A. Dunlop & C.M. Radaelli (Eds.), *Handbook of Regulatory Impact Assessment*, Cheltenham, Edward Elgar Publishing, 2017, pp. 127-141. The Court of Justice of the European Union increasingly relies on ex ante evaluation mechanisms in the context of judicial review of adopted legislation. *See* in this regard, J. Nowag & X. Groussot, 'From Better Regulation to Better Adjudication? Impact Assessment and the Court of Justice's Review', *in* S. Garben & I. Govaere (Eds.), *The EU Better Regulation Agenda: A Critical Assessment*, Oxford-Portland, Hart Publishing, 2019, pp. 185-203. *See also*, A. Alemanno, 'A Meeting of Minds on Impact Assessment: When Ex Ante Evaluation Meets Ex Post Judicial Control', *European Public Law*, Vol. 17, No. 3, 2011, pp. 485-505, who anticipates a 'meeting of minds' between the EU legislature and the judiciary: ex ante impact analysis, by offering a 'legality check' of each Commission proposal well before its adoption, may serve not only as 'aid to the legislator', but also as an 'aid to the parties' and an 'aid to court'.

4 Reg., Art. 20.

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each other across the whole regulatory cycle.[5] In view of this, Art. 2, Para. 1 of the Regulation expressly states that

> AIR, VIR and consultation are tools that, integrated with one another, contribute to the quality of the regulatory process, from the identification of needs and priorities, to the design of the interventions, their implementation, until their revision, according to a circular approach to regulation.

As pointed out by the Council of State, the primary objective of the Regulation is to further enhance the use of the regulatory tools that support the top-level political decisions of the public administration, not only to improve the quality of regulation but also to increase the transparency of decision-making and the subsequent accountability of policymakers, as well as strengthening the certainty of law as a factor promoting economic growth and social development of the country.[6] In addition, the Regulation addresses several critical areas in the design and implementation of the AIR, VIR and related consultation that have been identified in the 'OECD Review of Better Regulation in Italy'[7] as requiring improvement.

While the Regulation entered into force on 15 December 2017, it has become applicable as of the day following the publication of the implementing act referred to in Art. 3, Para. 1.[8] This provision stipulates that a directive of the President of the Council of Ministers shall regulate the techniques of analysis and evaluation, including consultation and monitoring activities, and shall provide the model templates for the AIR and VIR reports.[9] The directive was adopted on 16 February 2018 and sets forth in its Annex 1 the 'Guidelines to the analysis and evaluation of the impact of regulation' (hereinafter, 'the Guidelines').[10]

5 The Regulation, which consists of a Preamble and 21 articles, is broken down into six chapters, dedicated, respectively, to: general provisions; analysis of the impact of regulation; evaluation of the impact of regulation; consultations; report to Parliament; and final provisions.

6 Consiglio di Stato, *supra* note 3, Para. 13.

7 OECD, *Better Regulation in Europe: Italy 2012: Revised edition*, Paris, OECD Publishing, 2013, pp. 1-148. This is one of a series of country reports launched by the OECD in partnership with the European Commission. The objective is to assess regulatory management capacities in EU member states, including trends in their development, and to identify gaps in relation to good practice as defined by the OECD and the EU in their guidelines and policies for Better Regulation.

8 Reg., Art. 21, Para. 1.

9 The Regulation further provides (Art. 3, Para. 2) that, in matters of regulatory quality, the Unified Conference may define forms of cooperation concerning the techniques and procedures for the analysis and evaluation of the impact of regulation, as well as in relation to the exchange of experiences, provision of tools and information, and procedures of joint assessment, also related to EU legislation. The Unified Conference is regulated by Art. 8 of *decreto legislativo* 28 August 1997 No. 281. It is an advisory body made up of the State/cities Conference and the State/regions Conference, which is convened by the President of the Council of Ministers to foster cooperation between the central state and the system of local autonomies (*i.e.* regions, provinces, municipalities and mountain communities) by examining matters of common interest.

10 *Direttiva del Presidente del Consiglio dei Ministri 16 febbraio 2018 – Approvazione della Guida all'analisi e alla verifica dell'impatto della regolamentazione, in attuazione del decreto del Presidente del Consiglio dei Ministri 15 settembre 2017, n. 169*, in *Gazzetta Ufficiale* 10 April 2018 No. 83.

Along with their four Appendixes,[11] the Guidelines replace – and greatly expand the scope of – the existing ones, approved in Circular No. 1 of 16 January 2001,[12] by offering a wealth of technical instructions for the operationalization of the regulatory quality tools. The Guidelines have been prepared taking into account, with due adaptation to the Italian context, the recommendations drawn from the European Commission's Better Regulation Guidelines (2017)[13] and the Communication 'EU regulatory fitness' (2012),[14] as well as the methodologies developed in the framework of the 'Regulatory Fitness and Performance Programme' (REFIT) (2014).[15]

In addition to the Guidelines, the directive includes an updated version of the model templates used for drafting the AIR and VIR reports (respectively, Annexes 2 and 3), in accordance with Art. 3, Para. 1 of the Regulation.

Finally, the directive repeals the so-called gold-plating directive of the President of the Council of Ministers of 16 January 2013,[16] which governed matters of compliance with minimum levels of regulation set forth by EU directives and provided the old template for the AIR report.

B Subject Matter and Addresses of the Regulation

As stipulated in Art. 1, Para. 1, the Regulation governs the procedures and modalities for the performance of the ex ante analysis and the ex post evaluation of the impact of regulation, as well as related consultations, in accordance with Art. 14, Para. 5[17] of law 28 November 2005 No. 246 'Simplification and regulatory reor-

11 App. 1 – Evaluation of specific impacts; App. 2 – AIR Checklist; App. 3 – VIR Checklist; App. 4 – VIR two-year plan template.

12 *Presidenza del Consiglio dei Ministri (Nucleo per la Valutazione delle Norme e delle Procedure), Circolare 16 gennaio 2001, n. 1 – Guida alla sperimentazione dell'analisi d'impatto della regolamentazione (AIR),* in *Gazzetta Ufficiale* 7 March 2001 No. 55 – *Suppl. Ordinario* No. 46.

13 European Commission, Commission Staff Working Document, 'Better Regulation Guidelines', SWD (2017) 350, Brussels, 7 July 2017.

14 European Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – EU Regulatory Fitness', COM(2012) 746 final, Strasbourg, 12 December 2012.

15 European Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook', COM/2014/0368 final, Brussels, 18 June 2014.

16 *Direttiva del Presidente del Consiglio dei Ministri del 16 gennaio 2013 – Disciplina sul rispetto dei livelli minimi di regolazione previsti dalle direttive europee, nonché aggiornamento del modello di relazione AIR, ai sensi dell'art. 14, comma 6, della legge 28 novembre 2005, n. 246*, in *Gazzetta Ufficiale* 12 April 2013 No. 86.

17 This provision stipulates that "Within one hundred and eighty days from the date of entry into force of the present law, decrees of the President of the Council of Ministers, adopted pursuant to article 17, paragraph 3 of law No. 400/1988, shall define: (a) the general criteria and procedures of the AIR, ending with the issuance of a special report, as well as the relative phases of consultation; (b) the types, cases and modalities for exclusion of the AIR; (c) the general criteria and procedures, including the identification of the cases of execution of the VIR; (d) the criteria and general content of the report to Parliament referred to in paragraph 10."

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ganisation for the year 2005'.[18] It is worth mentioning that Art. 14 of law No. 246/2005 not only introduced the VIR in the Italian legal system,[19] but also ended the 'experimental phase' launched by Art. 5, Para. 1 of law 8 March 1999 No. 50[20] (also known as the 'First Simplification Law') by making the AIR a permanent requirement for all draft regulations of the Government. Moreover, the

18 *Legge 28 novembre 2005, n. 246 – Semplificazione e riassetto normativo per l'anno 2005*, in *Gazzetta Ufficiale* 1 December 2005 No. 280. Art. 14, Para. 1 of law No. 246/2005 defines the AIR as "the prior assessment of the effects of possible regulatory interventions on the activities of citizens and enterprises and on the organisation and functioning of public administrations, through the comparison of alternative options. In the identification and comparison of options, the competent administrations shall take into account the need to ensure the proper functioning of a competitive market and the protection of individual freedoms". On the other hand, the VIR consists, pursuant to Art. 14, para. 4, in "the evaluation, also periodical, of the achievement of the objectives and in the estimation of the costs and effects produced by regulatory acts on the activities of citizens and enterprises and on the organisation and functioning of public administrations".

19 Another significant step towards official recognition and codification of ex post evaluation was made in Italy through the adoption of the 2009 VIR Regulation, which implemented the provisions of Art. 14, Para. 5 of law No. 246/2005 by regulating in a more detailed way the VIR, thus adding a new element to the legal framework relating to the quality of regulation. In this regard, *see* S. Salvi, 'La sfida della verifica dell'impatto della regolazione', *Rassegna Trimestrale dell'Osservatorio AIR*, I/2, 2010, pp. 1, 34-36 and F. Sarpi, 'La valutazione dell'impatto della regolazione in Italia: una missione impossibile?' *Analisi Giuridica dell'Economia*, No. 2, 2013, pp. 447-464. *See also*, OECD, *supra* note 7, pp. 1, 81-82.

20 *Legge 8 marzo 1999, n. 50 – Delegificazione e testi unici di norme concernenti procedimenti amministrativi – Legge di semplificazione 1998*, in *Gazzetta Ufficiale* 9 March 1999 No. 56. The directive of the President of the Council of Ministers 27 March 2000 (*Gazzetta Ufficiale* 23 May 2000 No. 118) provided instructions for the early experimentation of the analysis of the impact of regulation on citizens, enterprises and public administrations. This directive had the merit of defining and formalizing the AIR process and structuring it as a 'quasi-administrative procedure'. The subsequent directive 21 September 2001 (*Gazzetta Ufficiale* 25 October 2001 No. 249) redefined the modalities of experimentation to make it more effective, also through strengthening the organizational and institutional arrangements, with a view to its future application to the whole regulatory activity of the Government. On this experimental phase, *see* A. Natalini, 'La sperimentazione dell'Air a livello statale', *Rivista Trimestrale di Scienza dell'Amministrazione*, No. 4, 2000, pp. 109-118; A. La Spina, 'L'analisi d'impatto della regolazione: i caratteri distintivi, le tecniche, la ricezione in Italia', *Rivista Trimestrale di Scienza dell'Amministrazione*, No. 4, 2000, pp. 11-17; E. Midena, 'Analisi di impatto della regolazione e analisi tecnico-normativa', *Giornale di diritto amministrativo*, No. 1, 2001, pp. 88-95; N. Lupo, 'La nuova direttiva sull'AIR: passi avanti o passi indietro?' *Giornale di diritto amministrativo*, No. 1, 2002, p. 13 and following; E. Morfuni, 'L'introduzione dell'AIR in Italia: la prima fase di sperimentazione', *Giornale di diritto amministrativo*, No. 7, 2002, p. 729 and following; A. La Spina & S. Cavatorto, 'L'analisi di impatto della regolazione nella recente esperienza italiana', *Rivista italiana di politiche pubbliche*, 2002, pp. 43-71; M. De Benedetto, 'Un "quasi-procedimento"', in N. Greco (Ed.), *Introduzione alla "analisi di impatto della regolamentazione"*, collana "Studi e Ricerche" No. 3, Rome, Scuola Superiore della Pubblica Amministrazione, 2003, pp. 223-242. *See also*, OECD, *Regulatory Reform in Italy. Government Capacity to Assure High Quality Regulation*, Paris, OECD Publishing, 2001, pp. 28-30.

AIR was regulated again, but in a much more precise and prescriptive way than in 1999.[21]

Following a recommendation of the Council of State,[22] the Regulation expressly applies to state administrations,[23] with the exclusion of the 'independent administrative authorities'.[24] In Italy, independent Authorities are generally understood as public agencies established by law, which are placed outside the sphere of political intervention. Such authorities perform regulatory functions in particularly important socio-economic sectors that are considered sensitive and/or of a highly technical nature. For this reason, a certain degree of autonomy and independence vis-à-vis the Government is required to ensure greater impartiality with respect to the public interests involved.[25]

21 Three years later, Art. 14 of law No. 246/2005 was implemented by the 2008 AIR Regulation. On the new AIR system introduced by law No. 246/2005, *see* F. Basilica, 'L'analisi di impatto della regolazione nell'ordinamento italiano', *in* F. Basilica (Ed.), *La qualità della regolazione. Politiche europee e piano d'azione nazionale*, Bologna, Maggioli Editore, 2006, pp. 543-546; Coco *et al.*, 'L'analisi di impatto della regolazione nell'esperienza applicativa italiana', *Ibid*., pp. 799-805. On the 2008 AIR Regulation, *see* specifically A. Natalini & F. Sarpi, 'L'insostenibile leggerezza dell'AIR', *Giornale di diritto amministrativo*, No. 3, 2009, pp. 229-239; A. Greco, 'L'analisi di impatto della regolazione: origini e tendenze recenti', *federalismi.it*, 2009. Available at: www.federalismi.it.

22 *See* Consiglio di Stato, *supra* note 3, Para. 46: "There is also the need to specify, in order to reduce the uncertainty concerning the subjective scope of application of the regulation, whether or not it is applicable [...] in respect of the independent administrative Authorities, which are also 'state administrations' (in a broad sense), and which, however, follow specific rules in the area of regulatory analysis, largely forged by the same Authorities in the exercise of their autonomy".

23 This means central administrations only. Starting from early 2000s, Italian regions, encouraged by the 'Better Regulation' agenda of the European Commission, and, in part, also by the OECD, have begun to pay more attention to the quality of legislation by inserting ad hoc provisions in their Statutes. Most regions have adopted, since 2001, regional laws and bylaws in this area. While Regional Councils engage primarily in ex post evaluation, Regional Governments are mostly involved in ex ante analysis. Experimental AIRs have so far been carried out in many regions (available at http://esperienze.formez.it/category/tag/air), with varying degrees of success. An overview of AIR-related regional activities can be found in *L'analisi d'impatto della regolamentazione. Le esperienze regionali*, Roma, Formez, 2003 and *L'analisi d'impatto della regolamentazione. Le esperienze regionali 2003-2006*, Roma, Formez, 2006. More information on regulatory quality infrastructure at the regional level is available at www.osservatorioair.it/lair-nelle-regioni/.

24 Reg., Art. 1, Para. 2.

25 Relevant examples include the Authority for the Guarantee of Communications (AGCOM), the Competition and Market Authority (AGCM), the Bank of Italy, the National Commission for Companies and the Stock Exchange (CONSOB), the Institute for the Supervision on Insurances (IVASS), the Commission of Vigilance on Pension Funds (COVIP), the Guarantor for the Protection of Personal Data (GPDP), the Regulatory Authority for Transports (ART) and the Regulatory Authority for Energy, Networks and Environment (ARERA). On independent Authorities, *see generally* R. Chieppa & G.P. Cirillo, 'Le autorità amministrative indipendenti', *in* G. Santaniello (Ed.), *Trattato di diritto amministrativo*, Padova, CEDAM, 2010, pp. 1-1008. With specific regard to RIA activities of independent Authorities, *see* A. Natalini, F. Sarpi, & G. Vesperini, *L'analisi dell'impatto della regolazione. Il caso delle Autorità indipendenti*, Rome, Carocci Editore, 2012, pp. 1-200. *See also*, Senato della Repubblica (Ufficio Valutazione Impatto), 'L'AIR nelle autorità indipendenti: Una panoramica sulla normativa vigente', July 2015, pp. 1-5.

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Independent Authorities have been compelled by law to perform RIA since 2003. Two years before the simplification law No. 246/2005 made the AIR mandatory for every draft regulatory act of the Government, Art. 12, Para. 1 of law 29 July 2003 No. 229[26] introduced the obligation for such authorities to conduct an ex ante impact analysis in relation to their own regulations.[27] While independent Authorities are legally bound to analyse the impact of draft regulatory acts, they are free to choose the methods and approaches that best suit their internal statutes and organizational needs. In their discretion on how to implement the above-mentioned obligation, certain authorities have developed an RIA system that meets international standards. The energy regulator is a case in point and is often described as the agency with the most advanced RIA experience in Italy.[28] In 2002, independent Authorities were already considered to have developed practices that went beyond the standards foreseen for state administrations.[29] As recently remarked, independent Authorities, such as the Authority for Electricity, AGCOM and CONSOB, stand out for their enhanced approach to regulatory quality, compared with the Government, and their experience offers several examples of good practice that can be looked at as a reference.[30]

By contrast, there is no general obligation on the part of independent Authorities to use the VIR in the context of decision-making. Art. 23, Para. 3 of law 28 December 2005 No. 262[31] merely provides that independent financial

26 *Legge 29 luglio 2003, no 229 – Interventi in materia di qualità della regolazione, riassetto normativo e codificazione – Legge di semplificazione 2001*, in *Gazzetta Ufficiale* 25 August 2003 No. 196.

27 This provision stipulates that "[i]ndependent administrative authorities, to which the law assigns functions of control, supervision, or regulatory functions, shall adopt, in the manner provided for by the respective organisation, "forms or methods of regulatory impact analysis for the adoption of acts within their competence and, in particular, of general administrative acts of a programming, planning and, in any event, regulatory nature". On Art. 12 of law No. 229/2003, *see* G. Savini & C. Campeggiani, 'L'articolo 12 della Legge 229/2003 e l'Air delle *authorities* di regolazione e garanzia', *Rivista elettronica di diritto pubblico, di diritto dell'economia e di scienza dell'amministrazione*, Rome, Centro di ricerca sulle amministrazioni pubbliche "Vittorio Bachelet" Luiss Guido Carli, 2004, pp. 1-12. The requirement to perform the AIR has been specifically reaffirmed by sectoral regulations in the case of the Bank of Italy, CONSOB and COVIP (Art. 23 of law No. 262/2005), IVASS (Art. 191, Para. 4 of *decreto legislativo* 7 September 2005 No. 209, as amended by Art. 1, Para. 119 of *decreto legislativo* 12 May 2015 No. 74/2015), AGCOM (Art. 13, Paras. 8 and 9 of *decreto legislativo* 1 agosto 2003 No. 259), as well as the Supervisory Authority for Public Contracts (AVCP) (Art. 8, Para. 1 of *decreto legislativo* 12 April 2006 No. 163). Furthermore, Art. 213, Para. 2 of *decreto legislativo* 18 April 2016 No. 50 (also known as the 'Code of Public Contracts') extends the same obligation to the National Anti-Corruption Authority (ANAC), which replaced AVCP in 2014. Some authorities have introduced the AIR in their policy-making process even in the absence of a specific provision in the law governing their establishment and organization. This is, for instance, the case of ART: *see* Art. 2, Para. 3, *Regolamento che disciplina i procedimenti per la formazione delle decisioni di competenza dell'Autorità* of 16 January 2014, and *Delibera* No. 136/2016 *Metodi di analisi di impatto della regolamentazione dell'Autorità di regolazione dei trasporti*), both available at http://www.autorita-trasporti.it/.

28 OECD, *supra* note 7, p. 80.

29 *Ibid.*, p. 52.

30 On this point, *see* Senato della Repubblica (Ufficio Valutazione Impatto), 'The Uncompleted Evaluation of Legislative Acts in Italy: Critical Issues, Prospects and Good Practice', April 2018, p. 5.

31 *Legge 28 dicembre 2005, n. 262 – Disposizioni per la tutela del risparmio e la disciplina dei mercati finanziari*, in *Gazzetta Ufficiale* 28 December 2005 No. 301 – *Suppl. Ordinario* No. 208.

Authorities – such as the Bank of Italy, CONSOB, IVASS and COVIP – "shall review periodically, at least every three years, the content of their regulatory acts, in order to adjust them to market trends and to the interests of investors and savers".[32] Although several authorities have adopted regulations to implement this revision clause, ex post evaluation has struggled, at least until now, to impose itself in the practice of such authorities.[33]

C Objectives of AIR and VIR Procedures

After generically stating that the AIR and VIR, together with consultation, "assist decision-making of the political body leading the Administration and contribute to its transparency",[34] the Regulation further explains that the purpose of the AIR is to provide, "in the course of the regulatory inquiry", through a transparent analytical process based on empirical evidence, informative support on the opportunity and content of the intervention.[35] Conversely, the VIR is intended to provide, through a transparent evaluation based on empirical evidence, informative support on the "enduring utility,[36] the effectiveness and the efficiency of the rules in force" that have a significant impact on citizens, enterprises and public administrations, with a view to determining whether the rules subject to evaluation should be maintained, amended, supplemented or abrogated.[37] As argued by the Council of State, the VIR, in this way, can dramatically reduce the phenomenon known as 'legal consumerism', notably the tendency of regulators to tackle problems by introducing new legal provisions, even where it would suffice to amend or adjust the existing ones.[38] Moreover, as the design of new rules necessarily builds on the evidence gradually accumulated in the application of existing

32 In addition, Art. 12, Para. 3 of law No. 229/2003 requires independent Authorities to evaluate the effects arising from the application of standard form contracts or contractual terms provided for by the law. For completeness, it should also be mentioned that Art. 6, Para. 3 of decree-law 13 May 2011 No. 70 (*Gazzetta Ufficiale* 13 May 2011 No. 110), converted with amendments by law 12 July 2011 No. 106 (*Gazzetta Ufficiale* 12 July 2011 No. 160), provides that, in order to reduce the administrative burden of regulation on business as required by the European Union, independent Authorities shall measure the administrative costs of enterprises within the framework of their regulatory systems, with the aim of reducing such costs by means of adequate measures.

33 F. Cacciatore, 'Autorità indipendenti e nuova disciplina della VIR: Tanto rumore per nulla?', *in I Paper dell'Osservatorio*, Rome, Osservatorio AIR, 2010, pp. 24-33.

34 Reg., Art. 2, Para. 2.

35 Reg., Art. 2, Para. 3, first sentence.

36 The Regulation originally used the word 'relevance' instead of 'enduring utility'. Although both the OECD and the EU place a great deal of emphasis on the 'relevance' criterion (which is designed to answer the question whether the original objectives of a regulatory initiative correspond to the current needs), the Council of State has expressed reservations about the use of this term by arguing that "[t]he meaning of this word is not of immediate perception". However, the Guidelines (as explained further below) still expressly refer to relevance under Sections 9.4 and 9.5. In any case, this is more a linguistic matter than a substantive issue.

37 Reg., Art. 2, Para. 5.

38 Consiglio di Stato, *supra* note 3, Para. 18.

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ones, the VIR plays a crucial role within the regulatory cycle in the identification of reform priorities and the shaping of regulatory interventions.[39]

It is interesting to note that the Regulation does not mention 'coherence' of the regulatory framework among the evaluation criteria, despite the fact that 'regulatory coherence' or 'legal consistency' is widely used as an evaluation benchmark in the Organization for Economic Cooperation and Development (OECD) countries,[40] besides being firmly rooted in EU impact assessment practice.[41] It would have been reasonable to expect, therefore, that a provision dedicated to the objectives of impact evaluation would have referred to all benchmarks commonly used in ex post evaluations, among which is the coherence criterion. This must be, however, just an oversight given that Art. 13, Para. 1(c), while regulating the VIR phases, requires the evaluation to assess the intervention through the application of four different criteria, including "4) coherence of the set of rules governing the regulatory area concerned, also with reference to any gaps, inefficiencies, overlaps, excessive costs of regulation".

The Regulation, under Art. 2, Para. 6, provides that

> In the course of the VIR, the Administrations shall, even in the absence of a previous AIR, make a comparison of the current social and economic situation with that existing at the time of the drafting of the rules, as well as assess the effects detected in comparison to those expected.

Essentially, this provision recognizes the need, when performing a VIR, to conduct the following three-step procedure: a) compare the state of affairs at the time of formulation of the rules and that existing at the time of implementation; b) identify the effects produced by the rules subject to evaluation; c) compare the latter with the effects that such rules were intended to bring about. Interestingly, the provision in question does not include express reference to subsequent technological and scientific advances, and just limits itself to referring to the past socio-economic situation. In addition, it seemingly overlooks the importance of legal changes that may have occurred meanwhile, especially as a result of the ongoing European integration process and the increasingly far-reaching scope of EU legislation.

39 Guidelines, Section 8.1, p. 28.

40 OECD, *OECD Regulatory Policy Outlook 2015*, Paris, OECD Publishing, 2015, pp. 119-139. This publication provides the first evidence-based, cross-country analysis of the progress made by OECD countries in improving the way they regulate. The practice of ex post evaluation is examined through four composite indicators that measure different areas: 1) oversight and quality control; 2) transparency; 3) systematic adoption; and 4) methodology. The 'methodology' indicator shows what types of assessments are used in conducting ex post evaluation. In this regard, the report notes that "[a]n evaluation of legal consistency (nationally and internationally) exists in about a third of countries" (*ibid.*, p. 130). A new edition of the Regulatory Policy Outlook was published on 10 October 2018. *See* OECD, *OECD Regulatory Policy Outlook 2015*, Paris, OECD Publishing, 2018, *passim*.

41 *See* European Commission, *supra* note 13, pp. 8, 50, 56 and, especially, 62-63: "*Question* 5: How coherent is the EU intervention internally and with other (EU) actions?".

In its original formulation, Art. 2, Para. 6 simply required that the administrations draw a comparison between the *current* socio-economic situation and that *expected* at the time of drafting the rules under scrutiny. However, the final wording has been supplemented along the lines of the advice given by the Council of State, which pointed out that such a comparison

> is not the only, and perhaps not even the most significant, comparative assessment required. Mention should thus be also made of the necessary comparison between the *current* situation and the situation *existing* at the time of drafting the rules. This comparison can indeed offer additional, and probably even more relevant information, about the effectiveness of the rules introduced and the actual changes that these have produced (emphasis added).[42]

It is also important to emphasize that, even where an ex ante analysis has not been carried out, and the administration may not therefore have at its disposal readily identifiable terms of comparison, it must nonetheless make an effort to assess the impact of the relevant rules in the light of the initial situation and current circumstances.

D The Role of DAGL

It is widely known that the 2012 OECD Recommendation on Regulatory Policy and Governance recommends that countries "[e]stablish mechanisms and institutions to actively provide oversight of regulatory policy procedures and goals, support and implement regulatory policy and thereby foster regulatory quality". Thus, RIA and ExPER need to be subject to regulatory oversight. The most important reason is that regulators have few incentives to voluntarily improve regulations, and thus incentives have to be provided by external mechanisms and institutions. As reported by the OECD,[43] most countries have instituted oversight bodies to ensure regulatory quality, and the majority of them have not one but several oversight bodies. Oversight bodies are usually located within the government, as only a few countries have external oversight bodies (*e.g.* independent body, Parliament, etc.). In Italy, the regulatory oversight system is based on a combination of internal and external mechanisms.

The Department for Legal and Legislative Affairs (*Dipartimento per gli affari giuridici e legislativi* – DAGL) supports the President of the Council of Ministers in coordinating the regulatory activity of the Government and ensuring regulatory

42 Consiglio di Stato, *supra* note 3, Para. 50.
43 OECD, *supra* note 40, p. 34.

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quality.[44] The Regulation intends to further enhance the role of the Department vis-à-vis the AIR and VIR activities, and more generally in relation to matters of regulatory governance.[45] In particular, DAGL is mandated to check the quality of the assessment procedures and of the reports that document them, to provide methodological support, and to strengthen staff skills and the institutional capacity of the administrations. In addition, the Department is expected to act as the single point of contact for the administrations in the area of domestic, European and international relations.[46] In this regard, the Regulation largely replicates the contents of the Decree of the Secretary General of 24 August 2011, which reorganized the structure of the Department.[47] At the same time, DAGL's powers of scrutiny have been reinforced to ensure higher levels of compliance and quality, as explained further below. DAGL is also responsible for verifying the existence of the grounds for exclusion from the AIR "indicated in the legislative Programme", and to give notice to the relevant administration if it considers that such grounds are not present (as further explained below).[48] Particularly important is, finally, Art. 12, Para. 4, which envisions DAGL's authority to coordinate the performance of the VIR, including consultation procedures, for regulatory measures having special relevance and impact.

DAGL fulfils its responsibilities in the area of regulatory quality through the Office for studies, legal documentation and quality of regulation (*Ufficio studi,*

44 DAGL is part of Italy's Better Regulation institutional infrastructure, together with the Unit for the Simplification and the Quality of Regulation (*Unità per la semplificazione e la qualità della regolazione*) and the Office for Simplification (*Ufficio per la semplificazione e la sburocratizzazione*) of the Department of Public Function, both supporting the Minister for Public Administration. DAGL, as the central coordination and oversight body, is charged with supervising and checking for compliance the process of both ex ante and ex post assessments.

45 In its opinion the Council of State argued that the Department's involvement should be increased not only quantitatively but also *qualitatively*. On the one hand, DAGL should act in full autonomy and authoritatively towards the single administrations (in line with international best practice and based on the US model of the Office of Information and Regulatory Affairs – OIRA); on the other hand, it should monitor their activities and draw attention to gaps and possible improvements, acting as a sort of 'institutional mentor', especially in the initial phase of implementation. *See* Consiglio di Stato, *supra* note 3, Para. 35.

46 Reg., Art. 2, Para. 9.

47 *Decreto del Segretario Generale – Organizzazione interna del Dipartimento per gli affari giuridici e legislativi del 24 agosto 2011*. *See also* Art. 28, Para. 1(b) of *decreto del Presidente del Consiglio dei Ministri 1 ottobre 2012 – Ordinamento delle strutture generali della Presidenza del Consiglio dei Ministri*, in *Gazzetta Ufficiale* 11 December 2012 No. 288.

48 Reg., Art. 4, Para. 3.

documentazione giuridica e qualità della regolazione),[49] one of the three units in which the Department is organized.[50] Since 2009 the Office is supported, technically, by the AIR Working Group (*Gruppo di lavoro AIR*), a team of four experts – also known as 'Nucleo AIR' – that operates within the Unit for the evaluation and verification of public investments (*Nucleo di valutazione e verifica degli investimenti pubblici* – NVVIP) established by the Presidency of the Council of Ministers, in accordance with Art. 1 of law 17 May 1999 No. 144.[51] The AIR Working Group also works alongside the Office in the evaluation of the AIR and VIR reports, with

49 This Office, in turn, includes the Service for the analysis and evaluation of the impact of regulation (*Servizio analisi e verifica dell'impatto della regolamentazione*), which is responsible for coordinating and monitoring the use by the administrations of regulatory quality tools, including the AIR and the VIR. In addition, the Service coordinates and monitors the 'Technical-regulatory analysis' (*Analisi tecnico-normativa* – ATN), which represents another tool to promote the quality of regulation and to ensure the transparency of the processes aimed at the proposal, amendment and approval of regulatory measures. The ATN report accompanies the draft regulatory acts adopted by the Government (and the ministerial or inter-ministerial regulations) and addresses the impact of proposed measures on the existing legal system, its conformity to the Constitution, EU legislation and international obligations, its compliance with the rules concerning the competences of regions and local autonomies as well as any deregulation initiatives previously undertaken. It also takes into account the relevant case law, at both the national and the EU levels, any similar matters pending before the courts, infringement procedures by the European Commission and reform initiatives presently under consideration. The ATN also illustrates the correctness of the definitions and legal references used in the text of the draft legislation and of the techniques of amendment and repeal of current provisions, and proposes alternative solutions if deemed necessary. The ATN-related rules do not provide for grounds of exclusion or exemption. The ATN report is drawn up according to the methodology provided for by *direttiva del Presidente del Consiglio dei Ministri – Tempi e modalitá di effettuazione dell'analisi tecnico-normativa (ATN)* 10 September 2008, in *Gazzetta Ufficiale* 18 September 2008 No. 219. On ATN, *see* R. Lignola, 'L'analisi tecnico normativa (ATN) nell'istruttoria del Governo', *Analisi Giuridica dell'Economia*, No. 2, 2013, pp. 437-446.

50 The other two units are the Office for coordination of the legislative initiative and regulatory activity of the Government (*Ufficio per il coordinamento dell'iniziativa legislativa e dell'attività normativa del Governo*) and the Office for litigation, legal advice and relations with the European court of human rights (*Ufficio contenzioso, per la consulenza giuridica e per i rapporti con la Corte europea dei diritti dell'uomo*).

51 *Legge 17 maggio 1999, n. 144 – Misure in materia di investimenti, delega al Governo per il riordino degli incentivi all'occupazione e della normativa che disciplina l'INAIL, nonché disposizioni per il riordino degli enti previdenziali*, in *Gazzetta Ufficiale* 22 May 1999 No. 118 – *Suppl. Ordinario* No. 99. In order to improve the quality and efficiency of the planning process of development policies, Art. 1 of law No. 144/1999 required central and regional administrations to establish, by 31 October 1999, special teams for the evaluation of public investments, with a view to ensuring technical support during the phases of planning, implementation, and evaluation of programmes and policies implemented by each administration. NVVIP was established within the Department for Planning and Co-ordination of Economic Policy (CIPE) of the Presidency of the Council of Ministers with Decree of the President of the Council of Ministers 25 November 2008, but its membership was broadened to incorporate the AIR Working Group, pursuant to Decree of the President of the Council of Ministers 15 July 2009.

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a view to improving their quality.[52] That is why Art. 2, Para. 10 of the Regulation provides that DAGL, in carrying out its responsibilities in the area of AIR, VIR and consultation, makes use of NVVIP, "whose evaluations are published on the institutional website of the Government simultaneously with the respective AIR and VIR reports".

E Linking Impact Analysis with Normative Planning

Constraints on RIA practice in Italy include several factors such as timing, allocation of resources and availability of expertise. As noted by the OECD,[53] AIR reports are often prepared too late, and time spent on preparing them is residual, which gives little chance to the officials responsible for drafting improvements in the content of the report. In this context, intervening in forward planning is of paramount importance. Basically, "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". The Prime Minister's Directive of 26 February 2009 on normative procedures[54] (hereinafter 'the 2009 Prime Minister's Directive') already paid close attention to the importance of bridging the RIA process to normative programming. With a view to ensuring proper planning of government initiatives, the directive recommends that administrations should plan their regulatory activity ahead so as to avail themselves of adequate time to perform the AIR, including the consultation procedures (Section 2.2.4). But it is the Regulation that makes a real breakthrough in addressing the aforementioned constraints since it foresees the requirement, for each administration, of preparing and publishing twice a year its legislative agenda for the next six months in

52 The evaluation forms prepared by the experts of the AIR Working Group help identify issues requiring further investigation and provide clarifications on methodological aspects. Based on the feedback received, the administrations revise and supplement the reports, which undergo evaluation again by the AIR Working Group. Admittedly, however, also in 2017, the interlocution initiated with the evaluation process did not lead, often, to a significant improvement in the quality of the AIR reports, which confirms the persistent difficulties faced by administrations in their preparation, despite the suggestions contained in the evaluation forms. *See* Senato della Repubblica (Ufficio Valutazione Impatto), 'L'AIR nel 2017: La relazione del Governo alle Camere', June 2018, p. 22.

53 OECD, *supra* note 7, p. 79.

54 *Direttiva del Presidente del Consiglio dei Ministri – Istruttoria degli atti normativi del governo*, in *Gazzetta Ufficiale* 8 April 2009 No. 82. This Directive regulates the proceedings concerning the preparation and adoption of regulatory acts by the Council of Ministers. It aims to provide a systematic framework of rules and procedures to ensure quality regulation in the implementation of the Government's programme. Quality regulation is understood as regulation that, besides adhering to certain formal canons, is also appropriate content-wise, consistent with the standards of the Constitution and of the legal system, and, lastly, apt to pursue the political objectives of the Government. Regulatory quality is a government priority to be pursued through appropriate programming of regulatory initiatives, in-depth analysis of the impact of interventions, comprehensive inquiry and efficient coordination of the administrations involved. Furthermore, the Directive underscores that the production of quality regulation not only represents an element of transparency and legal certainty but also constitutes a key factor for good governance, growth and economic development of the country.

order to give an account of future activities, including the AIRs that need to be prepared. More specifically, Art. 4, Para. 1 provides that each administration, by 30 June and 31 December, submits through DAGL to the Undersecretary of State to the Presidency of the Council of Ministers – who also acts as Secretary to the Council of Ministers (hereinafter 'the Secretary of the Council of Ministers') – the half-yearly legislative programme with the list of regulatory initiatives anticipated in the following semester, without prejudice to cases of necessity and urgency.[55] For each initiative, the programme indicates, in addition to a brief description of the content and objectives of each initiative, the consultations planned, as well as the existence of any possible grounds for exclusion of the AIR, giving a justification for each ground. Nevertheless, Art. 6, Para. 2 stipulates that the proposing administration, in the case where it has not indicated the existence of an exclusion ground in the legislative programme, shall inform DAGL at least 30 days prior to the request for placing the regulatory measure on the agenda of the preparatory meeting of the Council of Ministers (hereinafter 'the pre-Council meeting').[56] This time limit, which may be shortened at the request of the administration in cases of justified reasons of urgency,[57] supposedly aims to allow sufficient time for DAGL to ascertain the existence of the ground for exclusion invoked, in accordance with Art. 6, Para. 3 of the Regulation.

For the purposes of the regulatory inquiry, the programme shall also specify which administrations are involved in the procedure, what advisory opinions ought to be obtained, including those of independent Authorities and any time limits foreseen for the adoption of the relevant act.[58] Any changes to the programme in the course of the ongoing semester is to be communicated promptly to the Secretary of the Council of Ministers, through DAGL.[59]

The submitted programme, and any changes thereto, are published on the websites of the Government and the proposing administration.[60]

F AIR, VIR and 'Multilevel Regulation'

Legislative power is increasingly dispersed and shared by different entities. Regulatory activity does not exhaust itself in the mere adoption of a measure by one

55 The regulatory initiatives, which cannot be finalized within the semester's time frame, are transferred to the next semester, and the relevant time limits begin to run anew. *See* Reg. Art. 4, Para. 4.

56 The pre-Council meeting is a preparatory meeting of the Council of Ministers that takes place on a weekly basis and is coordinated by the Secretary of the Council of Ministers. All ministries (represented at the level of Heads of Legislative Office and/or Minister's Cabinet) attend the pre-Council meetings in order to determine which draft laws, normative acts or other administrative acts should be included in the Council of Ministers' agenda. The agenda of the pre-Council meetings is drawn up by DAGL, which also chairs the meetings, on the basis of the requests received from the Government, taking into account time limits and international and European obligations.

57 Reg., Art. 6, Para. 2.

58 Reg., Art. 4, Para. 2.

59 *Ibid.*, Para. 5.

60 *Ibid.*, Para. 6.

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single actor. The political-institutional actors involved, the procedural steps and the links with other processes are plentiful. In addition to the traditional (horizontal) co-existence in the lawmaking process of different institutions and bodies at the same level of government, the vertical mix of different levels of government is becoming more commonplace, on the one hand because of the phenomena of decentralization (regionalism) and federalism, and, on the other hand, because of the increasing importance of supranational organizations. Hence, the dispersion of decision-making power is occurring both upwards and downwards, and the quality of legislation cannot be improved without bearing in mind the mutual interactions between the different levels of government.[61]

Multilevel regulatory governance is becoming a priority in many OECD countries. Greater and more systematic integration of multilevel dynamics is identified in the 'OECD Review of Better Regulation in Italy' as a further area for improvement.[62] A multilevel regulatory system should embed horizontal and vertical coordination mechanisms for regulatory quality at different levels of government. The need for such coordination – with reference to impact analysis and evaluation – is acknowledged in the Regulation, which provides specific rules aimed at fostering the *participation* of the administrations in the ex ante analysis of the impact of draft legislation of the European Union (Art. 10) and in the ex post evaluation of EU law (Art. 15). In addition, the Regulation includes some provisions to make sure that the administrations *cooperate* in the performance of the VIRs (Art. 12, Para. 5) and in the evaluation of the impact of EU legislation (Art. 15, Para. 1), whether or not they belong to the same level of government. This marks significant progress in addressing a critical element of the Italian system of regulatory governance, which suffers from a certain lack of integration between different levels of government, especially with regard to relations between central government and the Regions.[63]

61 Although institutional and procedural settings vary from country to country, common challenges are emerging from the fact that more than one level of government (from supranational to local level) plays an active role in designing, implementing and enforcing regulation. Quality regulation at a certain level of government can be compromised by poor regulatory policies and practices at other levels. The most frequent problems affecting regulation are duplication, overlapping responsibility and low quality, which impinge on public service delivery, citizen's perception, business services and activities, as well as investment and trade. On this matter, D. Rodrigo, L. Allio & P. Andres-Amo, *Multi-Level Regulatory Governance: Policies, Institutions and Tools for Regulatory Quality and Policy Coherence*, OECD Working Papers on Public Governance No. 13, Paris, OECD Publishing, 2009, pp. 1-47.

62 OECD, *supra* note 7, p. 16.

63 Consiglio di Stato, *supra* note 3, Para. 14.

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G Consultation as an Integral Part of Impact Analysis and Evaluation

I General Rules

Consultation and communication are mechanisms that support transparency in regulatory reforms and incentivize the Government to deliver better regulation.[64] As constantly reiterated by the OECD in its country reports,

> [t]ransparency is one of the central pillars of effective regulation, supporting accountability, sustaining confidence in the legal environment, making regulations more secure and accessible, less influenced by special interests, and therefore more open to competition, trade and investment.[65]

Consultation is a method of inquiry that reduces the information asymmetry between regulators and regulated entities, through the collection of data and opinions from both stakeholders and experts. Consultation may also facilitate a dialogue among the recipients by encouraging information sharing between stakeholders. Therefore, consultation can be a learning process not only for the administrations but also for the stakeholders themselves. At the same time, an open and transparent consultation process helps to increase the degree of understanding and acceptance of the intervention, thus strengthening the implementation of regulation and, ultimately, its effectiveness.[66]

The 2008 AIR Regulation, under Art. 5, Para. 4, delegated the definition of the general criteria and procedures of the consultation phase to a subsequent Decree of the President of the Council of Ministers, which, however, was never adopted. The lack of guidelines in the field of stakeholder engagement has been a recurring criticism of the Italian RIA and ExPER systems. In 2012, the 'OECD Review of Better Regulation in Italy' assessed the consultation and communication mechanisms on regulatory activity as being "weak and non-systematic, giving discretionary powers to the administration to use them",[67] and stated that "there is little structure or formality to consultation and communication activities" in the framework of both ex ante and ex post analysis of regulation.[68] It was also reported that, although greater awareness of the necessity to enhance consultation practices as an integral part of decision-making is emerging, a more proactive relationship with the wider public in the development of new laws and policies is needed. The report, therefore, recommended that

64 *See* Para. 23 of 'OECD Best Practice Principles on Stakeholder Engagement in Regulatory Policy – Draft for Public Consultation', March 2017. Available at www.oecd.org/gov/regulatory-policy/public-consultation-best-practice-principles-on-stakeholder-engagement.htm. *See also*, Consiglio di Stato, *supra* note 3, Para. 19, according to which consultation, as a tool of transparency and participation in the decision-making process, contributes to increasing the legitimacy of the regulator. Moreover, consultation softens the 'top-down approach' and increases the 'sense of ownership' by the regulated parties, and, consequently, citizens' and businesses' compliance.

65 OECD, *supra* note 7, p. 55.

66 Guidelines, Section 11, p. 40.

67 OECD, *supra* note 7, p. 15.

68 *Ibid.*, p. 19.

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> speedy development and proper implementation [be ensured] of all the instruments aimed at promoting systematic, timely and transparent public consultation practices, including the forthcoming DAGL regulation on consultation and related detailed guidelines for administrations.[69]

In order to remedy this situation, the Regulation provides, for the first time, detailed rules (Arts. 16-18) for the conduct of consultations in the context of ex ante and ex post impact assessment procedures.[70] While Art. 16 sets forth general rules for both procedures,[71] Arts. 17 and 18[72] provide specific provisions for open consultations carried out in the framework of the AIR or VIR, respectively. Interestingly, there is no rule specifying when consultation should start; it is only foreseen that, where resort is made to open consultation, DAGL is to be informed simultaneously of the commenced consultation.[73] As specifically concerns the AIR, the drafters may have chosen not to be more specific as to the moment when consultation is launched, in view of the fact that the administration needs to prepare a 'pre-AIR' document for consultation purposes (as explained further below), and the time required to draft this document can vary considerably according to the circumstances. As is well known, international best practice suggests that consultations should start as early as possible in order to maximize their impact on policy development.[74] According to the Guidelines,[75] consultation should start from the moment the need for intervention is detected. Consultation carried out at a very late stage (*e.g.* when the type of intervention has been identified and a measure already drafted) may indeed provide very limited support for decision-making. In some cases, if delayed, consultations can even lead to a prolongation of the process by putting into question matters that should have been discussed at an earlier stage.

The Regulation[76] clarifies that the purpose of consultation is to acquire information that, with regard to the AIR, pertains to the current problem, the options of intervention and the assessment of the expected effects; on the other hand, in the case of the VIR, consultation aims to assist in assessing the effectiveness of the intervention, its implementation and main impacts. As an aid to decision-

69 *Ibid.*, p. 56.

70 Pursuant to Art. 8, Para. 3 of the Regulation, the administration makes use of consultation 'in the conduct of the AIR', as set forth in Arts. 16 and 17. Similarly, Art. 13, Para. 2 provides that 'in the conduct of the VIR', the administration shall resort to consultation, in accordance with Arts. 16 and 18.

71 The Council of State welcomes the fact that the Regulation introduces a general regulatory framework to govern consultation, in the context of both the AIR and the VIR. *See* Consiglio di Stato, *supra* note 3, Para. 25.

72 However, the provisions of these two articles are almost identical.

73 *See* Reg. Art. 17, Para. 1 for the AIR and Art. 18, Para. 3 for the VIR.

74 *E.g.*, European Commission, *supra* note 13, p. 8: "It is important to consult as early and as widely as possible in order to maximize the usefulness of the consultation and to secure an inclusive approach where all interested parties have the opportunity to contribute to the timely development of effective policies."

75 Guidelines, Section 11.2, p. 42.

76 Reg., Art. 16, Para. 2.

making, consultation is therefore crucial for both the choice of the regulatory intervention and the identification of the issues arising in the implementation of the chosen intervention. To reinforce this message, the Council of State has highlighted the importance of an effective involvement of stakeholders, both in the phase preceding the entry into force of the rules and in that subsequent to it.[77]

It is important to underscore that in the course of the AIR, the competent administration is under an obligation to consult the recipients of the regulatory intervention, except in 'extraordinary cases of necessity and urgency'.[78] The decision whether to invoke this exception is left to the political discretion of the administration. It would have been advisable, however, to foresee that DAGL should confirm that such circumstances actually exist. It is, however, possible to argue that, although no express reference is made to a power of scrutiny over such decision, DAGL may still *return* the AIR report to the proposing administration should it determine, in the context of its validation, that derogation from the consultation rule was not warranted. The same obligation is foreseen in relation to the VIR, except that no derogation from the consultation rule is allowed,[79] given that extraordinary reasons of necessity and urgency typically arise in the context of the lawmaking process, whereas ex post evaluation is less deadline-constrained and dependent on the legislative calendar.

The consultation can be 'open', when addressed at anyone who has an interest in participating, or 'restricted', if targeted at parties predefined by the administration on the basis of the interests involved.[80] The latter may include individuals or groups (*e.g.* associations) who have a vested interest in the regulatory intervention, or individuals that, owing to their activity, qualification or experience, possess information that is considered useful for analysis of the intervention (experts, witnesses, etc.).[81]

The decision to resort to open or restricted consultation, alternatively or jointly, depends on the subject matter and the recipients of the intervention, as well as the information needs relative to the assessment process.[82] This provision is a useful addition to the original text of Art. 16 made subsequent to the opinion of the Council of State, which reasoned that open and restricted consultations should not be considered to be alternative methods of inquiry, and thus recommended that the draft Regulation be amended to clarify that the two modalities of consultation may coexist within the same procedure. Conversely, the Regulation has not endorsed the Council's suggestion to require a formal justification for making use of restricted consultations.[83]

Based on the Guidelines,[84] the process of consultation in the framework of the AIR or VIR can be divided into three main stages: 1) *define a strategy of consul-*

77 Consiglio di Stato, *supra* note 3, Paras. 14, 17 and 19.
78 Reg., Art. 16, Para. 1.
79 *Ibid.*
80 Reg., Art. 16, Para. 3.
81 Guidelines, Section 11, pp. 40-41.
82 Reg., Art. 16, Para. 3.
83 Consiglio di Stato, *supra* note 3, Paras. 68 and 69.
84 Guidelines, Section 11.4, pp. 43-51.

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tation; 2) *carry out the consultation*; 3) *elaborate and disseminate the results of the consultation*. First and foremost, it is crucial to elaborate a *strategy* during the initial phase of the procedure, with a view to planning carefully the consultations that need to be carried out. In this respect, the Council has *repeatedly* recommended that the consultation process should be properly structured and efficiently managed, with particular attention given to the identification of the stakeholders, the selection of measures submitted for consultation, the modalities of participation of stakeholders and the impact of consultation on the final decision.[85] The administration has to determine not only whom to consult, but also why to consult, when to consult and what consultation techniques to use, bearing in mind that it may be necessary to conduct several consultations in the course of the AIR or VIR. Obviously, planning should be carried out before consultation starts and updated throughout the assessment procedure. It should cover, particularly, the objectives of the consultation,[86] the stakeholders to be consulted[87] and the operational modalities of the consultation. In order to facilitate the planning, the consultation strategy can be drawn up in the form of a 'consultation plan'.

The second phase of the process is that of conducting the consultation. In this connection, the first logical step for the administration is to *inform* the stakeholders about the consultation. The administration has an obligation to ensure that the public can obtain knowledge of consultation initiatives through its institutional website:[88] a webpage specifically dedicated to consultation is to be created, listing the initiatives completed and those in progress. For each consultation, the following information shall be provided, as a minimum: subject matter, type (open/restricted), stakeholders, and duration.[89] In the case of an open consultation, a document containing relevant information about the consultation must be published on the consultation web page, the structure of which is to be tailored according to the particular stage of the analysis.[90] Contact details that can be used to obtain information or clarifications (including an e-mail address, if

85 Consiglio di Stato, *supra* note 3, Para. 19 (which, in turn, makes reference to opinion No. 1142/2016).

86 For planning purposes, the administration should have as accurate an overview as possible of the data and information already available (including the results of previous consultations) so as to identify the information needs that must be satisfied.

87 In order to ensure effective participation, avoiding the risk of 'capture' of the regulator by interest groups with special influence, proper mapping of the stakeholders is essential. The Guidelines provide specific guidance on how to carry out the mapping exercise. In general, in making the selection of the stakeholders to be consulted, the administration should consider not only its own information needs, but also the need to guarantee that a plurality of interests and points of view are equally represented in the consultation. To this end, particular account should be taken of the needs of stakeholders who may face practical obstacles in participating in the consultation (for instance, because of inadequate technological skills, age, degree of knowledge of the subject matter, etc.).

88 Reg., Art. 16, Para. 5.

89 The consultation web page, in any case, is not a substitute for any other form of communication that the administration may wish to use in relation to each single initiative (newsletters, press releases, etc.).

90 The Guidelines provide examples regarding possible contents of consultation documents in the context of the AIR or VIR.

resort is made to open consultations)[91] shall also be provided. If an open consultation is conducted in the course of an AIR procedure, the document shall additionally include the information prescribed for the 'pre-AIR' report by Art. 17, Para. 1 (as explained further below). Finally, notice of open consultations must also be given on a dedicated page of the Government's website;[92] for this reason, such initiatives are communicated to DAGL before commencement.[93]

As regards the *collection* of stakeholder inputs, the choice of consultation techniques will depend on the intended objectives, the stakeholders to be consulted, the resources available and the costs associated with participating in the consultation. The combined use of different techniques may increase the chances of obtaining adequate information and of reaching a wider audience. Consultation techniques differ not only in the modalities under which they are implemented, but also with regard to the time needed for implementing them, the degree of interaction between the administration and stakeholders (as well as among stakeholders), their financial implications and their ability to provide qualitative or quantitative information. Certain techniques may require specialized staff equipped with special skills, *e.g.* moderating a focus group.[94]

The consultation process ends with the *processing* and *dissemination* of the results. Processing consultation results is crucial to ensuring that the administration makes well-informed decisions. Most importantly, the administration should prepare a summary of the main issues that have emerged and the most important and/or recurrent suggestions received. With a view to facilitating the qualitative assessment of contributions, the administration may disaggregate the data as per category of stakeholders, highlighting, for each stakeholder category, those who are in favour of or against the proposed intervention, the main changes proposed, the evidence presented in support of the different positions and an evaluation of their reliability/robustness.

Making the results publicly available increases the transparency of the regulatory activity and strengthens the level of trust of the regulated parties vis-à-vis the regulator. This, in turn, has positive effects on the level of participation, fuelling a virtuous circle of interaction. For this reason, the Guidelines require that, at

91 *See* Reg., Art. 17, Para. 5 for the AIR and Art. 18, Para. 8 for the VIR.

92 *See* Reg., Art. 17, Para. 6 for the AIR and Art. 18, Para. 9 for the VIR.

93 Guidelines, Section 11.4, p. 47.

94 In the case of restricted consultations, the most common and potentially useful techniques are focus groups, interviews, panels and sample surveys, whereas open consultations' methods include public hearings and online forums. Common to both types of consultation is the 'notice and comment' (N&C) technique, which may be used for all stakeholders or only selected ones, depending on the circumstances. As explained further later in the article, the Regulation provides for N&C procedure (possibly accompanied by other forms of consultation) in all instances of open consultation, both in the course of the AIR and the VIR, as well as for open consultations foreseen in the two-year evaluation plan. Typically, N&C procedures consist of an online questionnaire, with multiple choice and/or open-ended questions on a certain matter, or of open-ended comments regarding an analysis and/or a proposal elaborated by the administration. Nevertheless, it is always possible to identify intermediate solutions, for example using a combination of both approaches, depending on available resources and the capacity of stakeholders. Guidance on how to structure a questionnaire is provided on pages 49 and 50 of the Guidelines.

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the end of each consultation, the administration give an account of the results of the consultation, preferably through its consultation web page.[95]

The Guidelines warn against generalising opinions and data from only a few interest groups. Not all individuals, organizations, and associations are equally able to participate in a consultation. Administrations should take this into consideration, particularly when evaluating the results of open consultations. In particular, the administrations should aim to ensure the participation of all main stakeholders, also through the use of ad hoc modalities that encourage the involvement of less organized and resourceful ones. The design of the consultation must also consider the different perception and capacity of recipients, including the possibility of cognitive errors.[96]

The administration is expected to hold consultations according to the principles of transparency, clarity and completeness of the information provided, in compliance with the requirements of expediency of the lawmaking process and relevance of the analysis to the regulatory initiative. Consultations shall also be managed taking into account the time and cost of participation, focusing on solutions that are the least costly to the stakeholders consulted, as well as ensuring the clarity and brevity of the documents used during the consultations.[97] These principles partly reflect those provided for in Directive No. 2 of 31 May 2017 of the Department of Public Function of the Presidency of the Council of Ministers (also known as 'Madia Directive'), laying down the 'Guidelines on public consultation in Italy',[98] which do not specifically address consultations carried out within the framework of an AIR or VIR, but apply equally to all public consultations conducted by state administrations.

II Open Consultation in the AIR. The 'Pre-AIR' Report

As stated in the Guidelines,[99] the administration may resort to consultation to stimulate public debate in relation to the identification of policy options or with regard to the assessment of specific interventions. In the first case scenario, consultation aims to gather ideas, proposals and suggestions from a variety of stakeholders that can be used to define the main lines of the intervention. In this sense, consultation can prove to be a tremendous resource in shedding light on aspects of a problem that the administration does not yet understand well, or where public debate can help identify risks, opportunities and alternative solutions to traditional ones, thus offering a vital contribution in the delineation

95 The information supplied by the administration should include the following: description of the consultations carried out in each phase of the procedure, distinguishing between restricted and open consultations; consultation documents made available to stakeholders; list of stakeholders that participated in each consultation, specifying which of them represent associations, organizations, etc.; time frame of consultations; results of each consultation, including a summary of main comments, suggestions and assessments produced by stakeholders.

96 Guidelines, Section 11, p. 41.

97 Reg., Art. 16, Para. 6.

98 *Direttiva 32 maggio 2017. Linee guida sulla consultazione pubblica in Italia. (Direttiva n. 2/2017)*, in *Gazzetta Ufficiale* 14 July 2017 No. 163.

99 Guidelines, Section 11.2, pp. 42-43.

of a policy. For these reasons the consultation should involve the widest possible audience of stakeholders and be achieved through an open consultation. In the second case scenario, consultation supports the analysis of the impact of specific options and is intended to obtain information and data to identify and quantify the effects of the various policy alternatives and their distribution among the various categories of recipients.

In the case of resort to an open consultation in the context of an AIR procedure, the administration publishes on its consultation web page a 'preliminary' document about the regulatory initiative ('pre-AIR report'), which "gives account, at least, of the current critical issues, of the objectives and options of the intervention" (Art. 17, Para. 1). Thereafter, anyone who has an interest may submit comments electronically, within a reasonable period of time that may be not less than four weeks, according to the modalities set forth by the administration (Art. 17, Para. 2). Unless otherwise requested by the authors, the comments received in an open consultation are published on the administration's website, provided that disclosure is not prohibited for confidentiality reasons. Only remarks and proposals that are relevant to the subject matter of the consultation, and that are made in a non-anonymous manner, can be taken into consideration.[100] Within 12 months of the conclusion of the consultation, all the published information can be removed from the website of the administration.[101]

It is important to note that the first draft version of Art. 17 contemplated the publication of the 'draft regulatory act' for the purposes of consultation. However, the Council of State strongly criticized this provision, pointing out the flaws of an approach in which the AIR takes place at the end, rather than the beginning, of the policy cycle, that is, after the determination to draft an act is already made.[102] As constantly stressed by the OECD, if RIA is not integrated into policy-making it becomes simply an ex post justification of decisions already taken and contributes little to improving regulatory quality. Bearing this in mind, the Council argued that a preferable solution would be to perform a simplified 'preliminary AIR'[103] and hence carry out a first consultation solely with the aim of collecting data and information from stakeholders; only later, a proper AIR may be performed, and a second consultation may thus be conducted, this time on a draft regulatory act, if appropriate. The 'final AIR' should give an account of the analyses carried out and of the choice made as to the preferred option, *i.e.*, the drafting of a regulatory act. Interestingly, the Regulation adopts the concept of the preliminary AIR document but does not (at least expressly) require a consultation on the AIR report referred to in Art. 9, Para. 1. It is therefore unclear whether such report should undergo consultation again, as suggested by the Council of State. In principle, it would be desirable for the administration to consult the public on the AIR report, once completed, and not merely the pre-AIR report (as the latter is

100 Reg., Art. 17, Paras. 2 and 3.

101 *Ibid.*, Para. 4.

102 Consiglio di Stato, *supra* note 3, Para. 62.

103 In this respect, the Council uses as a reference model the French concept of *évaluation préalable* elaborated by the *Conseil d'État* in the 2016 report *Simplification et qualité du droit*.

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necessarily partial and incomplete). Ideally, Art. 17, Para. 1 should have provided that the AIR report must also be submitted to consultation. However, the administration may still decide to consult with stakeholders on the AIR report, if deemed necessary, given its discretion to conduct more than one consultation in each phase of the AIR.[104]

Although the Regulation does not specifically address this point, it goes without saying that the 'pre-AIR' report and the final AIR report might be amended or supplemented at the end of the consultation by making the necessary changes and additions to the relevant analysis. In this regard, the Regulation simply clarifies that stakeholders' inputs are meant to enrich the information at the disposal of the administration, with no obligation on the part of the latter to provide feedback, and are not binding on those conducting the regulatory inquiry.[105]

III Open Consultation in the VIR

The Regulation provides for the use of open consultation both in the preparation of the two-year evaluation plan (*infra*, X.1) and during the course of each specific VIR. However, other forms of consultation may be conducted alongside open consultation in the context of the VIRs.[106]

While open consultation is an option that the administration may resort to within the framework of an AIR procedure, open consultation is *mandatory* in the case of a VIR procedure. In fact, Art. 18, Para. 3 stipulates that

> [t]he Administration which is responsible for the VIR resorts to open consultation during the performance of the impact evaluation in order to gather opinions, data and assessments regarding the effectiveness of the acts subject to evaluation, the impacts on recipients and the criticalities observed.[107]

According to the Guidelines,[108] the phases of the VIR procedure in which it may be convenient to use consultation are:

a *the analysis of the current situation*, to highlight any problems in the process of implementation of the interventions subject to evaluation and how recipients adjusted to such problems; or the emergence of categories of recipients of the intervention that had not been identified at the time of the AIR;
b *the reconstruction of the intervention logic*, in order to find information on most relevant changes that occurred in the period between the adoption of the act subject to evaluation and the moment when the VIR takes place;
c *the evaluation of the intervention*, to obtain information and useful data to assess its effectiveness and the causes of any deviations with respect to its goals; to identify, analyse and quantify the main effects that occurred, with particular reference to those that were not expected; to highlight difficulties

104 *See* Guidelines, Section 14.4.1, p. 44.
105 Reg., Art. 16, Para. 3.
106 Guidelines, Section 11.3, p. 43.
107 Reg., Art. 18, Para. 3.
108 Guidelines, Section 11.3, p. 43.

in the implementation, overlaps or inconsistencies between the rules that regulate the same subject matter, even in the light of any cognitive bias that may have negatively affected compliance with regulations and their impact; to collect suggestions on changes that can achieve the same results with lower costs for recipients.

For the purposes of the consultation, the relevant documentation is published, for at least four weeks, in a dedicated section of the administration's website, which can use survey tools designed to gather opinions, data and proposals from the recipients of the regulatory acts that are under evaluation.[109] Within the said time frame, any interested party may submit comments electronically, according to the procedures set forth by the administration.[110] The publication, use and storage of comments received are governed by the same rules that apply to open consultations in the context of the AIR.[111]

H Responsibility to Perform the AIR and VIR Activities

Pursuant to Art. 2, Para. 8, first sentence, the 'proposing administration', *i.e.*, the administration proposing the regulatory measure, is responsible for performing the AIR. In practice, the Ministries have generally identified the legislative office as responsible for the activities regarding the AIR.[112] The Regulation further adds that for interventions proposed by two or more administrations, the AIR is performed jointly by the co-proponent administrations with respect to matters within their sphere of competence, while the same administrations draw up together a single AIR report.[113] By demanding cooperation between the administrations, this provision answers specific criticism of the OECD.[114] Previously, Art. 3, Para. 2 of the 2008 AIR Regulation merely contemplated that, in the case of regulatory acts involving more than one administration, "the competent offices may agree on the joint performance of the AIR", thus leaving it to the discretion of administrations whether to cooperate or not in the execution of the AIR. The emphasis on the requirement to perform a joint AIR for co-sponsored measures certainly represents an enhancement of earlier rules. However, it is unclear why it is no longer foreseen that specific phases or activities of the analysis can be carried out by one of the administrations, as was provided flexibly under the former regulation.

109 Reg, Art. 18, Para. 4.
110 *Ibid*., Para. 5.
111 *See* Art. 18, Paras. 5-7.
112 This practice is acknowledged by Art. 1 of *decreto del Presidente del Consiglio dei Ministri del 21 dicembre 2012, n. 262 – Regolamento recante disciplina dei nuclei istituiti presso le amministrazioni centrali dello Stato con la funzione di garantire il supporto tecnico alla programmazione, alla valutazione e al monitoraggio degli interventi pubblici*, in *Gazzetta Ufficiale* 22 February 2013 No. 45.
113 Reg, Art. 5, Para. 2.
114 *See* OECD, *supra* note 7, p. 66: "more efforts could be made to improve cross-sectoral RIAs produced by teams from more than one department. […] RIAs are often carried out by individual ministries and seeking cross-departmental inputs at an early stage is not systematic".

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With the exception of the aforementioned Art. 2, Para. 8 (which refers, improperly, also to the VIR[115]), the Regulation, unlike its predecessor,[116] does not include ad hoc provisions concerning the responsibility to perform the VIR. This can be easily explained by the fact that, under the new rules, each administration is required to prepare a two-year plan regarding regulatory acts, *falling within its competence*, on which it intends to carry out an ex post evaluation (*infra*, X.1). As the legislative power is increasingly shared among different institutions, the Regulation clarifies that if the regulatory acts involve more administrations, the VIR can be carried out jointly by the competent offices of the relevant administrations, regardless of whether they are institutionally part of the same level of government.[117]

With regard to the internal organization of the impact analysis and evaluation functions of the administrations, Art. 14, Para. 9 of law No. 246/2005 stipulates that

> [t]he administrations, in the exercise of their own organisational autonomy, and without extra costs, identify the office responsible for the coordination of the activities related to the execution of the AIR and of the VIR within the scope of their respective competence.

In order to ensure an adequate capacity of data acquisition and the expertise required for the application of the analysis methods, including the organization of consultation and monitoring processes, the Regulation introduces the requirement for the administrations to establish, in accordance with the instructions set forth in the Guidelines, *special organizational units* to carry out the AIR and VIR activities, which can involve the competent offices in the respective areas of regulation, as well as other administrations and public bodies in possession of relevant information.[118] This provision represents a significant improvement over the original version of the draft Regulation,[119] since it takes into account the views of the Council of State, which has stressed that the quality of the AIR, VIR and consultations cannot be guaranteed without setting up dedicated structures, consisting of adequately trained staff.[120]

Under Section 3, the Guidelines clarify that the 'responsible office' referred to in Art. 14, Para. 9 of law No. 246/2005 has a purely 'coordinating role' and that it

115 Ex post evaluation is about assessing an existing measure rather than a 'proposed' one – as is the case with ex ante impact analysis.

116 Reg, Art. 12, Para. 1. By contrast, Art. 2, Para. 3 of the 2009 VIR Regulation provided that "the administration that has carried out the AIR on the regulatory act which is subject to evaluation, or, in the absence of a previous AIR, the administration responsible for the initiative concerning the regulatory act subject to evaluation is responsible for performing the VIR". *See also*, Section 2.2.5 of 2009 Prime Minister's Directive.

117 Reg, Art. 12, Para. 5, last sentence.

118 Reg., Art. 2, Para. 7.

119 Along the lines of Art. 3, Para. 1 of the 2008 AIR Regulation, the earlier text merely recalled Art. 14, Para. 9 of law No. 246/2005 – a provision considered largely ineffective by the Council of State – as it made no reference to the need to establish special organizational units.

120 Consiglio di Stato, *supra* note 3, Para. 34.

is only expected to ensure the coordination and planning of the assessment activities performed by technical directorates (which have the necessary expertise and information to conduct the assessments, and often represent the driving force behind regulatory action), as well as compliance with the Regulation and the Guidelines, and to manage relations with DAGL and with other administrations. Section 3 also acknowledges that the execution of an AIR or VIR requires 'cross-cutting skills', which vary according to the measure considered and may not be limited to those possessed by the technical directorates of the relevant ministry. For this reason, the responsible office must set up, *for every* AIR or VIR, a 'working group' to ensure the involvement (in addition to competent directorates) of legal professionals, economists and statisticians, drawing on, for example, the evaluation units established under law No. 144/1999, the central statistical office and the legislative office. In the case of regulatory acts involving more administrations, the working group shall include staff from the various administrations concerned. Where necessary, the same office may also make use of experts or specialized research firms, in accordance with the law and, in any case, within the limits of available resources, as already foreseen by Art. 14, Para. 9 of law No. 246/2005.

I Analysis of the Impact of Regulation (AIR)

I Scope of Application

The requirement to conduct the AIR applies, as per previous rules,[121] to the draft normative acts of the Government, including the acts issued by a Minister, the inter-ministerial acts and the draft laws initiated by the Government.[122] However, with a view to solving one of the critical issues that have emerged in the past – notably, the excessive number of AIR reports that needed to be drafted each year and the challenge of producing high-quality analyses within a short timeline – the scope of application of the AIR has been narrowed down, as recommended by the 'OECD Review of Better Regulation in Italy'.[123] In particular, the Regulation introduces a 'threshold test', based on the principle of proportionality, to ensure that the AIR is selective, *i.e.*, "limited in scope to the regulatory initiatives with significant impact on citizens, businesses and public administrations".[124] Against this background, the grounds for exclusion and the criteria for the identification of the initiatives that can be exempted from an impact analysis have been significantly revised, as explained further below. In this respect, the Council of State – which welcomes the revised rules on exclusion and exemption as a useful instrument to improve the quality of the AIR reports[125] – has acknowledged that the effective implementation of the regulatory quality tools, which may be facilitated by giving preference to quality over quantity of the impact analyses, "can

121 *See* 2008 AIR Regulation, Art. 2.
122 Reg, Art. 5, Para. 1.
123 OECD, *supra* note 7, pp. 1, 20, 65.
124 Reg., Art. 2.3, last sentence.
125 Consiglio di Stato, *supra* note 3, Para. 26.

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lead to incredible benefits for our legal system, and, above all, for its recipients and for the entire country".[126]

1 Grounds for Exclusion of the AIR

The Regulation envisions a broader exclusion regime than its predecessor.[127] Art. 6, Para. 1 excludes from the AIR the rules that implement the statutes of special statute Regions, the laws that approve state budgets and general accounts and the rules that merely transpose provisions of ratified international agreements. It also excludes the single texts that are non-authoritative compilations of existing law. Further exclusions are set forth with regard to the regulations adopted by Decree of the President of the Council of Ministers, which determine the organization of the offices of the Ministries or which provide for the periodic revision of the rules in force, the identification of those that have been implicitly repealed, and the express abrogation of the rules that have achieved their purpose or have no actual regulatory content or are otherwise obsolete. All these exclusions are provided for in addition to those already existing for constitutional laws, laws authorising the ratification of international treaties and rules adopted in the state security sector.[128]

It should be noted that the Regulation removes the power of the Parliament's Committees, Council of Ministers, and Inter-ministerial Committee for Strategic Direction and Guidance for Simplification Policies and Regulatory Quality to request that an AIR be performed in spite of the existence of a ground for exclusion.[129] Currently, in the case of exclusion of the AIR, the Committees and the Council of Ministers may only require that the explanatory report accompanying the regulatory measure be supplemented with the expected impacts on citizens, enterprises and public administrations, as well as the comparison of the various regulatory options considered.[130]

In order to offset the risk of an unwarranted use of the exclusion clause through an overly broad interpretation, the Regulation provides authority for DAGL to ascertain the existence of a ground for exclusion. Should DAGL take the view that the latter does not occur as the regulatory measure pertains, in whole or in part, to regulatory acts other than those referred to in Para. 1 of Art. 6, it will request that the AIR be performed and will make the inclusion of the measure in the agenda of the pre-Council meeting conditional upon the drafting of the AIR report.[131]

2 Request for Exemption from the AIR

The exemption regime has also undergone considerable reform aimed at making more rational use of it. The 2008 AIR Regulation provided that

126 *Ibid.*, Para. 44.
127 *See* 2008 AIR Reg., Art. 8, Para. 1.
128 More precisely, the Regulation refers to "provisions directly impacting on fundamental interests in the field of internal and external state security".
129 *See* 2008 AIR Reg., Art. 9, Para. 4.
130 Reg., Art. 6, Para. 4.
131 *Ibid.*, Para. 3.

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> [u]pon motivated request by the concerned administration, DAGL may allow an exemption from the AIR, particularly in extraordinary cases of necessity and urgency, as well as in instances of specific complexity and size of the regulatory intervention and its likely impacts.[132]

This provision attracted criticism from the OECD, which in its country report observed that "the 2008 RIA regulation allows for exempting administration from doing RIAs on urgent and complex proposals – typically the areas where such a tool would bring value",[133] and "when *ex ante* assessments are most opportune".[134] The report additionally questioned the logic of an exemption from doing AIRs on urgent proposals "at a time when central normative action in Italy was mainly promoted through decree-laws,[135] whose rationale is exactly to respond to urgency and emergency situations".[136]

In the light of the foregoing, the Regulation states, under Art. 7, Para. 1, that on request of the proposing administration, DAGL may grant an exemption from the AIR – even with regard to specific aspects of regulation[137] – where all of the following conditions are met: 1) low compliance costs in relation to the individual recipients, also taking into account their extension in time; 2) small number of recipients of the intervention; 3) limited value of the public resources invested; and 4) limited impact on the competitive structure of the market.[138] Therefore, the Regulation goes further than expected, given that both the exemption for more complex issues and the exemption for urgent interventions have been removed, beyond all expectations.[139] As a result, extraordinary cases of necessity

132 *See* 2008 AIR Reg., Art. 9, Para. 1.

133 OECD, *supra* note 7, p. 20.

134 *Ibid*., p. 65.

135 Decree-laws (*decreti legge*) are government normative 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 60 days of their publication, they lose validity retroactively. The Parliament may regulate by means of laws any relations that have arisen by virtue of unconverted decrees.

136 OECD, *supra* note 7, p. 65.

137 Reg., Art. 7, Para. 3. This paragraph originally provided for the possibility of applying for an exemption with respect to *single* legal norms. However, the Council of State noted that this provision implied a wrong approach to impact assessment, based on the assumption that there is always a legal text to be analysed ex ante, thereby placing the AIR at the end of the procedure rather than its beginning. In addition, this approach presented the danger of an erroneous analysis of the interrelations between different provisions of the same legal text and of their consequences. Consequently, the Council suggested the removal of Para. 3 or, at least, the replacement of the expression 'single provisions' (*singole disposizioni*) with the words 'specific regulatory aspects' (*specifici aspetti della disciplina*). *See* Consiglio di Stato, *supra* note 3, Para. 58.

138 The exemption request shall describe why each of the enumerated conditions is met. *See* Reg., Art. 7, Para. 4.

139 *See* OECD, *supra* note 7, p. 65: "While the exemption from RIA for urgent interventions (typically passed through a decree-law) may be difficult to avoid because time is of the essence to address sudden and unpredictable emergencies, the new RIA regulation envisaged by DAGL is expected to modify the exemption assumptions to reduce the number of RIA and to cancel the exemption 'for more complex issues'".

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and urgency can presently only provide grounds for derogation from the obligation to conduct a consultation (as explained further below).

The Regulation[140] provides specific rules for the exemption of regulations adopted pursuant to Art. 17, Para. 3 of law 23 August 1988 No. 400.[141] This law determines the activities, organization and regulatory power of the Presidency of the Council of Ministers. While Art. 17 relates to government regulations, Para. 3 specifically governs the procedure for the issuance of ministerial and inter-ministerial regulations.[142] Such regulations may be exempted from the AIR – owing to the limited impact of the intervention – through a declaration signed by the relevant Minister/s. This declaration shall be attached to the request for an opinion of the Council of State and to the communication sent to the President of the Council of the Ministers. At the time of the request of the Council's opinion, the AIR report regarding the draft regulation must have been checked already by DAGL.[143]

To be granted, the exemption must be requested at least 30 days before the request for including the measure in the agenda of the pre-Council meeting, and the request shall be published on the website of the administration.[144]

As in the cases of exclusion, it is foreseen that the explanatory memorandum accompanying the regulatory measure that has been exempted from the AIR shall be supplemented with the expected impacts on citizens, enterprises and public administrations, as well as the comparison of the various regulatory options considered, where so requested by the parliamentary committees or the Council of Ministers.[145] In any event, the explanatory memorandum makes reference to the exemption granted and the respective grounds of justification.[146]

II The Process

The Regulation stipulates in Art. 8 that the AIR process starts as soon as the need for regulatory intervention is identified.[147] Clearly, in the case where the proposing administration has indicated in the legislative Programme (or later notified DAGL of) the existence of a ground for exclusion as referred to in Art. 6, or has requested an exemption pursuant to Art. 7, the process can commence only when

140 Reg., Art. 7, Para. 2.

141 *Legge 23 agosto 1988, n. 400 – Disciplina dell'attività di Governo e ordinamento della Presidenza del Consiglio dei Ministri*, in *Gazzetta Ufficiale* 12 October 1988 No. 214 – *Suppl. Ordinario* No. 86.

142 Regulations on matters within the competence of a minister (or of authorities subordinated to the minister) may be adopted by ministerial decree (or inter-ministerial decree, if related to matters within the competence of more ministers). Ministerial and inter-ministerial regulations, which may not be contrary to the regulations issued by the Government, shall be communicated to the President of the Council of Ministers prior to their enactment. Government, ministerial and inter-ministerial regulations are adopted following the opinion of the Council of State, stamped and registered by the Court of Auditors, and published in the *Gazzetta Ufficiale*.

143 Reg., Art. 9, Para. 5.

144 Reg., Art. 7, Para. 5.

145 *Ibid*., Para. 7.

146 *Ibid*., Para. 6.

147 Reg., Art. 8, Para. 1.

DAGL has determined that the ground for exclusion does not exist or it has refused to grant an exemption.

1 AIR Methodology

According to Art. 8, Para. 2 of the Regulation, the AIR consists of several, logically interconnected steps, as follows:

a framework analysis and identification of the problems to be addressed that justify the new intervention, taking into account the needs and the legal, administrative, economic and social criticalities observed in the current situation, also having regard to the failure of other measures in force to attain the expected effects;
b identification and quantification of potential recipients of the intervention, both public and private;
c definition of the objectives of the regulatory intervention, consistent with the analysis of the problems referred to under letter a) above;
d identification of options, including non-regulatory alternatives, such as that of non-intervention (the 'zero option');
e preliminary assessment of the options, taking into consideration their effectiveness, proportionality and feasibility, and the consequent identification of feasible options;
f comparison of feasible options, through the assessment and, where possible, the quantification of the main social, economic, environmental and territorial impacts, having regard to the different categories of recipients; such evaluation also takes into account the effects on SMEs, administrative burdens, effects on competition and compliance with minimum levels of EU regulation;[148]
g identification of the preferred option, specific conditions for its implementation, monitoring modalities and modalities of subsequent evaluation.

In essence, the AIR process can be broken down into five main stages. First of all, it is of utmost importance that the AIR explain the context of the initiative and the motivations behind it; primarily, the social, economic and legal background. A good AIR does not merely describe a problem but also investigates the root causes as the identification of appropriate solutions is dependent on the outcome of such inquiry. In parallel, the potential recipients of the intervention should be identified and quantified: this is important for the purpose of not only understanding the scope of the intervention, but also planning the consultations accordingly (as the choice of consultation techniques will depend on the type and numbers of stakeholders to be consulted) and properly evaluating the costs and benefits of options.[149] The logical next step is the definition of the general and specific objectives that the intervention intends to achieve (including the defini-

148 This latter provision reflects the amendments made to law No. 246/2005 (*i.e.* Art. 14, Para. 5-*bis* e 5-*ter*) by *legge 11 novembre 2011, n. 180 – Norme per la tutela della libertà d'impresa. Statuto delle imprese*, published in *Gazzetta Ufficiale* 14 November 2011 No. 265.

149 The recipients, however, can vary according to the options considered, and, therefore, their full identification may be possible only after having defined the content of the options.

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tion of measurable indicators in view of the future VIR).[150] Objectives are a crucial factor in the comparison of options, as well as for setting up the monitoring and evaluation activities in connection with the VIR. The core of the process, however, is the comparison between the different options, which requires first their identification and then their evaluation. Once options have been identified, a preliminary assessment of the same should be conducted to exclude those that are clearly not implementable and to limit the subsequent stage of comparison only to feasible options. The option evaluation is always both qualitative and quantitative and relates to the positive and negative effects that each option is expected to produce on recipients (mainly, citizens and enterprises, but also administrations), as compared with the present situation (so-called baseline). The comparison between the effects of each option and the baseline is essential to avoid attributing to the option considered costs or benefits that would arise anyway, even without any intervention. For this reason, the 'zero option' (also known as the 'do-nothing' option), *i.e.*, leaving the existing regulatory framework unchanged, shall always be considered among the options.[151] Last but not least, the AIR also contemplates an assessment of specific impacts – particularly the impact on competition, the SME test, administrative burdens,[152] and exceeding the minimum level of EU regulation ('gold-plating')[153] – which are relevant only

150 Although Art. 8, Para. 2 does not expressly require the administration to set up the indicators against which the intervention will be monitored and evaluated, Art. 12, Para. 6 provides that "the Administration ensures the monitoring of the implementation of normative acts, through the continuous collection and processing of data and information necessary for the execution of the VIR, with particular regard to those relative to the indicators identified in the respective AIRs, according to the instructions contained in the directive referred to in article 3, paragraph 1". However, for the sake of better coordination between these two provisions, it would have been desirable to insert in Art. 8, Para. 2(g) – which generally refers to monitoring modalities – an additional provision expressly requiring the administration to formulate the indicators against which implementation will be monitored and evaluated. For the avoidance of doubt, the Guidelines regulate indicators under Section 5.2, p. 14, Section 5.6, pp. 21-22 and Section 9.5.1, pp. 35-36. Furthermore, the 2009 Prime Minister's Directive already encouraged the administrations to take into account, during the preparation of the AIR (with special regard to the indicators relating to objectives and expected results), the future need to carry out the VIR (Section 2.2.4).

151 In the case of transposition of EU directives, the zero option would be not to proceed with the incorporation of their provisions into the domestic legal system, which is not a feasible option. Nonetheless, the national implementing rules should also be compared with the current situation, although the zero option would be considered only for the purpose of evaluating the alternative options. Similar arguments can be made in relation to the implementation of legislative delegations. *See* Guidelines, Section 5.3, p. 17, and Ann. 2, p. 67.

152 Administrative burdens are costs imposed on individuals and businesses, when complying with information obligations stemming from regulation.

153 In the case of transposition of EU directives, regardless of whether the subject matter is already regulated (entirely or in part) by national law, adherence to the minimum levels of EU regulation should always be considered as the preferred option. *See* Art. 14, Paras. 24-*bis*, 24-*ter* and 24-*quater* of law No. 246/2005, as amended by Art. 15, Para. 2(b) of law 12 November 2011 No. 183 (in *Gazzetta Ufficiale* 14 November 2012 No. 265 – *Suppl. Ordinario* No. 234): the acts transposing directives may not provide for the introduction or maintenance of levels of regulation higher than the minimum levels required by the same directives, unless exceptional circumstances documented in the AIR report warrant an exception.

for certain categories of interventions.[154] After justification for the preferred option has been provided on the basis of the comparative evaluation carried out, the final stage aims at clarifying the 'closing' phases of the regulatory cycle, such as monitoring and ex post evaluation.

As pointed out in the Guidelines,[155] although the phases described above are somewhat sequential, the AIR is, by its nature, 'interactive': each phase can bring out considerations and evidence that may suggest a rethinking of the results of a previous phase. In other words, the analytical process should not be understood in a rigid way. Although, in fact, for the sake of clarity, the different phases are presented sequentially, in practice, they often intersect with each other. The AIR is a structured way to collect, develop and produce information and, as such, facilitates the accumulation of knowledge along the way, leading also to a reconsideration of elements already evaluated as new information and evidence emerge.

The AIR methodology is one of the areas of RIA where the Regulation is most innovative and breaks with the past. In line with an OECD recommendation,[156] Art. 8, Para. 2(f) provides for the comparison of alternative options and the assessment (where possible in quantitative terms) of the relative impacts for different categories of recipients. The impact analysis is therefore not limited to the single preferred option and to the zero option, which was the case in the 2008 AIR Regulation.[157] According to international best practice, RIA is a 'comparative process' that requires feasible alternatives to be assessed, *i.e.*, compared in terms of benefits and costs, using the same technique, so as to inform decision makers about the effectiveness and efficiency of different options and enable the most effective and efficient option to be systematically chosen.[158] The comparative nature of the AIR is emphasized by the Regulation in Art. 2, Para. 4, which requires the administrations, in the execution of the AIR, to identify and compare the alternative regulatory options, including that of non-intervention, and to analyse the respective feasibility and expected effects.[159]

154 App. 1 to Guidelines illustrates the modalities of carrying out each such specific assessment.

155 Section 5, pp. 11-12. *See also*, App. 2 'AIR Checklist', p. 66.

156 *See* OECD, *supra* note 7, p. 66: "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 receive 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". It is therefore recommended to "[r]einforce the requirement to consider alternative forms to regulatory interventions at an early stage in the impact assessment process".

157 Art. 6, Para. 3 of 2008 AIR Regulation refers to "d) the analysis of the non-intervention option ('zero option')" and "f) the analysis of the intervention option selected, highlighting the related collective net benefits, the analysis of the legal organizational, socio-economic, conditions, and the indication of the information obligations and related administrative costs incurred by enterprises and citizens".

158 Most frequently used evaluation techniques include the 'Cost/Benefit Analysis' (CBA), the 'Cost-Effectiveness Analysis' (CEA) and the 'Multi-Criteria Analysis' (MCA). On evaluation techniques, *see* broadly OECD, *Introductory Handbook for Undertaking Regulatory Impact Analysis (RIA)*, Paris, OECD Publishing, 2008, pp. 1, 9-16.

159 Reg., Art. 2.4.

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It is also important to stress that Art. 6, Para. 3(e) of the 2008 AIR Regulation provided that the AIR report should describe "the main relevant options of intervention, alternative to that of non-intervention, including description of the different levels of regulatory intervention, highlighting the absolute need for normative intervention by primary legislation". Hence, the consideration of alternatives to regulation was lacking from the previous rules, the assumption being that intervention is regulatory by default. As noted by the OECD, the Italian legal system is very complex, drawing from a rather legalistic decision-making tradition. As a result, the pathway for drafting regulation is more immediately evident to civil servants than options for developing alternative instruments.[160] Although Italy has developed self-regulation practices in a variety of sectors (such as environmental policy), the use of alternatives to regulation remains limited. This approach leads to continuous accumulation of regulatory stock that needs regular cleaning out. Against this backdrop, the OECD country report recommended to '[s]tart 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'.[161] By allowing the identification of non-regulatory alternatives, the Regulation adheres to the aforementioned recommendation and brings Italian practice closer to international standards. Nevertheless, we should recognize that such a remarkable *revirement* would probably not have occurred if the Council of State had not criticized the original formulation of Art. 8, Para. 2(d) in the draft Regulation (which made no reference whatsoever to non-regulatory options). In particular, the Council argued that the 'zero option' should not only be used for comparison in relation to the issuance of a regulatory act, but also regarding the opportunity of a non-regulatory intervention,[162] thus intrinsically advocating in favour of the inclusion of such an intervention among the various options identified.

Another novel feature of the AIR methodology is that it enhances the potential synergy and interaction between regulatory quality tools with the aim of promoting functionally intertwined mechanisms. As argued by the OECD,[163] RIA and ExPER are strongly linked and mutually reinforcing. They represent different yet interconnected steps of a 'circular' process, where each stage feeds off the other. While ex ante analysis provides elements to assess whether regulation has ach-

160 OECD, *supra* note 7, p. 20.

161 *Ibid*., p. 65.

162 Consiglio di Stato, *supra* note 3, Para. 60.

163 OECD, *Evaluating Laws and Regulations: The Case of the Chilean Chamber of Deputies*, Paris, OECD Publishing, 2012, p. 24.

ieved its objectives,[164] ex post evaluation helps to understand the shortcomings of existing regulation and thus assists in the formulation of new regulatory policies. In other words,

> ex post evaluation should not be considered as the final stage in the life of regulations, but as a deliberate and responsible 'loop back' into the regulatory cycle, providing an understanding of areas for potential improvement and issues with implementation. In this way, countries could do more to connect the ex ante and ex post evaluation processes together.[165]

The need for linking circularly AIR, VIR and consultation has also been noted by the Council of State, which has observed that the use of these three instruments should be dynamically integrated in such a way that the consultation drives the AIR that becomes the reference point for the subsequent VIR, which in turn involves another consultation, and is used as a basis for the future AIR with a view to further fine-tuning existing regulations.[166] Along these lines, the Regulation affirms in Art. 8, Para. 4 that the AIR shall take into account the results of any VIR previously carried out, also with regard to regulations concerning similar matters. This provision firmly anchors evaluation results in the policy development cycle with a view to connecting past and present decision-making.

2 Preparation of the AIR Report

In accordance with Art. 9, Para. 1 of the Regulation, for each regulatory initiative in respect of which DAGL has verified the non-existence of a ground for exclusion referred to in Art. 6 or has not granted an exemption pursuant to Art. 7, the proposing administration shall draft a report to document the various phases of the analytical process set forth in Art. 8. According to the Guidelines (and the model

164 In order to be effective, ExPER requires clarity of the intended policy objectives, which provide a framework by which a regulation can be evaluated after it is implemented. RIA is central to this process, since it is during the ex ante analysis that the problem should be properly defined and policy objectives should be clearly established. *See* OECD, *supra* note 163, p. 23. Conversely, ex post evaluation can help determine the extent to which RIA benchmarks and assessments have proved accurate. This crucial aspect is highlighted in Section 2.2.5 of the 2009 Prime Minister's Directive, which states that the VIR is based on the 'retrospective' verification of the data and predictions contained in the AIR report, aimed at assessing the actual impact on the legal system and on the recipients of the regulatory acts. *See* Consiglio di Stato, *supra* note 3, Para. 18: "The VIR also serves to verify (and, if necessary, to correct) the methodology followed in the AIR where, in the course of implementation, effects have emerged that were not considered at the time of the analysis of the framework subject to regulatory intervention. This allows the VIR to provide an 'experience feedback', which may render the future AIRs more and more accurate".

165 *See* OECD, *supra* note 40, pp. 120-121, which adds at 121: "To enhance overall government efficiency, retrospective analysis should be integrated into the policy-making process. For instance, no new regulatory initiative should be adopted unless it is preceded by a retrospective analysis of the existing regulatory environment. To ensure this, a close link should be formally established between the *ex ante* and the *ex post* phases and be embedded in the Regulatory Impact Analysis process. These requirements are generally spelled out in formal guidelines adopted by a number of OECD countries".

166 Consiglio di Stato, *supra* note 3, Para. 36.

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AIR report annexed thereto),[167] the report begins by providing an executive summary of no more than two pages about the main results of the analysis carried out, with particular reference to: (a) the reasons for the intervention; (b) the objectives pursued; (c) a brief description of the option chosen; (d) the main findings regarding the evaluation of the impacts on recipients; and (e) the consultations conducted. The remainder of the report follows essentially the various phases of the AIR.[168] In addition to illustrating the results of the analysis undertaken, the report gives an account of the sources of information and evaluation methods used, stating clearly the assumptions made and highlighting the possible margins of uncertainty of the evaluations carried out.[169] Although the Guidelines do not specifically mention it, it must be assumed that the RIA report should comment on how consultation contributed to shaping the regulatory measure and to the identification and definition of the alternative options. Acknowledgement of the consultation's impact on the evaluations underpinning the RIA report is in fact considered one of the areas in need of improvement highlighted by Parliament.[170]

If the regulatory interventions involve different sectors or subject areas, the AIR is carried out separately for each sector or subject area. In this case, the proposing administration draws up the general AIR report, which consists of the distinct sectoral or subject matter reports.[171]

In the preparation of the AIR report, the administration resorts to quantitative evidence, including that derived from reports issued by control and supervisory authorities.[172]

3 Validation of the AIR Report by DAGL

After the AIR report is finalized by the administration, it is submitted to DAGL for validation, together with a request for inclusion of the regulatory measure in the agenda of the pre-Council meeting.[173]

Pursuant to Art. 34, Para. 5 of decree-law 6 December 2011 No. 201,[174] as converted with amendments by law 22 December 2011 No. 214,[175] the AIR report concerning draft laws and regulations of the Government that introduce restric-

167 Guidelines, Section 5.7, pp. 29-30.

168 The AIR report should, therefore, be articulated into the following chapters: 1. 'Background and Problems to Be Solved'; 2. 'Objectives of the Intervention and Related Indicators'; 3. 'Intervention Options and Preliminary Assessment'; 4. 'Comparison of Options and Justification of the Preferred Option'; 5. 'Modalities for Implementation and Monitoring'. Each section can be broken down into one or more subsections. In addition, the following two sections are included: 6. 'Consultations Carried Out in the Course of the AIR' and 7. 'Assessment Process'.

169 Guidelines, Section 5.7, p. 30.

170 Senato della Repubblica, *supra* note 52, p. 23.

171 Reg., Art. 5, Para. 2.

172 Reg., Art. 8, Para. 3.

173 Reg., Art. 9, Para. 2.

174 *Decreto-legge 6 dicembre 2011, n. 201 – Disposizioni urgenti per la crescita, l'equità e il consolidamento dei conti pubblici* (in *Gazzetta Ufficiale* 6 December 2011 No. 284 – *Suppl. Ordinario* No. 251).

175 *Legge 22 dicembre 2011, n. 214 – Conversione in legge, con modificazioni, del decreto-legge 6 dicembre 2011, n. 201, recante disposizioni urgenti per la crescita, l'equità e il consolidamento dei conti pubblici* (in *Gazzetta Ufficiale* 27 December 2011 No. 300 – *Suppl. Ordinario* No. 276).

tions to the access and exercise of economic activities shall be submitted to DAGL only after the AGCM (*i.e.* the competition agency) has rendered its opinion, which shall be forwarded to DAGL along with the AIR report.[176] In this way, the Regulation further strengthens the focus on the effects of regulation on the competitive structure of the market, thus marking another important step in a process that began in 2008, when the analysis of the impact of regulation on competition (also known by the acronym 'AIRC') was first introduced in the Italian legal system.[177] Although the AIRC is required by law, in reality, AIR reports do not always give a thorough account of the effects of regulation on competition. In general, the whole assessment of the economic effects of regulation is, to date, still lacking, as evidenced by DAGL's Report on the state of implementation of the AIR for 2015.[178] The aforesaid provision intends to solve this problem by ensuring that any draft measure that may have anti-competitive effects undergoes an ex ante review by the Italian antitrust authority, and it is not processed by DAGL without an in-depth assessment of those effects.

According to Art. 9, Para. 3 of the Regulation, before the proposal is discussed in the pre-Council meeting, DAGL checks the appropriateness and completeness of the analysis activities carried out in the report and the correctness of the evaluation methods used. If DAGL is not satisfied, it can request clarifications and additions in order to make the report consistent with the requirements set forth in the Regulation.[179]

It is noteworthy that, in comparison with the old rules,[180] the Regulation does not limit itself to requiring that DAGL check the appropriateness and completeness of the AIR but also stresses the importance of verifying the 'correctness of the evaluation methods applied'. Moreover, the Regulation places emphasis on the 'analysis activities' rather than referring, more generically, to the 'activities carried out for the AIR'. Another important innovation is that failure to comply

176 Reg., Art. 9, Para. 4.

177 In the original text of Art. 14 of law No. 246/2005, which introduced the generalized use of the AIR procedure, the AIRC was not given explicit recognition. However, the 2008 AIR Regulation stated that a special section of the AIR report should "estimate the impact on the proper functioning of a competitive market of regulatory proposals likely to have a significant bearing on business activities" (Art. 6, Para. 3(g)). The AIR report template further clarified that in order to determine whether new rules produced harmful effects on competition, recourse could be made to checklists such as those developed by the OECD. Afterwards, law No. 180/2011 amended Art. 14, Para. 1 of law No. 246/2005 by providing expressly that "in the identification and comparison of options, the competent administrations shall take into account the need to ensure the proper functioning of a competitive market".

178 *See* G. Mazzantini, 'L'analisi d'impatto della regolazione sulla concorrenza', *in* F. Cacciatore e S. Salvi (Eds.), *supra* note 3, pp. 83, 99. *See also*, Senato della Repubblica, *supra* note 52, p. 13. For an earlier paper, *see* L. Cavallo, *L'analisi dell'impatto della regolazione sulla concorrenza*, Rome, Osservatorio AIR, 2010, pp. 1-25.

179 In 2017, the administrations amended the AIR report, on request of DAGL, in 82 cases, equal to 60% of the total number of AIR reports. *See* Senato della Repubblica, *supra* note 52, p. 21.

180 Art. 7, Para. 2 of 2008 AIR Regulation stipulated as follows: "DAGL verifies the appropriateness and completeness of the activities carried out for the AIR, and may request additions and clarifications from the proposing administrations; for the purposes of inclusion in the agenda of the Council of Ministers, it formulates its remarks on the AIR report."

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with DAGL's request to apply the necessary changes may result in the formulation of a 'notice of impediment' (*avviso ostativo*),[181] which is communicated to the Secretary of the Council of Ministers for the purposes of the decision whether or not to include the regulatory measure in the agenda of the pre-Council meeting.[182] Thus, such notice does not automatically prevent the proposal from entering the agenda, as a decision of the Council of Ministers may, in principle, overrule it.[183]

Overall, the impression is that the focus of DAGL's review is gradually shifting from a procedural and technical analysis, typically checking that the assessments are in line with minimum requirements, to one of *quality control*. This is consistent with the OECD's recommendation to consolidate the quality control mechanisms and incentives for compliance, which are considered crucial for the success of any regulatory policy reform system.[184] The use of the word 'verification' in the heading of Art. 9 ('Presentazione e verifica della relazione AIR'), as well as in its text, would appear to confirm such a conclusion. Nevertheless, the fact that a 'political' decision may override DAGL's remarks regarding the appropriateness, completeness and correctness of the AIR raises concerns in terms of the effectiveness of such quality control.

Another cause for concern is that in case of lack of response, or failure to request clarifications or additions, within seven days of the receipt of the report, the latter is deemed as positively verified by DAGL.[185] As a consequence of this provision, DAGL does not have to provide a specific response to each administration, when there is no need for clarifications or modifications of the AIR report. The success of the mechanism rests on the assumption that DAGL will be able to scrutinize all AIRs. However, should this not be the case, this provision may turn into a non-selective and passive acceptance tool and would thus raise the risk that inadequately performed AIRs could be formally accepted. It is, however, reassuring that the newly introduced 'silence implies consent' rule applies only if the

181 While it is a foregone conclusion that the notice should state the grounds for its issuance and be accompanied by supporting documentation, the Regulation does not clearly say so.

182 Reg., Art. 9, Para. 3. Inclusion of a proposal in the agenda of the pre-Council meeting is crucial because, as set forth in Arts. 4 and 5 of the Decree of the President of the Council of Ministers 10 November 1993 on the internal regulation of the Council of Ministers (in *Gazzetta Ufficiale* 18 November 1993 No. 271), proposals concerning draft laws, normative acts or general administrative acts may not be included in the agenda of the Council of Ministers if they have not been previously examined in the pre-Council meeting. In fact, at the end of the meeting, the list of measures that can be included in the Council of Ministers' agenda is transmitted, through the Secretary of the Council of Ministers, to the President of the Council of Ministers, who convenes the Council of Ministers and sets the agenda of the meeting.

183 It is actually unclear who should take such a decision, *i.e.*, the Secretary of the Council of Ministers, the Council of Ministers or the President of the Council of Ministers. Art. 4, Para. 1 of law No. 400/1988 provides that "[t]he Council of Ministers is convened by the President of the Council of Ministers, who sets up the relative agenda". As the pre-Council meeting is just a preparatory meeting of the Council of Ministers, the decision would seemingly belong to the President of the Council of Ministers. Nonetheless, it would have been desirable to have more clarity on this issue in the Regulation.

184 OECD, *supra* note 7, pp. 17, 21 and 33.

185 Reg., Art. 9, Para. 5.

report is related to the regulations referred to in Art. 17, Para. 3 of law No. 400/1988.[186]

4 *The AIR Report as a Precondition for Including Draft Acts in the Council of Ministers' Agenda*

The Regulation, under Art. 9, Para. 6, provides that in order to be included in the agenda of the Council of Ministers, the draft regulatory acts are accompanied by the AIR report, unless otherwise provided in Arts. 6 and 7 (*i.e.* grounds for exclusion and exemption). In this sense, one may note the softening of the mandatory language, in comparison with Art. 7, Para. 1 of the 2008 AIR Regulation. This latter provision, which the OECD has identified as one of the main factors determining the large number of analyses produced,[187] stipulated that

> [t]he proposals of regulatory acts to be submitted for consideration to the Council of Ministers *shall not* be included in the agenda if they are not accompanied by an *adequate* AIR report, except in the cases of exclusion and exemption provided for in Arts. 8 and 9 (emphasis added).

A possible reason for such a change in the language style may lie in the fact that the Regulation, as discussed above, allows inclusion of a regulatory proposal in the agenda of the pre-Council meeting (and, once approved in that forum, on the Council of Ministers' agenda), despite the issuance of a notice of impediment *ex* Art. 9, Para. 3. Hence, neither the absence of the AIR report nor the inadequacy of the analysis constitutes any longer an obstacle per se to the inclusion of a proposal in the agenda of the Council of Ministers, even where the administration has failed to fulfil DAGL's request for clarifications or modification.

It is debatable whether it would have not been prudent, in order to strengthen the effectiveness of DAGL's quality check, to retain the negative form used in the formulation of Art. 7, Para. 1 of the repealed 2008 AIR Regulation and the express reference made therein to the 'adequacy' standard prescribed for the AIR report. In other words, the Regulation could have stipulated that a notice of impediment prevents *tout court* a proposal from being placed on the agenda of the pre-Council meeting. Yet it may be contended that construing the AIR report as a *condicio sine qua non* to inscribe draft legislation in the Council of Ministers' agenda could have contributed to an overproduction of RIAs, as that experienced with the implementation of the 2008 AIR Regulation. On the other hand, one may respond that the reform of the system of exclusions and exemptions by the new rules, together with the special procedure introduced for decree-laws (as explained further later), would have probably represented an adequate counterbalance to such outcome, curbing the risk of producing an excessive number of

186 *Ibid*., Para. 5.

187 *See* OECD, *supra* note 7, p. 65: "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 DAGL, has led to a sharp increase of the production of RIAs."

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AIRs, even in the presence of the aforementioned requirement. At the end of the day, while it is legitimate to pursue a rational and sensible use of RIA, this should not be accomplished at the expense of regulatory quality.

5 Submission of the AIR Report to Parliament

Legislatures can play a central role in ensuring that the RIA process within an administration effectively supports policymaking by supplying valuable empirical data. In the exercise of their oversight role, parliamentary committees and other bodies supporting committees are ideally placed to communicate with the Government about the quality of RIAs and to ensure that the executive learns any lessons for improvement.[188] A specific aspect to be reviewed is whether the methodology used within the administrations to perform the RIA was as technically sound as possible. To this end, the legislature may seek information from the executive about the process and methods used to produce the RIAs.[189] In order to scrutinize the assessments of the Government and seek explanation, information and justification, where needed, the legislature should have scrutiny and accountability mechanisms in place.[190]

In Italy, parliamentary scrutiny of RIAs was contemplated for the first time by Art. 12, Para. 2 of law No. 229/2003, which required independent Authorities to forward their AIR reports to Parliament.[191] The Regulation makes this requirement a general practice by stating that the AIR report that accompanies a regulatory measure, after DAGL's validation, is to be submitted to Parliament.[192] This is

188 OECD, *supra* note 163, p. 25.

189 In principle, RIAs will command more attention and will be taken more seriously if they are subject to parliamentary scrutiny. *See* OECD, *Improving Regulatory Governance: Trends, Practices and the Way Forward*, Paris, OECD Publishing, 2017, p. 208.

190 OECD, *supra* note 163, p. 26.

191 This requirement represented a relative novelty among OECD countries. *See* OECD, *supra* note 7, p. 81. However, until 2017, Art. 12, Para. 2 had not been fully implemented, and, as a matter of fact, the Parliament was informed of the activities carried out by the Authorities in the area of regulatory quality only through the references contained in the Government's annual report on the state of application of the AIR and, possibly, in the annual reports submitted by the Authorities to the Chambers. The information thus arrived at the Chambers late and in a rather succinct form. In order to guarantee complete and timely information to the Parliament, the President of the Senate, in June 2017, invited the presidents of the Authorities to transmit their AIR reports to the Senate as soon as they were completed. The reports are announced in plenary session and assigned to the responsible committees, pursuant to Art. 34, Para. 1, second sentence of the Senate Regulation (according to which the President of the Senate may transmit to the Committees reports, documents and acts received by the Senate regarding matters within their competence). *See* Senato della Repubblica, *supra* note 52, pp. 34-35.

192 Reg., Art. 9, Para. 7. Likewise, Art. 10, Para. 4 stipulates that the AIR report accompanying a decree-law, after having been verified by DAGL, is transmitted to the Parliament.

yet another confirmation of the leading practice of the Italian Parliament in this area.[193] As noted by the OECD,

> [i]n a context where neither the Council of State nor the Court of Audit have so far carried out evaluations of the AIR system and feedback from academia, think tanks and stakeholders associations is not organized, the [Italian] Parliament plays an important oversight role.[194]

This role is increasingly performed through various dedicated bodies, within both Chambers, with responsibilities that relate specifically to regulatory quality.

A major part in this regard is played by the Legislation Committee (*Comitato per la legislazione*),[195] which was set up pursuant to an amendment of the Regulation of the Chamber of Deputies – Art. 16-*bis* – that entered into force on 1 January 1998.[196] The Committee has been the answer to a need felt since the 1990s to introduce institutions that would help improve the quality of legislation. It is no coincidence that, in those years, the practice of the (annual) simplification law was introduced, which, in its very first usage, imported into the Italian legal system the RIA policy tool. The Committee's establishment, therefore, is the product of the development of a Better Regulation 'culture' in Italy and one of the first means available to Parliament for addressing the problem of the improvement of lawmaking. It also represents an example of the new mechanisms that are taking hold within the parliaments of majoritarian democracies, by virtue of which the dialectic of parliamentary debate over wide-ranging issues takes place not at the level of political antagonism and confrontation, but of common senti-

193 In 2010, the OECD praised the role of the Italian Parliament with respect to regulatory reform and its internal organization as being more developed than in other countries. In particular, it was noted that "[t]he Italian Parliament has established a number of committees and procedures specifically addressing regulatory policies. It also periodically reviews the quality of the proposed legislation and basic guidelines and criteria are in place to this end. Thanks to this setting, in this area Italy ranks among the top positions in OECD comparisons for parliamentary oversight of regulatory policy". *See* OECD, *OECD Reviews of Regulatory Reform: Italy 2009: Better Regulation to Strengthen Market Dynamics*, Paris, OECD Publishing, 2010, p. 117.

194 OECD, *supra* note 7, p. 79.

195 The institutional website of the Committee can be found at www.camera.it/leg17/736.

196 The Legislation Committee issues opinions on all decree-laws, draft laws that contain provisions on legislative delegation or deregulation, or that assign to the regulatory authority of the Government or other regulatory authorities matters already regulated by law, and draft laws for which a request is made by at least a fifth of the members of a committee (as a rule, 10 deputies). The Committee, in particular, renders an opinion about the *quality* of draft legislation, by assessing the consistency, simplicity, clarity and proper formulation, as well as its effectiveness in achieving the simplification and reorganization of the existing rules. When reviewing decree-laws, the Committee additionally assesses the adherence to the rules on specificity and consistency and those regarding the limits of content provided for by the legislation in force.

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ment and constructive opposition.[197] Interestingly, the Legislation Committee is the only parliamentary body with an equal number of government and opposition representatives that takes part in the formation of the law to achieve the objective of legislative quality. To that end, it constantly monitors the AIRs annexed to the measures submitted to the Chamber for consideration and comments on their quality or content. The reports prepared at the end of each presidential round by the pro tempore presidents of the Committee[198] devote a specific section to monitoring, which is intended to verify not only whether the AIR reports have been duly prepared – or, alternatively, whether an exemption from their preparation was granted – but also if they are drawn up in accordance with the required template.

Another regulatory body active at the parliamentary level is the Service for the quality of legislation (*Servizio per la qualità degli atti normativi*), which has been operating within the Senate since 2010. In addition to the technical preparation, revision and printing of legislative acts, the Service carries out research and documentation activities through the Office for the verification of the administrative feasibility and for the analysis of the impact of the acts in progress (*Ufficio per la verifica della fattibilità amministrativa e per l'analisi di impatto degli atti* in itinere). As of September 2015, the Office publishes a bulletin, on a monthly basis, that monitors the presence of the AIRs in the draft laws and acts of the Government submitted for an opinion of the relevant parliamentary committee (or, otherwise, the existence of a ground for exclusion or exemption). Since October 2017, the bulletin has been enriched with a section dedicated to the AIRs performed by independent Authorities and forwarded to the Senate pursuant to Art. 12, Para. 2 of law No. 229/2003.

6 Publication of the AIR Report

One of the most important functions of RIA systems is to increase the openness and transparency of policymaking. Involving stakeholders in consultation is one way to do this. Another way is to publish the RIA reports so that they can be easily located and scrutinized by stakeholders. In its review of Italy's Better Regulation system, the OECD observed that

> [f]inal 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 an RIA report, unless one knows exactly the number of the parent act, and that this latter has already been transmit-

197 The Legislation Committee is composed of ten deputies chosen by the President of the Chamber in equal numbers among the members of the majority and opposition, and is chaired alternately by each of them for a ten-month period. Therefore, the rule that the composition of the committees must be based on the proportional representation of the parliamentary groups has been expressly waived in this case. On this matter, P. Piciacchia, 'Il Comitato per la Legislazione e la Verifica della Qualità dei Testi Legislativi', *Il Politico*, Vol. 65, No. 1 (192), 2000, pp. 29-72.

198 Available at www.camera.it/leg17/797.

> ted to Parliament. It is also unclear if it is possible to request RIAs to the responsible administrations, directly.[199]

Accordingly, the OECD's recommendation was to make AIRs systematically available to the public on 'one single point of access'.[200] Unfortunately, this recommendation is still valid today, at least in part, as no such point of access has been created, either in the website of the Chamber or in that of the Senate. However, a new section on the AIRs of independent Authorities has been created in the database of non-legislative documents available on the website of the Senate.[201] Furthermore, the Senate's bulletin makes it possible to keep track of all AIRs prepared every month and provides direct links to the relevant files, which also include the AIR report, if available.[202]

In the interest of ensuring greater transparency and accessibility of information regarding ex ante impact analysis, the Regulation imposes an obligation to publish the AIR reports on the websites of the proposing administration and of the Government.[203] This represents an important novelty compared with the previous regulation, which merely stipulated that 'the AIR report can be made public' by the competent administration, including by electronic means or through a dedicated section of its website.[204]

III Ad Hoc AIR Procedure for Decree-laws

In the previous system, the reasons of necessity and urgency leading to the adoption of decree-laws were regarded as a ground for exemption from the AIR. However, not only has the use of decree-laws increased significantly over the years but the rules introduced therethrough have often had a substantial impact on citizens and businesses. With a view to striking a balance between opposite needs, the Regulation sets forth in Art. 10 ad hoc rules for performing the AIR on decree-laws that, consistent with the typical expediency of such laws, provides minimum core information to support decision-making. In comparison with the procedure foreseen by Art. 8, the 'special procedure' for decree-laws is characterized by three main features:

199 OECD, *supra* note 7, p. 78.

200 *Ibid.*, p. 67. In a previous report on regulatory quality in Italy, the OECD had noted that "RIAs should be systematically published, and the government should provide stakeholders and the public with a single online access point for all documents. This access point should also be used to provide feedback to respondents". *See* OECD, *OECD Reviews of Regulatory Reform: Italy, 2009: Better Regulation to Strengthen Market Dynamics*, Paris, 2009, p. 159.

201 Check out the link www.senato.it/static/bgt/listadocumenti/17/0/2208/0/index.html?static=true.

202 As expressly mentioned in the introductory notes, the monthly bulletin "is intended to facilitate the retrieval of the AIRs within the parliamentary acts, as well as provide useful information for the parliamentary activity both for the purpose of better exercise of the functions of direction and control, and to make more significant the role of the Chambers in the process of analysis and evaluation of the legislation".

203 Reg., Art. 9, Para. 7. The same requirement applies to the AIR report concerning a decree-law. *See* Reg., Art. 10, Para. 4.

204 Art. 6, Para. 6 of 2008 AIR Regulation.

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a Unless otherwise provided in the Guidelines,[205] 'lighter' requirements apply in relation to the various phases of the AIR and in the preparation of the relative report. In particular, a framework analysis is not necessary and, when identifying the problem to be addressed and explaining the needs and criticalities that justify the intervention, the Government is not required to consider whether other measures have failed to achieve the same or similar objectives. More importantly, the Regulation does not provide for the identification and comparison of alternative options (including the 'zero option' and alternatives to regulation) but merely requires the evaluation of the option selected and the general description – and, possibly, quantification – of key impacts in terms of benefits and costs for both intended recipients and the community as a whole.[206]

b In consideration of the specific time demands of the procedure concerning the adoption of decree-laws, no requirement is imposed on the Government to conduct consultations. In a sense, decree-laws can be considered, given their urgent nature, as a typical, 'pre-codified' exception to the legal obligation to carry out consultations. The derogation to the consultation rule is not expressly foreseen; however, it can be inferred from the fact that, unlike Art. 8 (general procedure), Art. 10 does not make reference to the provisions on consultation set forth in Arts. 16 and 17. Furthermore, Art. 9 provides that, for each initiative requiring the AIR, the proposing administration shall draw up a report documenting the process referred to in Art. 8 (including consultation), "[e]xcept as provided in Art. 10 for decree-laws". Obviously, as consultation does not take place in the simplified procedure for decree-laws, there is no legal requirement for a 'pre-AIR' report.

c The AIR report must be submitted to DAGL for validation, together with a request for including the decree-law in the agenda of the pre-Council meeting. However, DAGL plays a less incisive role than in the general procedure: it is simply expected to communicate the results of its review to the Secretary of the Council of Ministers, without the possibility of requesting further clarifications and additions, or of issuing a notice of impediment, given that the rules of 'Art. 9, Para. 3 do not apply'.[207]

Interestingly, the 'simplified' procedure laid down in Art. 10 has not found favour with the Council of State, which has called for 'realism' when dealing with the AIR in respect of decree-laws.[208] According to the Council,

205 According to the Guidelines, the administration may always perform a broader assessment and carry out further steps as envisaged for the impact analysis of other types of regulatory measures. *See* Guidelines, Section 6, p. 24.

206 Reg., Art. 10, Para. 1. Para. 2 further adds: "The proposing Administration drafts the AIR report, which documents the analysis referred to in Para. 1 and the results of the evaluations carried out".

207 *Ibid.*, Para. 3.

208 Consiglio di Stato, *supra* note 3, Para. 65.

> the execution of the AIR, at best, would be completely superfluous, given that it inevitably would be limited to a surreptitious justification of policy decisions already taken; in the worst case scenario, however, the AIR could affect the prompt regulatory action of the government.

Furthermore, the Council noted that if the decree-laws were preceded by a thorough AIR carried out for an appropriate time, it may even be possible to question the existence of the requirements prescribed by the Constitution for their issuance, and, therefore, their constitutional legitimacy.[209] In view of the foregoing considerations, the Presidency of the Council of Ministers was invited to consider whether or not to retain the provisions of Art. 10, taking also into account the possibility of foreseeing the AIR on decree-laws as optional.[210] Notwithstanding the Council of State's reservations regarding Art. 10, this article has been retained in the final version of the Regulation.

IV Participation in the Impact Analysis of EU Legislation. The AIR in the 'Ascending Phase'

A significant part of national legal norms originates from rules designed at the European level. That is the reason why the Regulation contains specific provisions (Art. 11) that aim to enhance the role of the administrations in the 'ascending phase' of the EU lawmaking process.[211] Before looking at these provisions, it should be recalled that the modalities of Italy's participation in the formation of decisions and the preparation of acts of the European Union, as well as the fulfilment of obligations and exercise of powers deriving from EU membership, are

209 Pursuant to Art. 77 of the Constitution, decree-laws are to be used only in 'extraordinary cases of necessity and urgency'.

210 The powers of the Council of State, however, do not exclude the possibility that in certain situations, which are not specifiable in advance, it may be warranted to carry out an AIR for decree-laws. This may occur, for instance, when a social or economic problem, which has long been studied by the Government, has suddenly become an urgent matter that needs to be rapidly addressed by primary legislation.

211 In Italian legal scholarship, the concept of 'ascending phase' refers to a set of rules and procedures that govern the Italian participation in the formation of EU law and policies. Additionally, some authors distinguish between two main stages of the ascending phase: a) a sub-phase involving the elaboration of the Italian position in Europe, which consists of policy-setting and fact-finding procedures; and b) a sub-phase concerning the representation of this position at the European level. By contrast, the 'descending phase' refers to the rules through which the constitutional and administrative bodies ensure compliance with the obligations imposed by EU law. In particular, the 'descending phase' includes three different regulatory actions: a) the transposition of non-self-executing EU rules into Italian law; b) the implementation of EU legal acts; and c) the repeal of domestic rules incompatible with EU law. Remarkably, Italian constitutional case-law also has adopted the same terminology. Referring to EU law, the Constitutional Court used the expression 'ascending phase' for the first time in Decision No. 239/2004. More recently, the 'descending phase' was addressed in Decision No. 63/2012. On this matter, R. Ibrido, 'Formulating and Implementing EU Law and Policies: "Ascending" and "Descending" Phases and Beyond', *in* N. Lupo & G. Piccirilli (Eds.), *The Italian Parliament in the European Union*, Oxford-Portland, Hart Publishing, 2017, pp. 55-66.

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governed primarily by law 24 December 2012 No. 234.[212] This legal act, which repealed the out-of-date law 4 February 2005 No. 11, represents a substantial overhaul of the rules governing the participation of Italian institutions in the formation and implementation of European policies and legislation. In fact, it takes into account the considerable changes stemming from the entry into force of the Lisbon Treaty, especially vis-à-vis the enriched role of parliaments in ensuring compliance with the principles of subsidiarity and proportionality.[213] Participation in the ascending phase is enhanced through a close coordination between the procedures set forth in the Regulation and those provided for by law No. 234/2012, with a view to strengthening the involvement of the Government and Parliament in the formation of the acts of the European Union.

The most effective way to influence the development of EU law is to participate in the stakeholder consultation procedures conducted at the European level, where consultation increasingly serves as a tool to define proposals and legal acts or amendments. For this reason, the Regulation provides that the administrations carry out an impact analysis on the draft acts of the European Union that have a significant impact at the national level[214] and make use of the results of such analysis to participate in the consultations launched by the European Commission.[215] In addition, the impact analysis may also provide relevant information in the framework of the legislative procedures of the Council of the European Union, particularly with regard to the Working Parties and other bodies (*e.g.* Coreper) responsible for considering legislative initiatives and for formulating proposals to the competent Ministers.

As explained in the Guidelines,[216] the impact analysis must be timely and selective. For the analysis to be of use, it should start as early as possible and be carried out consistently with the timing of the decision-making process of the European Commission. Therefore, within 30 days of the publication of the work

212 *Legge 24 dicembre 2012, n. 234 – Norme generali sulla partecipazione dell'Italia alla formazione e all'attuazione della normativa e delle politiche dell'Unione europea*, in *Gazzetta Ufficiale* 4 January 2013 No. 3.

213 *See* A. Kreppel, 'The Influence of the Chamber of Deputies on EU Policy-making', *in* N. Lupo & G. Piccirilli (Eds.), *supra* note 211, p. 278: "The Lisbon Treaty added to the potential of national legislatures to engage early in the legislative process through the Subsidiarity Control Mechanism, also known as the 'early warning system' (Lisbon Treaty, Protocol No. 2). This process is limited to areas of shared EU member state competence. At best, however, this process merely demands that the Commission reconsider its proposal in light of the subsidiary concerns of national legislatures".

214 Reg., Art. 11, Para. 1.

215 *Ibid.*, Para. 6. As part of its Better Regulation agenda, the Commission regularly consults with stakeholders, who can share their views on initiatives at key stages of the policy and lawmaking cycle, including at the initial stage (road maps and inception impact assessments), before the law becomes final (impact assessment of legislative proposals), as well as in the context of evaluations and 'fitness checks' of existing laws.

216 Guidelines, Section 7.2, p. 25.

programme of the European Commission,[217] administrations are required to notify DAGL of the list of draft acts on which they intend to carry out an impact analysis – or any subsequent changes to such list – and to initiate the analysis at the same time of the notification.[218] As regards the scope of the analysis, only strategic initiatives should be chosen, *i.e.*, initiatives that substantially affect national interests (also taking into account the government programme) or impact significantly on citizens and enterprises.

The AIR in the ascending phase, however, does not necessarily consist in the replication, at the national level, of the whole EU impact assessment, it being sufficient to focus on the most relevant and controversial aspects of the latter, by highlighting as much as possible the information, data, and, more in general, the empirical evidence in support of the Italian position.

For the purposes of the analysis, the administrations may also conduct consultations in accordance with Art. 28 of law No. 234/2012,[219] which aims to ensure the broadest possible involvement of social and economic stakeholders in the process of formation of the Italian position on the initiatives of the European Union. When considered necessary, or at the request of the competent administration or Technical Committee of Evaluation, DAGL may convene 'coordination meetings' for the performance of both the impact analysis and the consultations.[220] The consultation of national stakeholders, within the framework of the AIR in the ascending phase, helps to collect opinions and information that can:

a verify if and to what extent the problem that the Commission intends to solve is also relevant to national interests, highlighting in particular all the information that is not adequately considered at the European level;
b provide data that are as far as possible accurate and up-to-date on the direct and indirect recipients of the legislative proposal being considered by the Commission, highlighting any national peculiarities that may have an impact on the effectiveness or impacts of the European rules under discussion;
c suggest alternative options to those identified by the Commission, particularly with regard to changes that can ensure a more cost-effective approach for Italian citizens and businesses, or an implementation timetable that is more sustainable;
d assess the impact at the national level of the options developed by the Commission, as well as the main effects associated with alternative options that the Government intends to propose in view of the final proposal of the Commission or of the debate in the EU Council.[221]

217 Reg., Art. 11, Para. 3. The Commission sets out every autumn a plan of action for the next 12 months, which describes how political priorities will be turned into concrete actions. This facilitates a good advance knowledge of the legislative initiatives and consultations planned by the Commission. Commission work programmes available at https://ec.europa.eu/info/publications/european-commission-work-programme_en.
218 Reg., Art. 11, Para. 4.
219 *Ibid*., Para. 6.
220 *Ibid*., Para. 7.
221 Guidelines, Section 11.4.4, p. 51.

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After having been verified by DAGL (and, possibly, supplemented by the competent administration following validation), the results of the impact analysis are sent to the Department for European Policies[222] of the Presidency of the Council of Ministers and are included in the report referred to in Art. 6, Para. 4 of law No. 234/2012,[223] which is intended to provide the Parliament 'with qualitative and timely information' regarding the draft acts of the European Union.[224]

The ultimate goal of the impact analysis is to support the Inter-ministerial Committee for European Affairs (*Comitato Interministeriale per gli Affari Europei* – CIAE)[225] in its efforts to advocate for the amendment of proposals and draft acts of the Commission, or to influence the relative impact assessment with a view to stressing relevant effects for the Italian jurisdiction that have been ignored or not adequately appraised.

As stressed by the Council of State, strengthening participation in impact analysis procedures is also crucial for facilitating from the outset adherence to the principles of the Italian legal system, conformity with the structure and other

222 The Department for European Policies coordinates all governmental activities regarding Italy's membership in the European Union.

223 This provision stipulates that, as soon as they have been received by the President of the Council of Ministers or the Minister for European Affairs, the draft acts of the European Union and their amendments, as well as their preparatory acts, are transmitted to the Chambers of the Parliament. Within 20 days of the transmission, the responsible administration drafts for the Chambers a report that gives an account of the following: a) compliance of the draft act with the principle of attribution, particularly with regard to the correctness of the legal basis, and its conformity with the principles of subsidiarity and proportionality; b) overall evaluation of the draft act and the perspectives of the negotiation process, highlighting the points considered consistent with the national interest, and those for which changes are regarded as necessary or desirable; c) assessment of the financial impact of the draft act and of its effects on the national legal system, on the jurisdiction of the Regions and local autonomies, on the organization of the public administration and on the activities of the citizens and enterprises.

224 Reg., Art. 11, Para. 8.

225 The mandate of CIAE, which was established by law No. 234/2012 within the Department for European Policies, is to agree at the political level a unitary national position on EU legislative proposals and policies. The Committee is governed by the Decree of the President of the Republic No. 118 of 26 June 2015 (*Regolamento per il funzionamento del Comitato interministeriale per gli affari europei, istituito presso la Presidenza del Consiglio dei Ministri, a norma dell'articolo 2 della legge 24 dicembre 2012, n. 234*, in *Gazzetta Ufficiale* 6 August 2015 No. 181). CIAE is convened and chaired by the President of the Council of Ministers or, by virtue of a delegation of authority, by the State Secretary for European Affairs. Members of the Committee are the Minister of Foreign Affairs, the Minister of Economy and Finance, the Minister for Regional Affairs and other Ministers that are responsible for the measures and matters on the agenda. The President of the Conference of Italian regions, the President of the National Association of Italian Municipalities and the President of the Union of the Provinces of Italy may also participate when matters falling within their competence are discussed. The results of the meetings are set out in official documents ('position papers'), which are then supported in agreement with the Ministry of Foreign Affairs in all negotiations at the European level. CIAE is assisted by the Technical Committee of Evaluation (*Comitato Tecnico di Valutazione* – CTV), which prepares CIAE's meetings and coordinates the process of elaboration and implementation of the position papers. In particular, CTV collects the views of the administrations on issues under discussion in the European Union, defines the positions that will be expressed by Italy in the EU context, transmits those positions to the competent Italian representatives responsible for presenting them in the appropriate fora of the European Union and verifies that CIAE's decisions are implemented.

specific features of the Italian administrative system, and the capacity of the Italian state and non-state actors to comply with the new rules.[226]

J Evaluation of the Impact of Regulation (VIR)

I Scope of Application

Art. 2, Para. 1 of the 2009 VIR Regulation stipulated that the VIR is performed on all regulatory acts in respect of which an AIR has been carried out and, even in the absence of a prior AIR, on the legislative decrees and the laws of conversion of decree-laws, after a period of two years from their entry into force, and, thereafter, every two years. Nevertheless, this instrument was never fully implemented, with the result that the quality regulatory cycle is essentially *unfinished*: only in very rare cases has existing legislation undergone ex post evaluation.[227] Probably, the main reason behind the non-implementation of Art. 2, Para. 1 of the 2009 VIR Regulation lies in the fact that the two-year evaluation clause – which required the VIR for any measure that had been subject to AIR as well as for all legislative decrees and conversion laws – has proved to be rather *impractical*: the lack of prioritization of ex post evaluations, coupled with the absence of rules aimed at ensuring effective planning and timely implementation, have basically discouraged the administrations from undertaking evaluations more systematically.[228]

Drawing on internationally recommended practices,[229] the Regulation provides in Art. 12, Para. 1, a mechanism to overcome the aforementioned issues. In particular, each administration is expected to adopt, in consultation with DAGL, a two-year Plan (*Piano biennale per la valutazione e la revisione della regolamentazione*) on the evaluation and revision of regulatory acts in force concerning matters within its subject matter competence, for which it intends to undertake the VIR.[230] As the information available to the administration as well as the assumptions made in the Plan may no longer be relevant owing to a change of priorities or circumstances in the course of the two-year period, the Regulation also pro-

226 Consiglio di Stato, *supra* note 3, Para. 30.

227 Between 2013 and 2016, central administrations generated 59 VIR reports, whereas the number of AIR reports is far higher: 1.283 in the period 2007-2016. It is unknown how many ex post evaluations were undertaken by independent Authorities. *See* Senato della Repubblica, *supra* note 30, pp. 1, 2.

228 *See* OECD, *supra* note 7, p. 37: "As in most other EU countries, *ex post* evaluations have not been undertaken systematically."

229 One of the potential tensions that may emerge when organizing and carrying out ex post evaluations is about how much to evaluate. There is a "trade-off between quantity and quality – *i.e.* between the number of the evaluations and their relevance to decision making in terms of comprehensiveness (depth), timing, and hence the usefulness of the analysis. To address these tensions, there is a clear need to identify what to evaluate, when and how. A practical problem faced by any government is to identify the regulations that need to be reviewed. One approach is through regulatory planning. Sunset clauses can also be used as an automatic trigger for evaluation". *See* OECD, *supra* note 189, p. 16.

230 Reg., Art. 12, Para. 1.

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vides for the possibility to update the Plan.[231] In the initial stage, the latter will be adopted within 120 days of the publication of the Guidelines.[232] A template model for the preparation of the Plan is enclosed in Appendix 4 to the Guidelines.

According to Art. 12, Para. 1, last sentence, the Plan includes, regardless of whether an AIR has been previously carried out, laws of conversion of decree-laws, normative acts that contain an 'evaluation clause',[233] as well as acts (such as delegation laws) providing for the adoption of corrective or integrative measures.[234] The wording used – 'the plan includes' (in Italian, 'nel piano rientrano') not only suggests that the acts enumerated in Art. 12, Para. 1 are obligatorily included in the plan but also implies that acts other than those enumerated may also be included. In fact, the list is provided in advance of the rules concerning the criteria for the identification by the administration of the acts to be included in the Plan (Para. 7). It is therefore safe to conclude that Art. 12 distinguishes between regulatory acts that *are required* to be evaluated (Para. 1, last sentence) and those that *may be considered* for evaluation (Para. 7). Among the measures falling in the first category are, in addition to laws containing an explicit evaluation clause, the laws of conversion of decree-laws: it makes sense, indeed, that legislation adopted under fast-track procedures would always be subject to ex post evaluation. Less apparent, but equally understandable, is the reason why the list refers to normative acts that envisage the adoption of corrective or integrative measures. In this case, the inclusion is motivated by the need to support the Government in adjusting or refining delegated legislation, through an evaluation of the implementation of the decree-laws initially adopted, and is therefore closely connected with the specific nature of the legislative delegation in question.

231 Guidelines, Section 8.3, p. 30.

232 Reg., Art. 21, Para. 2.

233 An evaluation clause (*clausola valutativa*) is a specific article of a legislative act, which expressly mandates the (central or regional) Government to conduct an ex post evaluation of its implementation after a certain number of years and to inform the legislative assembly (Parliament or Regional Council) about the results of such evaluation.

234 The provision of a specific delegation to the Government, aimed at enabling it to amend or supplement, sometime after the entry into force of a legislative decree, the rules provided for by the latter, made its appearance for the first time in our legal system at the beginning of the 1970s, in the context of the legislative delegation for tax reform. However, this remained an isolated case for a long time: throughout the 1970s, and for a good part of the next decade, no new delegation of this kind was in fact given to the Government. In the 1990s the delegation laws enabling the Government to issue corrective legislative decrees became more frequent, also encouraged by the fact that the corrective delegation contained in the tax reform law had, in the meantime, in the mid-80s, substantially passed the scrutiny of legality by the Constitutional Court. *See*, among others, N. Lupo, 'Lo sviluppo delle deleghe e dei decreti legislativi "correttivi"' *Osservatorio sulle fonti 1996*, Torino, Giappichelli, 1996, pp. 1, 45-82. Corrective delegation is nowadays a consolidated practice of the Government: it has lost over time its exceptional character to become a common clause of legislative decrees and may also be found in the 'Law of European delegation', through which Italy, every year, incorporates the rules enacted by the European Union into its legal system. More specifically, Art. 31, Para. 5 of law No. 234/2012, which governs Italy's implementation of EU legislation, provides the legal basis for the adoption of integrative or corrective measures within 24 months from the date of entry into force of the legislative decrees implementing EU directives.

As regards the measures comprised in the second category, Art. 12, Para. 7 stipulates that the identification of the specific acts to be included in the Plan is made on the basis of several criteria, including the following: a) relevance to the objectives pursued by the policies that the acts relate to; b) significance of the effects, also with reference to those anticipated in the AIR report, where available; c) implementation issues and criticalities; d) changes in the socio-economic context of reference, including those arising from technological and scientific progress. The Guidelines further specify that the choice of acts submitted for the VIR takes into consideration the current status of implementation of the intervention, as well as the priorities of the government programme and legislative planning.[235] Actually, ExPER represents a valid aid for decision-making only if it is fully integrated into the legal reform process; hence, the 'prioritization' of acts to be evaluated, also on the basis of the legislative agenda of the Government, assumes paramount importance.

Taking stock of the difficulties encountered in the application of the 2009 VIR Regulation, when ex post evaluation was often undertaken on regulatory acts that could hardly be assessed in isolation from other related measures, and following the recommendations of the 'OECD Review of Better Regulation in Italy',[236] the Regulation expressly allows for execution of the VIR in respect of a *set of acts* that are 'functionally connected'.[237] Clearly, the scope of the evaluation is defined, in such circumstances, by interventions that share the same goals or recipients, thus contributing to the production of the same impacts. The simultaneous review of interrelated measures can give a broad overview of an area of regulation, enabling the administration to assess the degree of coherence and the overall ability to achieve the expected results. As such, it may be particularly use-

235 Guidelines, Section 8.2, p. 30.

236 OECD, *supra* note 7, pp. 22 & 68: "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". *See also*, European Communication, *supra* note 14, p. 7: "Various issues have come to the fore in the effort to strengthen evaluation and in the public consultation responses. Evaluations have traditionally examined individual funding programmes or pieces of legislation, with less attention being paid to evaluation of broad areas of legislation and cross-cutting issues".

237 Reg., Art. 12, Para. 5, first sentence.

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ful in the case of 'principles-based reviews',[238] as well as reviews on a specific sector or policy, which look at a wide range of regulation and are designed in such a way that a bundle of measures is evaluated at the same time. The fact that the VIR can scrutinize the 'cumulative' effects of regulatory acts, and may thus extend beyond the scope of single measures, has been positively appraised by the Council of State.[239]

With a view to ensuring an efficient use of resources, the VIR should focus (as in the case of the AIR) on regulation that may benefit more from a broad, in-depth and empirically grounded inquiry. However, this choice cannot be made by the responsible administration alone but also requires the contribution of stakeholders. For this reason, the Regulation states that the list of acts to be included in the Plan is drawn up "also taking into account the results of the [open] consultation referred to in Art. 18".[240] This provision takes into account the fact that stakeholder involvement can greatly assist the public administration in its efforts to identify priority areas for ex post evaluation.[241] In particular, prior to adoption the Plan is published in a dedicated section of the website of the administration that prepared it, and notice regarding the launch of the consultation is contextually given to DAGL.[242] Within a period of at least four weeks, anyone who has an interest can submit electronically, according to the modalities set forth by the administration, comments concerning the preliminary list of acts included in the

238 Principle-based reviews are a top-down approach to review regulations in a specific sector. In some countries they are designed and performed by the Prime Minister's Office and other sectoral ministries. Especially regulations concerning many ministries can be revised only through principles-based reviews. Principles-based reviews are planned and implemented with a clear objective that regulations shall be reformed and thus usually result in massive deregulation. In practice, a guiding principle is applied to screen all regulation for reform – for instance, removal of all statutory provisions impeding competition. *See* OECD, *supra* note 189, pp. 317-319. Interestingly, the majority of ex post evaluations conducted in OECD countries are of a principles-based nature. These are largely administrative burden reduction-based evaluations. Competition based-evaluations are the second most popular principles-based evaluations, followed by compliance costs-based evaluations. However, the OECD has argued that, while principles-based review provides an initial basis to expand the scope of ex post evaluation practices to assess economic and societal outcomes of policies more broadly, "countries could be more strategic and systematic in their evaluation efforts by conducting comprehensive reviews that assess the cumulative impact of laws and regulations in a sector as a whole, with a particular focus on the policy outcomes". This could entail an evaluation of an entire regulatory framework, such as education, health, energy, or small and medium-sized enterprises (SMEs). Moreover, countries should place a greater emphasis on evaluating the extent to which the policy goals that were initially identified have been achieved. *See* OECD, *supra* note 40, pp. 120 & 130.

239 Consiglio di Stato, *supra* note 3, Para. 28.

240 Reg., Art. 12, Para. 7.

241 As pointed out by the OECD, "[s]takeholders can be involved both in the process of identifying areas that may require reform as well as during the actual review process. […] A calendar of planned evaluations should be discussed with stakeholders and published regularly. This would further contribute to structure the official evaluation activity and to increase transparency and accountability". *See* OECD, *supra* note 40, pp. 121-122.

242 Reg., Art. 18, Para. 1.

Plan and the application of the criteria referred to in Art. 12, Para. 7,[243] as well as proposals for other acts to be included in the Plan before it is finally adopted.[244] Therefore, the selection of which regulatory measures should be subject to VIR is entrusted to both the competent administration and to the recipients who are involved through an ad hoc consultation procedure.

As noted in the Guidelines, the identification of the acts (or set of acts) to be evaluated is instrumental in arranging properly the working group referred to in Section 3 of the Guidelines, *i.e.*, equipping it with the necessary competences to organize and manage the evaluation: starting from a preliminary analysis of the rules subject to evaluation and their objectives, the working group should identify the main evaluation questions, the required information that is available or needs to be sought, the need for the involvement of additional professional resources and administrations, the modalities of consultation and the calendar of activities.[245]

After the consultation is carried out, the Plan is submitted to DAGL, which verifies its compliance with the provisions of Art. 12 and with the Guidelines.[246] The Plan sent out for validation shall include the following information:

a a list of acts or sets of acts that the administration intends to submit to VIR in the two-year reference period, divided by year;
b an indication, for each act or set of acts, of the primary reasons for which the administration considers it appropriate to conduct the VIR, having regard to the criteria referred to in Para. 7;
c an indication, for each act or set of acts, of any other administrations involved in the evaluation process;
d the expected start and end dates of each VIR;
e a summary of the consultation results referred to in Art. 18.[247]

In the case a VIR is not foreseen in the Plan, it must still be performed where so requested by the Council of Ministers.[248] A parliamentary committee may also request the preparation of an ex post evaluation in the exercise of its scrutiny and oversight function.[249]

243 The Regulation erroneously refers to Para. 8, which, on the contrary, specifies the information that the Plan shall contain.
244 Reg., Art. 18, Para. 2.
245 Guidelines, Section 9.1, p. 31.
246 Reg., Art. 12, Para. 9.
247 *Ibid*., Para. 8.
248 Reg, Art. 12, Para. 11.
249 *Ibid*.

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Unlike its predecessor,[250] the Regulation does not include specific instructions concerning the timing of the VIRs. Generally speaking, there are no strict rules in this regard, and much depends on the type and characteristics of the intervention. In practice, ex post evaluation takes place most often between 2 to 5 years after a law is adopted. Typically, laws to be selected for ex post evaluation must have been in force for at least one year.[251] For illustrative purposes, the Guidelines distinguish between interventions that have a predefined duration, such as time-limited business incentive schemes, and those that produce effects on an ongoing basis (*e.g.* regulations in the field of health and safety at work). In the first case, the evaluation can be conducted at the end of the intervention, when only some results have materialized, or a few years after its termination, when all or most of the expected effects have occurred (and it is therefore possible to verify the achievement of goals). In the second case, the evaluation is conducted after a period of time deemed appropriate for the occurrence of the main results of the intervention, in order to lead the process of revision of the legislation in force.[252]

The Plan is adopted, with ministerial decree, taking into account the results of the open consultation and the validation by DAGL, by 31 December of the year preceding the two-year reference period.[253] If the set deadline is not met, the Plan is adopted by the President of the Council of Ministers, with its own decree, within 30 days of the expiration of the said time frame.[254] Once adopted, the Plan

250 The 'two-year rule' provided for in Art. 2, Para. 1 of the 2009 VIR Regulation was in accordance with Art. 14, Para. 4, last sentence, of law No. 246/2005, which originally stated that the "VIR will be carried out after the two years from the date of entry into force of the law subject to evaluation. Subsequently, it is carried out periodically every two years". However, this provision was removed because of the changes made by decree-law 9 February 2012 No. 5, also known as *'Semplifica Italia'* decree (in *Gazzetta Ufficiale* 9 February 2012 No. 33 – *Suppl. Ordinario* No. 27), converted with amendments by law 4 April 2012 No. 35 (in *Gazzetta Ufficiale* 6 April 2012, No. 82 – *Suppl. Ordinario* No. 69).

251 As noted by the OECD, "[t]he timescale for evaluation will vary and may be contingent upon the individual law. […] Some laws may take considerably longer than others before evaluation can begin. Some may have immediate effects, others will have cumulative effects and others involve long term changes in behaviour and attitude. A period of up to five years may be needed for full impact to show if there is a slow accumulation of results". *See* OECD, *supra* note 163, p. 16. The matter at hand has also been addressed by the Council of State, which notes that for each measure subject to evaluation the date of performance of the VIR should be fixed in advance in a year or two after entry into force. In addition, the Council refers to 'sunset clauses' and other regulatory mechanisms that could make a significant contribution to the 'fight against legislative inflation and pollution', thus improving the overall quality of the legal system. According to the Council, such a review mechanism exists already in the Italian legal system, although it has seemingly never been applied in practice. This mechanism is foreseen in Art. 13-*bis*, Para. 3 of law No. 400/1988, which stipulates that "periodically, and at least every seven years, codes and single texts shall be updated based on the same criteria and procedures laid down in Art. 17-*bis*, by making appropriate highlights in the body of the updated text". *See* Consiglio di Stato, *supra* note 3, Para. 65.

252 Guidelines, Section 8.1, p. 29.

253 Reg, Art. 12, Para. 2.

254 *Ibid*., Para. 3.

(or any update) is published on the websites of the Government and of the administration that oversaw its preparation.[255]

II The Process

1 VIR Methodology

In accordance with Art. 13, Para. 1 of the Regulation, the VIR involves several phases:

a analysis of the current situation and problems, using quantitative data and also checking the status of implementation of the legislation, having regard to the different levels of government involved, where appropriate;[256]

b description of the intervention logic in relation to problems expected to be addressed and objectives intended to be achieved, actions undertaken, subjects directly and indirectly involved and progress achieved in the relevant context;

c evaluation of the intervention, by applying the following criteria: 1) *effectiveness*, by verifying the degree of achievement of objectives and the extent to which the observed effects originate from the regulation that is being evaluated, or derive from other circumstances that have occurred over time; 2) *efficiency* in relation to resources used; 3) continuing *relevance* of the regulation with respect to the needs and the objectives of current policies; 4) *coherence* of the set of rules governing the relevant sector, also in view of gaps, inefficiencies, overlaps and excessive regulatory costs;

d formulation of possible suggestions for revision, repeal and improvement of the implementation of the regulatory act, taking into account the results of the evaluation.

Based on the Guidelines,[257] the first phase of the VIR consists of the analysis of the current situation, with particular attention to the underlying problems and the changes that have occurred in respect of the circumstances existing at the time of the introduction of the rules subject to evaluation – the 'baseline' for the evaluation. In the analysis of the current situation, the VIR should consider the

255 *Ibid*., Para. 10.

256 It is interesting to note that the Regulation places the evaluation of the status of implementation, including the compliance test, under the analysis of the current situation and problems, while it would make more sense, also in line with international best practice, to address matters of implementation and compliance when assessing the intervention against the effectiveness indicator. For instance, the Code of Good Regulatory Practice provides a series of criteria, such as effectiveness, which have to be observed for ex post evaluation of regulations in New Zealand. Among the effectiveness guidelines is the 'reasonable compliance rate': "A regulation is neither efficient nor effective if it is not complied with or cannot be effectively enforced. Regulatory measures should contain compliance strategies which ensure the greatest degree of compliance at the lowest possible cost to all parties. Incentive effects should be made explicit in any regulatory proposal." *See* OECD, *supra* note 163, p. 86. *See also* OECD, *supra* note 40, p. 40: "Regulatory implementation and enforcement remain the weakest link in regulatory governance. Focusing on increasing compliance with regulations would help to improve the effectiveness of regulation at achieving its goals and, ultimately, would strengthen the case for regulatory quality."

257 Guidelines, Section 9.2, pp. 31-32.

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legal, socio-economic and territorial dimensions. As in the case of the AIR, the assessment must be supported by quantitative evidence and by the findings of the consultations carried out.

At this stage, it is also critical to identify any obstacles, shortcomings, inconsistencies in the implementation of the legislation under scrutiny, which may be one of the causes (if not the primary factor) affecting the effectiveness of the intervention. The implementation analysis consists of two stages:

1 assessment of whether the administrations have undertaken the actions foreseen by law, *i.e.*, adoption of implementing regulation by all different levels of government involved and of any other measures necessary for the operationalization of the intervention, *e.g.* setup of control systems and digitalization of procedures;
2 evaluation of the degree of compliance (distinguishing, where appropriate, between territories, economic sectors, social groups, etc.), the underlying reasons for non-compliance and the modalities of compliance by regulated parties.

In this phase, in addition to the evidence drawn from monitoring activities and from existing or ad hoc surveys, information obtained from the AIR report and through consultation is essential.

Each regulatory intervention is designed to pursue specific goals and provides a range of tools to achieve them, *i.e.*, performance of certain actions by the responsible administration and/or the imposition of certain obligations on the final recipients. It therefore relies on assumptions about how the envisaged actions and obligations will determine the desired outcomes also on the basis of anticipated behavioural reactions. Taking this into consideration, the Guidelines clarify that the second phase of the VIR consists of the preparation of the 'intervention logic' – the objectives-tools-expected results sequence – which provides a graphical description of the cascade of cause and effect leading from an intervention to its desired effects. The elements, both qualitative and quantitative, that make it possible to develop the intervention logic can be inferred from the AIR previously performed, if available. The AIR report, in fact, should contain the definition of the objectives, the description of the intervention and the assessment of expected effects. In the absence of a prior AIR, such strands of information can be pulled together, retrospectively, through the analysis of the content of the intervention, the explanatory reports and the information obtained through consultation or from the framework analysis.[258]

258 Guidelines, Section 9.3, pp. 32-33. The Guidelines do not contemplate, even though it would have been advisable, that the Intervention Logic should be accompanied by a description of the Theory of Change (TOC) – *i.e.* a 'narrative' explanation of how the intervention is expected to work, including the assumptions that must hold for the change to happen, as well as the identification of potential risks and factors most likely to inhibit the change from happening. In fact, the Intervention Logic and TOC provide together a 'powerful' benchmarking tool for developing the greater part of the evaluation.

The next phase of the VIR represents the core of the evaluation. As explained in the Guidelines,[259] the evaluation is carried out on the basis of four criteria,[260] which correspond to the following 'evaluation questions':

1 *Effectiveness*:[261] The effectiveness criterion aims to determine whether, and to what extent, the regulatory intervention has achieved the intended objectives or whether there have been any deviations from the expected results. In the event of such deviations, the factors and causality links that have led to alteration of the effects of the intervention, in comparison with what was expected or desired, must be clearly identified. In a sense, the 'intervention logic' is critically reviewed in the light of the changes observed. However, in order to evaluate properly the effects of an intervention, one should determine the extent to which such intervention has actually contributed to the achievement of the changes observed, distinguishing between exogenous causes and those that are inherent in the formulation and implementation of the rules. In fact, the situation that one observes at the time of the evaluation may incorporate changes that would have occurred even in the absence of the intervention as a result of factors unrelated to it. Therefore, the effects attributable to an intervention are given by the difference between what happened after its adoption ('factual situation') and what would have happened anyway ('counterfactual situation'). In essence, the VIR should evaluate the 'additional' effects of the intervention – *i.e.*, the changes, expected or not, that can be directly attributed to it, exclusive of the influence exerted by other external factors – and the reason why they occurred.[262] The achievement of objectives is to be measured, as far as possible, on the basis of quantitative and qualitative indicators. As a rule, indicators can be inferred from the AIR report. Where the AIR has not been carried out (or in the case of decree-laws, in relation to which it is not mandatory to have indicators), indicators will have to be defined on the basis of an analysis of the objectives of regulation and the results expected by the regulator. Once the indicators have been identified, the current value of each indicator should be compared with that expected. To this end, it is good practice to first identify the data necessary for the calculation of the indicator and then check whether they are already available. This is typically the case of data collected in the course of the monitoring required by the AIR or otherwise acquired by the administra-

259 Guidelines, Section 9.4, pp. 33-34.

260 As noted in the Guidelines, it may be necessary to use additional criteria to evaluate an intervention. As in the case of the AIR, the evaluation may refer to specific aspects provided for by law No. 245/2005 – *i.e.*, impact on SMEs, administrative burdens, effects on competition, gold-plating – or even other evaluation criteria, such as fairness – between genres, generations, territories, or specific social groups; complementarity and coordination with other policies; capacity to promote or reduce research and innovation; sustainability, in relation to the permanence of the changes produced; usefulness and acceptability from the point of view of the recipients. *See* Guidelines, Section 9.4, pp. 34-35.

261 Guidelines, Section 9.5.1, pp. 35-36.

262 Guidelines, Section 9.4, pp. 33-34 and Section 9.5.1, pp. 35-36.

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tion. In the absence of a monitoring system, it is still possible to rely on existing information or data collected for other purposes (*e.g.* a statistical source).

2 *Efficiency*:[263] Determining whether regulation is effective is not sufficient per se: ex post evaluation should also seek to determine whether regulation has achieved its objectives efficiently. A regulation that produces the intended effects but at an unreasonable cost cannot be regarded as quality, smart or sustainable regulation. The efficiency with which objectives are reached is, indeed, of as much importance as reaching those objectives. For this reason, the Guidelines provide that the evaluation should identify and analyse the positive and negative effects of the intervention, *i.e.*, the 'costs' and 'benefits' associated with the regulation, in relation to each category of recipients.[264] More specifically, one should assess the regulatory costs (administrative, compliance, etc.), whether foreseen or not, deriving from the effects of regulation. The purpose of this assessment is not only to determine whether costs are justified, but also to identify costs that can be reduced or eliminated, without prejudice to the achievement of objectives, through measures of simplification and administrative burden reduction. Particular attention should be paid, at this stage, to 'unintended' effects, *i.e.*, effects of regulation not anticipated by the regulator at the time of formulation.

3 *Relevance*:[265] The VIR cannot limit itself to analysing the extent to which regulation has achieved its objectives and to the identification of regulatory costs and benefits. It is equally important to understand whether, and to what extent, the original goals correspond to current needs and policies. The latter may have changed, in fact, from the time the intervention was formulated as the factors (legal, social, economic, environmental and technological) that underpin the need to regulate are, by their nature, evolving constantly. Consequently, the framework analysis made in the early stages of the AIR is the most valuable asset to assess regulation against this criterion. Clearly, the relevance criterion requires more and more in-depth analysis as the distance increases between the time of the evaluation and that of the formulation of the intervention.

4 *Coherence*:[266] Another essential criterion for the evaluation of an intervention – and, in particular, of a group of interventions – is represented by its degree of coherence, both internal and external. 'Internal coherence' refers to the possible presence of inconsistencies, overlaps and redundancies among the rules subject to evaluation. On the other hand, 'external coherence' refers to the possibility of inconsistencies, overlaps and redundancies between those rules *and* the broader regulatory context. Hence, the analysis of the current situation, and, above all, of the legal dimension, may be particularly useful.

263 Guidelines, Section 9.5.2, pp. 36-37.

264 The analysis of the distribution of costs among the various categories of recipients can shed light on the existence of inequalities and sustainability issues (for example, for the SMEs).

265 Guidelines, Section 9.5.3, p. 37.

266 Guidelines, Section 9.5.4, p. 37.

Each evaluation question is answered on the basis of the original rationale of the intervention, the analysis of the current situation and the outcome of consultations.[267] Any difficulty or uncertainty in answering them should be reported and described with maximum transparency in the VIR report.[268] In the identification, quantification and analysis of the effects of regulation, and especially of unexpected ones, a key role is played by stakeholder consultation. It is imperative, however, that the assessments made in the context of the VIR are not based exclusively on the opinions of interested parties, which should always be subject to verification, *i.e.*, analysed accurately and, where possible, triangulated with statistical data or other objective sources of information.[269]

The last phase of the VIR is dedicated to drawing conclusions from the results of the evaluation and to providing recommendations concerning the validation, repeal or revision of legislation. In the case of suggested changes, it is critical to identify the areas in which an opportunity for intervention has arisen. This phase, thus, can also extend to include the formulation of some initial ideas about possible ways to improve the ability of regulation to achieve its objectives, to adapt the intervention to a change in the circumstances, or to introduce amendments aimed at reducing the costs for recipients. In addition to legislative changes, proposed solutions may also pertain, where appropriate, to the modalities of implementation (for instance, administrative, organizational or technological interventions).

2 Preparation of the VIR Report

Pursuant to Art. 14, Para. 1 of the Regulation, the administration draws up the VIR report that documents the various phases referred to in Art. 13, Para. 1 (as explained above) and the evaluation results.

For the purpose of preparing the VIR report, the administration *always* resorts to consultation as stated in Art. 16, Para. 1.[270] It also makes use of quantitative data, including those that can be inferred from reports previously issued by control and supervisory bodies,[271] and takes into account the findings of any other analysis, however denominated, carried out in the context of monitoring and assessing the regulation subject to evaluation.[272]

In order to facilitate the process of organizational learning and ensure the progressive improvement of the VIR reports and the capacity to use them within the decision-making process, the Guidelines advise each administration to perform a 'self-evaluation' on the evaluations performed in a given period (*i.e.*, a maximum of two years). This evaluation should serve as a means of identifying the main strengths and shortcomings, with a view to disseminating information regarding the solutions that have proved most effective and taking appropriate

267 Guidelines, Section 9.3, p. 35.
268 Guidelines, Section 9.5.1, p. 36.
269 Guidelines, Section 9.5.2, p. 36.
270 Reg., Art. 13, Para. 2.
271 *Ibid*., Para. 2.
272 *Ibid*., Para. 3.

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corrective measures with respect to weaknesses. An indicative set of questions that the self-evaluation may address is provided for in the Guidelines.[273]

3 Validation of the VIR Report by DAGL

As for the AIR, the responsible administration submits the draft VIR report to DAGL, which verifies the appropriateness and completeness of the analysis and the correctness of the assessments carried out and of the evaluation methods applied. DAGL may request additions and clarifications from the administration, for the purposes of validation of the VIR report.[274]

4 Publication and Submission of the VIR Report to Parliament

As soon as it is validated by DAGL, the VIR report is published on the website of the administration that conducted the evaluation and on the website of the Government.[275]

Similarly to the 2009 VIR Regulation,[276] the Regulation provides that, after validation, the VIR report shall be forwarded to Parliament as the last step of the procedure.[277] As will be further explained in Section K of this article, besides serving as a Better Regulation tool, ExPER is also an important instrument for increasing government accountability. For this reason, some national parliaments carry out their own ex post evaluations of legislation and policies, while others merely scrutinize, to a greater or lesser extent, the evaluations performed by the Government. As pointed out by the OECD, even where parliaments are not primarily responsible for ex post evaluations, "[p]eriodic appraisals of the performance of the evaluation function should be carried out by independent bodies and parliaments should hold the executive accountable for the evaluation process and outcome".[278]

There is no uniform model for ExPER institutional arrangements at the parliamentary level. Ex post evaluation can be undertaken using a range of organizational structures, some formal, others more ad hoc. Although some parliaments do have units dealing with evaluation, many others do not, and use instead a mixture of committees, research services and other bodies to undertake ex post

273 Guidelines, Section 9.8, p. 38.
274 Reg., Art. 14, Para. 2.
275 *Ibid*., Para. 3.
276 2009 VIR Regulation, Art. 4, Para. 1.
277 Reg., Art. 14, Para. 3.
278 *Ibid*., p. 122. In some countries, like Australia or Canada, one central motivation of ex post evaluation by the legislature is to assess the effectiveness of RIA and seek improvement from the executive when shown to be required.

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evaluation.[279] As far as the Italian Parliament is concerned, the Senate of the Republic established, on 1 August 2017, the Impact Assessment Office (*Ufficio Valutazione Impatto* – UVI), chaired by the President of the Senate, whose mandate is to disseminate, develop and foster the evaluation culture across the institutional landscape. The Office carries out public policy evaluations, which are performed by an ad hoc working group employing the Senate's staff and experts from other institutions, aimed at helping lawmakers to make better laws, by providing them with an objective assessment of risks, costs, benefits and effectiveness.[280]

III VIR and Monitoring

As with RIA and ExPER, monitoring is an essential tool to improve regulatory quality. It has been noted that "RIA is the initial link in a chain in which monitoring of implementation and ex post assessment of regulation help to close the regulatory governance cycle".[281] As an intermediate step, monitoring follows the analysis carried out prior to the adoption of a measure and precedes the evaluation of its implementation. Monitoring can be defined as an ongoing and systematic process of data collection regarding the implementation of a regulatory measure, which generates information that otherwise would be extremely difficult or expensive to obtain.[282]

In connection with the VIR, the Council of State has frequently highlighted the key importance of monitoring for the purposes of adequate maintenance and

279 *Ibid*., p. 26. A number of European countries have already established evaluation units or services within their parliaments. These include Belgium, Sweden, Switzerland (and, more recently, Italy). Similarly, at the EU level, the 'Unit for Ex Post Impact Assessment' was established in 2013 in the Directorate-General for Parliamentary Research Services of the European Parliament. However, in many European countries ex post evaluation is performed mainly at the committee level (*e.g.* UK, France, Montenegro). For an overview of ExPER practices in 10 different countries, *see* F. De Vrieze & V. Hasson, *Post-Legislative Scrutiny: Comparative Study of Practices of Post-Legislative Scrutiny in Selected Parliaments and the Rationale for Its Place in Democracy Assistance*, London, Westminster Foundation for Democracy, 2017.

280 Since its foundation, UVI (*see*www.senato.it/4744) has published some 30 dossiers, 39 monthly economic and financial newsletters and 34 studies illustrating evaluation experiences in Italy, Europe and several OECD countries. UVI is also responsible for a (2nd level) Master in analysis and evaluation of public policies. In September 2017, UVI was the first parliamentary body in Europe to adopt, after submitting them for consultation, guidelines on public consultations, aimed at reducing the distance between citizens and institutions and gathering stakeholder feedback on public policies implemented by the Government. Through the support of the Senate and a network of contacts and collaborations with prestigious institutions such as the World Bank, the Global Parliamentarians Forum for Evaluation, Venice Ca' Foscari University and the University of Pennsylvania, in less than one year UVI has gained the respect of mass media as an impartial and credible voice. *See* Senato della Repubblica (Ufficio Valutazione Impatto), '2017-2018. Un anno di valutazione in Senato', August 2018.

281 OECD, *supra* note 40, p. 95.

282 According to the OECD, monitoring "refers to the continuous assessment of implementation in relation to an agreed schedule" and is "concerned with the systematic collection of data on specified indicators of policy interventions that provide administrative management, affected parties and other stakeholders with an indication of progress and achievement of the objectives". *Ibid*., p. 124. *See also*, European Commission, *supra* note 13, pp. 44-45.

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proper functioning of the regulatory system.[283] Monitoring enables regulators to observe, dynamically, the evolution of the problems addressed by regulation,[284] which facilitates the adjustment to circumstances as they arise and the correction of the flaws that emerged in the initial stages of the application of a regulatory act.[285] Furthermore, monitoring allows the recording of both best practices deserving dissemination and worst practices that should be ceased or avoided.[286]

Monitoring is an essential tool for a meaningful ex post evaluation of regulatory interventions. The need for the VIR to be coupled with monitoring to be feasible and effective is acknowledged in the Regulation: Art. 12, Para. 6 provides that the administration shall ensure that the implementation of regulatory acts is constantly monitored through the collection and processing of information and data required by the VIR, "with special regard to those relative to the indicators identified in the respective AIRs". This means that monitoring activities must be developed on the basis of the indicators previously developed in the AIR report. As explained in the Guidelines, the administration should determine, already in the context of the ex ante analysis, in which way it will monitor whether the actions required to implement a measure have been undertaken and the expected effects have occurred.[287] Therefore, indicators include both indicators that define progress in the implementation of the intervention ('procedural indicators') and indicators that determine the extent to which the objectives of the intervention are being achieved.[288]

In this respect, the Regulation clearly reflects current trends as it is an emerging good practice, when carrying out a RIA, to include a choice of indicators that

283 *See e.g.* opinion No. 1784 of 4 August 2016.

284 Consiglio di Stato, *supra* note 3, Para. 33.

285 *Ibid*., Para. 18.

286 *Ibid.*

287 The explanation given in the Guidelines for planning monitoring in advance is that it helps to: a) identify, from the early stages of preparation of the intervention, the steps required to ensure a consistent and timely implementation; b) make timely arrangements not only in terms of internal staff but also as regards coordination between different levels of government, with a view to ensuring that relevant information (which would help to verify whether implementation is proceeding as planned and results produced are consistent with expected ones) are generated in such a way that it is possible to take prompt corrective actions; c) reduce costs: the planning and timely commencing of monitoring activities is far less onerous than a belated data collection activity, which can often meet insurmountable obstacles or require expensive research. *See* Guidelines, Section 5.6, p. 21.3

288 On such indicators, *see* Guidelines, Section 5.2, p. 14.

will form the basis of future monitoring and evaluation activities.[289] As noted by the OECD,[290] RIA

> is supposed to serve mainly at the stage of designing new regulations. However, the forward-looking perspective is substantially requested while conducting RIA. More specifically, it needs to clarify the ways and indicators in relation to how to monitor and evaluate a regulation that has been introduced and enforced. In view of the policy cycle, a well-designed monitoring and evaluation roadmap in RIA can make it possible to identify policy issues for government actions easier and more clearly when the regulation is being enforced.

IV Participation in the Evaluation of the Impact of EU Legislation

In parallel with the provisions regarding the participation in the ex ante impact analysis of EU legislation, the Regulation provides rules (Art. 15) intended to promote the participation of administrations in the ex post evaluation of the impact of EU legislation. According to Para. 1,

> [t]he Administrations participate, in their respective fields of competence, and even involving other levels of the government, in the evaluation activities launched by the institutions of the European Union, with specific regard to those related to rules governing areas of particular importance to national policies.

Before taking part in the evaluations carried out by the European Commission, the administration is required to inform DAGL, the Department of Public Function and the Department for European Policies of the Presidency of the Council of Ministers.[291]

Over the last few years – as reported in the Guidelines[292] – the European Commission has put in place, also as a result of repeated calls by the EU Council, a complex system of ex post evaluation of EU legislation within the framework of

289 OECD, *supra* note 40, p. 101. For instance, the Better Regulation Guidelines of the European Commission (*see supra* note 13) require that new regulatory proposals should identify how actual impacts would be monitored and evaluated. They specifically state that "[h]aving the entire policy cycle in mind, the IA [impact statement] should identify monitoring and ex post evaluation arrangements to track whether the policy measure actually delivers the intended results and to inform any future revisions of the policy. At the end of this process, policy-makers should know how the policy will be monitored and evaluated, allowing for future policy-adjustments whenever needed". The guidelines also specify that indicators must allow measurement of the extent to which the objectives of the policy have been achieved and potential negative impacts. Additionally, "underlying data should be easily available and the cost of data collection, proportionate. If lack of data was a significant concern for the IA, the IA Report should sketch out how this issue will be addressed for the future policy evaluation". *See* European Commission, *supra* note 13, pp. 29-30.

290 OECD, *supra* note 189, p. 241.

291 Reg., Art. 15, Para. 1.

292 Guidelines, Section 10, p. 38.

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the REFIT programme.[293] The (ex post) evaluation of legislation has, alongside (ex ante) impact assessment, a growing role in the reform of the EU regulatory framework, as confirmed by the 'evaluate first' principle underscored by the Commission in the 2015 Better Regulation agenda.[294]

Participation in REFIT activities (or other evaluation initiatives at the EU level, however denominated) represents a great opportunity to support actions aimed at reducing unnecessary or excessive burdens, simplifying the regulatory framework or facilitating its codification, in line with national priorities and interests. The administrations can participate in the REFIT programme through the same channels already described with regard to the AIR in the ascending phase. This includes, in particular, contributing to the working groups and consultations arranged by the institutions of the European Union.[295] In addition, the administrations may take part in the so-called 'REFIT platform'.[296]

As for the AIR in the ascending phase, participation in the evaluations carried out by the Commission should focus on EU legislation governing matters that are of special importance to national policies, either because they are particularly relevant to policy priorities or because of their significant impact on citizens or businesses. To this end, the administrations proceed as early as possible to identify the REFIT initiatives that are considered strategic by reviewing the Commission work programme and, in particular, 'Annex 2: REFIT initiatives'.[297]

The effectiveness of the participation in European evaluation processes, in the context of both the REFIT programme and other evaluation initiatives,

293 Through this programme, the Commission reviews and carries out maintenance of the stock of regulation in force in order to ensure that EU regulation is always 'fit for purpose'. The relative actions are described in the Commission work programme and may include new legislative initiatives (*e.g.* simplification rules), repeals or withdrawals of previous initiatives (including pending legislative proposals), as well as fitness checks.

294 Before revising or introducing legislation, the Commission has undertaken to evaluate existing policies. In 2016, evaluations were carried out for just under 50% of impact assessments. The 'evaluate first' principle has been more widely applied in 2017: 75% of the impact analyses were supported by an evaluation, which is a considerable increase compared with 2016. *See* Regulatory Scrutiny Board (RSB), Annual Report 2017.

295 Reg., Art. 15, Para. 2.

296 Guidelines, Section 10.2, p. 39. The REFIT Platform is a discussion forum, set up by the May 2015 Better Regulation Communication (C(2015) 3261 final, 19 May 2015), which brings together the Commission, national authorities and other stakeholders in regular meetings to improve existing EU legislation. It therefore supports the process of simplifying EU law and reducing regulatory burdens, for the benefit of civil society, business and public authorities. Platform members' work includes reviewing suggestions received via the online 'Lighten the load – Have your say' form and making recommendations to the Commission. The REFIT Platform consists of a Government Group, with one seat per member state and a Stakeholder Group with 18 members and two representatives from the European Social and Economic Committee and the Committee of the Regions. The implementation of the REFIT programme is subject to a periodical evaluation: the Commission publishes annually a scoreboard on the results achieved, the actions undertaken and those planned, and takes into account the changes introduced by the European Parliament and the EU Council during the legislative procedure. For more information, *see*https://ec.europa.eu/info/law/law-making-process/evaluating-and-improving-existing-laws/refit-making-eu-law-simpler-and-less-costly/refit-platform_en.

297 Guidelines, Section 10.2, p. 39.

depends crucially on the consultation of national stakeholders. Before participating in the evaluations carried out by the Commission, the administrations are expected to assess the effects of EU legislation at the national level.[298] As clarified by the Guidelines,[299] the administration carries out an evaluation of the national impact of the initiatives selected, with specific reference to the following:

a the effectiveness of EU legislation, which is assessed on the basis of the degree of achievement of its goals;
b the difficulties encountered in the implementation (including those related to non-compliance), describing, in particular, those directly arising from the EU rules; those resulting from their transposition; and those associated with administrative implementation;
c the main positive and negative impacts produced by European regulation at the national level on its main recipients, highlighting, in particular, unjustified or disproportionate costs; effects on competitiveness; inconsistencies with other legal provisions.

In order to collect the relevant data, opinions and evidence, the administrations have to consult the national recipients of the legislation under evaluation[300] and, with respect to matters falling within their respective competences, the regional or local authorities.[301] For sectors involving independent Authorities, the evaluation is performed in liaison with such authorities.[302] When considered necessary, or at the request of the competent administration, DAGL may convene coordination meetings to conduct the evaluation and related consultations of social partners and economic categories.[303]

The evaluation results shall be promptly reported to DAGL, for the purposes of validation, as well as to the Department of Public Function and the Department for European Policies.[304] According to the Guidelines, the aforesaid results may be used by the administration not only to take part in the evaluations carried out by the Commission but also in the context of the work of the EU Council, in order to support the Italian position, including proposals for the amendment of the draft acts under examination.[305]

298 Reg., Art. 15, Para. 2.
299 Guidelines, Section 10.2, pp. 39-40.
300 Reg., Art. 15, Para. 3.
301 Guidelines, Section 10.2, p. 40.
302 *Ibid.*, p. 40.
303 Reg., Art. 15, Para. 4.
304 *Ibid.*, Para. 5.
305 Guidelines, Section 10.2, p. 40.

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K The Annual Report to Parliament

Lawmaking is a responsibility that governments share with parliaments, which play a growing role in regulatory quality.[306] The OECD Regulatory Policy Outlook 2015 notes that "[a]s the institutions responsible for approving legislation, parliaments can exercise oversight and control over the application of better regulation principles for new and amended regulation".[307] Moreover, through the public debate on proposed laws and amendments, parliaments contribute to a transparent dialogue on new and amended regulation, and through the control they exercise on public expenditures and government performance, they can help monitor the effectiveness and efficiency of legislation.[308]

One way to ensure regulatory quality oversight is to forward RIA and ExPER reports to Parliament for review. The Regulation provides for the submission of AIR and VIR reports to Parliament in Art. 9, Para. 7 and Art. 14, Para. 3, respectively. This form of parliamentary scrutiny has already been discussed in Sections I.II.5 and J.II.4 of this article. Regular progress reports to Parliament represent another modality of government oversight, along the lines of the 2012 OECD Recommendation on Regulatory Policy and Governance, which recommends to "regularly publish reports on the performance of regulatory policy and reform programmes", and adds that such reports "should also include information on how regulatory tools such as Regulatory Impact Assessment (RIA), public consultation practices and reviews of existing regulations are functioning in practice". Under the 2008 AIR Regulation,[309] DAGL was tasked with the preparation of the annual report of the President of the Council of Ministers to Parliament referred to in Art. 14, Para. 10 of law No. 246/2005. Based on the strict formulation of this provision of law, which refers to 'the status of application of the AIR' only, the 2009 VIR Regulation did not envisage a similar requirement. In order to overcome this gap, the Regulation goes beyond the *litera legis* and, in view of a policy cycle approach, prescribes an annual report to Parliament on the application of both the AIR and the VIR tools.[310]

According to Art. 14, Para. 10 of law No. 246/2005, the annual report is submitted to Parliament by 30 April. To this end, DAGL collects from each adminis-

306 OECD, *supra* note 40, p. 52. The 2012 OECD Recommendation on Regulatory Policy and Governance highlights that "[e]nsuring the quality of the regulatory structure is a dynamic and permanent role of governments *and Parliaments*" (emphasis added).

307 The arrangements adopted to institutionalize parliamentary oversight vary across countries. The functions and responsibilities of oversight bodies range from legal quality, RIA, ex post evaluation, administrative simplification, stakeholder engagement and other tasks such as coordination across the government or compliance with legal requirements. *Ibid.*, pp. 35-36.

308 The potential of parliaments, as non-traditional actors of regulatory governance, remains, however, untapped: there are still a number of jurisdictions where parliaments have not yet adopted regulatory quality practices. This translates into missed opportunities in the institutional setup of countries to promote regulatory reforms. As noted by the OECD, "Parliaments should be encouraged to set up their own procedures to guarantee the quality of legislation, such as consultation, RIA, and *ex post* evaluation." *Ibid.*, p. 52.

309 Art. 11, 2008 AIR Regulation.

310 Reg., Art. 19, Para. 1.

tration the relevant data and information by 31 March. However, the Regulation shortens this time limit by requesting each administration to provide DAGL with data and information regarding the previous year by the end of February.[311]

The annual report includes the following information:

a the number of AIRs and VIRs concluded;
b the number of cases of exclusion and exemption from the AIR;
c the number of AIR reports modified on request of DAGL, the Parliament or upon the advice of the Council of State in its advisory capacity;
d applied methodologies and organizational arrangements made by the administrations;
e the number of consultations made in the context of the AIR and VIR procedures and related methodologies;
f two-year Plans for the evaluation and revision of regulation and their updates;
g experiences relevant to the AIR and VIR of the institutions of the European Union, independent Authorities, Regions, local entities, also highlighting international best practices;
h any difficulties encountered by the administrations in the conduct of the AIR and VIR activities;
i initiatives for the improvement of institutional capacities in carrying out the AIR, VIR and the consultations.[312]

Together with the annual reports of the independent Authorities, DAGL's annual report is an important source of information on the progress and achievements in the implementation of the RIA and VIR tools, as well as the overall appraisal of Better Regulation initiatives in Italy.

311 *Ibid.*, Para. 2. The Department for Regional Affairs, after consulting, where necessary, the Unified Conference, provides information regarding the activities of regions and local entities. *See* Reg., Art. 19, Para. 2.

312 Reg., Art. 19, Para. 1. This provision substantially reproduces the content of Art. 11 of the repealed 2008 AIR Regulation, except that it also requires information on the newly introduced two-year evaluation Plan and on training initiatives aimed at improving institutional capacities. On the other hand, it is no longer necessary to include information on initiatives concerning the impact analysis and evaluation of the regulatory acts undertaken at the parliamentary level.

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L The Council of State's Opinion

On 19 June 2017, the Consultative Section for Normative Acts[313] of the Council of State issued opinion No. 807 on the draft Regulation.[314] While the Council of State highlights the positive changes brought about and expresses appreciation for the innovative contents of the draft Regulation, it does not refrain from pointing out persistent deficiencies and formulating proposals for modification, which have largely been taken into consideration in the final version of the Regulation. Examples include establishing special units to carry out the AIR and VIR activities, enhancing the role of DAGL, publishing a 'pre-AIR' document in case of resort to open consultation, and strengthening the circular approach to regulatory quality.

Nevertheless, the Regulation still presents some shortcomings highlighted in the opinion of the Council of State, as specifically concerns the execution of the AIR.[315] For instance, the Regulation does not envisage recourse to newly emerging regulatory tools – such as 'behavioural economics'[316] – to foster better compliance, nor does it endorse the use of the so-called 'regulatory budget' provided for in Art. 8 of law No. 180/2011[317] – a mechanism designed to reduce regulatory burdens by offsetting any increases in the cost of regulation through deregulatory

313 *See* Art. 17, Para. 28 of law No. 127/1997: "A consultative section of the Council of State is hereby established for the review of draft normative acts in relation to which the opinion of the Council of State is required by law or is otherwise requested by the administration. The section also reviews, if so requested by the President of the Council of Ministers, the draft normative acts of the European Union."

314 The request for an opinion of the Council of State was filed on 8 May 2017 by DAGL as the author of the draft Regulation. On the Council's opinion, *see* M. Filice, 'Il nuovo regolamento sulla better regulation: il parere del Consiglio di Stato', *Rassegna trimestrale dell'Osservatorio AIR*, VIII/4, 2017, pp. 1, 7-13.

315 Consiglio di Stato, *supra* note 3, Paras. 39 and 40.

316 *See* P. Lunn, *Regulatory Policy and Behavioural Economics*, Paris, OECD Publishing, 2014. The use of behavioural economics by governments to regulate is a growing trend globally. The influential book by R.H. Thaler & C.R. Sunstein, *Nudge. Improving Decisions about Health, Wealth and Happiness*, New Haven, Yale University Press, 2008 demonstrates a form of regulatory intervention that applies behavioural economics. Nudging is one type of intervention using behavioural economics. The nudge, according to its theorizers, is "any aspect of the choice architecture that alters people's behaviour in a predictable way, without forbidding any options or significantly changing their economic incentives". Other types of behaviourally informed intervention include simplified information and choices, defaults and convenience, debiasing, and salience. For a more recent publication, *see* P. John, *How Far to Nudge? Assessing Behavioural Public Policy*, Cheltenham, Edward Elgar Publishing, 2018. Various initiatives to integrate behaviourally informed policies into the regulatory process have been undertaken, with success, in the OECD area, most notably the United States and United Kingdom. The European Commission's Behavioural Economics Taskforce and a host of other countries (including Australia, Denmark, Netherlands, Norway and Sweden) are also introducing and institutionalizing the discipline, but such an approach is still relatively unexplored in Italy. *See* Consiglio di Stato, *supra* note 3, Para. 38. *See also*, L. Di Donato, 'Regulatory Impact Assessment (RIA) and Behavioural Research: A New Perspective?', *in I Paper dell'Osservatorio*, Rome, Osservatorio AIR, 2014, pp. 1, 5-26.

317 *See supra* note 148.

measures of at least an equivalent value (also known as 'one-in-one-out' rule).[318] In this respect, the Council also advised reviewing the Decree of the President of the Council of Ministers 25 January 2013,[319] which intended to implement the regulatory budget system but has remained largely unimplemented to date.[320] However, such gaps have been partly addressed in the Guidelines, which highlight the potential contribution of behavioural sciences to the analysis and evaluation of regulation, particularly with regard to the identification of policy options[321] and to consultation processes.[322]

At a more general level, the Regulation has not introduced – as advocated by the Council[323] – 'reputational sanctions' such as performance ratings and other behavioural incentives for the administrations that do not abide by the principles of regulatory quality. Currently, the Regulation merely foresees penalties (managed by DAGL) that are intended to preclude the closing of the regulatory procedure.[324] Such penalties, however, are regarded by the Council as ineffective and, above all, likely to be counterproductive. Most frequently, they are not implemented, and the conduct to be punished remains deep-rooted in practice. But in extreme circumstances they can also be used instrumentally to slow down the approval of regulatory measures. Probably, a combination of both procedural penalties and reputational sanctions could be more effective in securing compliance.[325] Another critical point is the 'feasibility' of certain solutions developed in the Regulation – *i.e.*, the realistic prospect of effective implementation in the short run – such as the linking of the RIA process with normative planning and the special AIR procedure on decree-laws. Despite the Council's suggestions, the drafters have not considered the possibility of gradual implementation – and,

318 On regulatory budget, *see* G. Coco, 'Il Regulatory Budget: La Nuova Frontiera nei Limiti alla Discrezionalità del Governo sugli Oneri da Regolamentazione', *Astrid Rassegna 2009* – No. 104 of 4 December 2009 (21/2009), pp. 1-9.

319 *Decreto del Presidente del Consiglio dei Ministri 25 gennaio 2013 – Criteri per l'effettuazione della stima dei costi amministrativi di cui al comma 5-bis dell'articolo 14 della legge 28 novembre 2005, n. 246, ai sensi del comma 3, dell'articolo 6 della legge 11 novembre 2011, n. 180*, in *Gazzetta Ufficiale* 16 April 2013 No. 89.

320 According to the Council, in the light of the experiences of other countries that are developing a 'one-in-two-out' – or even 'one-in-three-out' – regulatory budget system, it is about time to start using, at least, the 'one-in-one-out' mechanism introduced by law five years ago but never applied in practice, in order to support the competitiveness of the country system.

321 Guidelines, Section 5.3, pp. 15-17.

322 Guidelines, Section 11.4.2, p. 49.

323 Consiglio di Stato, *supra* note 3, Paras. 39 and 54.

324 One of the major issues addressed in the initial years of implementation of the AIR system was the lack of incentives and sanctions for administrations that did not perform the impact assessments as required. To overcome this problem, the 2008 Regulation made the AIR a necessary step in order to inscribe new draft legislation in the Council of Ministers' agenda, thus leading to a sharp increase in the production of AIRs. The Regulation strengthens this sanctioning mechanism even further by making provision for a 'notice of impediment' in case of failure to change the report as requested (*see* above for further details).

325 Although traditional sanctions may be useful and effective in some circumstances, the apparatus of coercive measures may be enriched by additional compliance tools, which sometimes appear the most effective way of producing quality regulation. *See* Consiglio di Stato, *supra* note 3, Para. 39.

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at least initially, on an experimental basis – of the obligations foreseen in the Regulation.[326]

Finally, the Regulation does not enhance as expected the advisory role of the Council as a 'neutral guarantor' of the quality of regulation. In its opinion, the Council asked to be fully involved in the regulatory cycle so that it could contribute, albeit within the limits of a strict proportionality, to improving the quality of ex ante and ex post impact assessments.[327] Hence, the suggestion to be granted the right to request the performance of the AIR when reviewing draft normative acts pursuant to Art. 17, Para. 28 of law 15 May 1997 No. 127.[328] This suggestion, however, was disregarded by DAGL and is thus not reflected in the final version of the Regulation.

M Conclusions

The Regulation signals a renewed commitment to rationalize the use of Better Regulation tools and make them work in practice. If it is true that the drafters could have gone further than what is provided in the current text, it is also true that the Regulation has the potential to further enhance regulatory quality in Italy. It will very much depend on how the Regulation will be applied concretely whether the new rules will have a positive impact on the quality of regulation. As highlighted by the Council of State in several opinions,[329] the problems are not so much related to the theoretical approach of the regulatory framework of AIR, VIR and consultation as to the weaknesses in its practical implementation.[330] Although there has been, in recent years, an overall improvement in the quality of analyses generated, thanks to continuous monitoring and checks by DAGL, coupled with training programmes delivered by the *Scuola Nazionale dell'Amministrazione* (SNA), data collection and interpretation remain challenging: a growing number of AIRs provide quantitative data on the existing situation (from 48% in 2015 to 69% in 2016), but on average only one out of ten provides data on the intervention objectives or quantitative estimates on specific effects.[331] This, in turn, leads to adverse effects on the lawmaking process: because they are of little

326 *Ibid*., Para. 41.

327 *Ibid*., Para. 43.

328 *Ibid*., Paras. 43, 56 and 59.

329 On this point, *see* Filice, *supra* note 314, p. 9.

330 Assessment tools are applied using a 'formalistic approach', that is to say, as though they were a mere bureaucratic compliance issue, of no real usefulness. Not infrequently, AIRs are not thorough enough, fail to use qualitative/quantitative indicators or are openly carried out as an *a posteriori* justification of legislative choices that have already been made rather than as a policy tool to inform and lead regulatory decision-making. Moreover, AIRs are often deficient with respect to the feasibility of proposed regulation in terms of resources available for the purpose of its implementation. This continues to happen despite the fact that the Council of State has often held (*see*, among others, opinion No. 2113/2016) that, in the light of a modern conception of the constitutional canon of the right to good administration, feasibility must be understood as a 'prerequisite' for the legitimacy of regulatory intervention. *See* Consiglio di Stato, *supra* note 3, Paras. 14, 17 and 19.

331 Senato della Repubblica, *supra* note 30, p. 4.

relevance to decision-making, AIRs tend to be neglected during the parliamentary phase.[332] A paradigm shift is therefore needed in the approach of the public administration to the Better Regulation tools.[333] For this reason, it is essential to invest in the 'regulatory culture' of those that are called to perform the lawmaking function so that they become fully aware of the convenience of a circular approach to regulatory quality.[334] To this end, significant resources should be allocated for the training of staff in charge of conducting analyses, evaluations and consultations.[335]

That being said, the adoption of the Regulation as an integral part of Italy's Better Regulation policy is in itself a positive development and represents a step in the right direction in terms of the growing culture of impact assessment and public consultation. In this regard, DAGL continues to stand out in its efforts to change the underlying culture within both the Presidency of the Council of Ministers itself and the administrations. Yet, as noted by the Council of State,[336] the Regulation should not be an end goal, a one-off reform effort as far as regulatory quality is concerned. On the contrary, the new rules on AIR, VIR and consultation should represent only the first, albeit indispensable, starting point of a dynamic and permanent process aimed at improving the quality of regulations.

332 OECD, *supra* note 7, p. 67.

333 According to the Council, the root causes of this situation can be found in cultural reluctance – and are probably partly related to some deficiencies in the training of legislative staff, who have an almost exclusively legal-administrative background and lack the necessary expertise to fully understand and operate regulatory quality tools. *See* Consiglio di Stato, *supra* note 3, Para. 17.

334 The Council has consistently argued that the assessment, both prospective and retrospective, of the impact of regulation does not constitute an unnecessary aggravation of the lawmaking process. To think otherwise would actually mean choosing to allocate to citizens and businesses costs of compliance far greater than those resulting from the performance of the assessments and, in essence, would imply a willingness to make an essential common good such as the legal system deteriorate. *Ibid.*, Para. 44.

335 The training should be aimed at the acquisition of basic 'multidisciplinary skills' – including economic and comparative ones – enabling staff to search for and extract the relevant data and information (not merely from the consultation results but also from expert studies, surveys, focus groups, specialized databases, behavioural analyses, etc.), as well as to manage and process such data and information in a reasonable time. *Ibid.*, Para. 32.

336 *Ibid.*, Para. 31.

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