

**PRINCIPLES FOR ENSURING AN EFFECTIVE REGULATORY
ENFORCEMENT AND INSPECTIONS**

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INTRODUCTION

Regulatory enforcement and inspections are crucial aspects for understanding how the regulatory system affects businesses and the economy and for ensuring effective compliance with regulation. Nonetheless, most countries have focused their efforts in analysing the processes of how regulations are designed and developed, and on how to improve them and make them “smarter”¹. Therefore, enforcement strategies and inspections are relatively new and understudied elements of the regulatory policy.

In the last years, the emergence of new regulatory challenges (such as environmental protection, public corruption, financial stability, and so on), combined with the growing constraints on public budget have raised the governments’ concern over how business and the public sector implement regulation. The policy debate has started to revolve around the efficacy of regulation enforcement and inspections in order to achieve a more substantial compliance by regulated entities.

This report provides a short overview on some of the main recommendations issued both at the national and international level on enforcement and inspections. It especially focuses on the 2014 OECD Best Practice Principles and on the key principles for improving the effectiveness and the efficiency of regulatory enforcement and inspections contained in it. Some of these principles stem from national experiences. The UK government, for example, has started tackling some of the problematic issues in relation to enforcement and inspections since the 2005 Hampton Review. The Italian government has also issued in 2012 Guidelines and a Dossier concerning public controls and inspections on private enterprises with the goal of simplifying the procedures and improving the enforcement outcome.

The aim of this report is to examine the recurring problems in the field of enforcement and inspections in the light of the principles recommended by the OECD in order to overcome them. The study shows a common trend of governments attempts of improving the efficiency of controls and achieving better regulatory outcomes.

¹ See R. BALDWIN, *Is better regulation smarter regulation?*, in *Public Law*, 2005, 485 – 511

The report starts with a brief overview on one of the earliest documents regarding the issue, the 2005 UK Hampton Review. It, then, investigates in more detail the OECD Best Practice Principles for Regulatory Enforcement and Inspections. Finally it analyses the Italian Guidelines and Dossier on public controls on business. It concludes with a highlight on the common features of all the above mentioned documents, which all pursue the ultimate objective of reducing the costs of monitoring business and the public sector, while increasing the effectiveness of the enforcement activity.

1. THE UK HAMPTON REVIEW

One of the first governments which have realised the importance of effective inspection and enforcement mechanisms was the United Kingdom, which in 2005 issued the Hampton Review “Reducing administrative burdens: effective inspection and enforcement”². The Hampton Review is part of the broader “New Public Management” programme of the UK government, aimed at simplifying and reducing administrative burdens for business. The review has dealt specifically with the cumulative loads which affect business, particularly the small ones, such as multiple inspections, overlapping data requirements, and inconsistent practice and decision-making between regulators.

Notably, the Hampton Review has stressed the advantages of employing risk assessment in the regulatory process. The development of internal risk management systems in governmental bodies is based on the transposition of private sector risk analysis strategies to the public policy. Risk based regulation, essentially, means targeting the enforcement resources on the basis of the identification and the assessment of the risks that a regulated entity poses to the regulator’s objectives³.

² P. HAMPTON, *Reducing Administrative Burdens: Effective Inspection and Enforcement: Final Report* (HM Treasury, London, March 2005) (“Hampton Review”), FSA, NRNM, n.85, available at <http://webarchive.nationalarchives.gov.uk/>

³ See J. BLACK, *The emergence of risk-based regulation and the new public risk management in the United Kingdom*, in *Public Law*, 2005, 512 – 549.

One of main reasons for adopting a risk based approach is that it provides a transparent means to prioritise regulatory resources on the firms which pose the highest risk. Proper analysis of risk directs regulators' efforts at areas where they are most needed. It also should enable governments to reduce the administrative burdens of regulation, while maintaining or even improving regulatory outcomes. Moreover, risk assessment provides regulators with information on the nature of businesses and on all external factors affecting the risk the business poses to regulatory outcomes, helping them to avoid unnecessary inspections or data requirements on less risky businesses. For these reasons, the Hampton Review has recommended that all regulatory agencies adopt a comprehensive risk-based approach to regulatory enforcement.

The principles stated in the review are also aimed at securing the accountability of regulators for the efficiency and the effectiveness of their activities, as well as their independence. In order to achieve a greater transparency, it suggests that regulations should be written and drafted having consulted all the interested parties. A further principle stated in the review is to reduce inspections and data requirements, particularly for less risky businesses, and to redirect resources released from unnecessary inspections towards authoritative and accessible advice provided by regulators to improve compliance.

Moreover, the review addresses the need to simplify the forms and to improve co-ordination across regulators' data requirements. It advises regulators to explicitly consider the efficiency of the enforcement mechanisms when designing new regulations. Finally, it states that governments should reduce the number and the size of national regulators.

Many of these recommendations were built on earlier work or established trends. The Health and Safety Executive and the Environment Agency, for example, both published strategy documents focused on risk assessment. Consolidation of regulators around single themes has been common in recent years, such as with the creation of Ofcom and the Financial Services Authority.

2. THE OECD BEST PRACTICE PRINCIPLES FOR REGULATORY ENFORCEMENT AND INSPECTIONS

The design of an effective enforcement model changes according to the institutional framework of each Country. Furthermore, inspections are often considered to be sector-specific. Nonetheless, the OECD has recently provided a general, informal, non-binding guidance, with the aim of helping governments to design more effective, efficient, less burdensome and less resource-demanding inspection mechanisms. The guidelines address the design of the policies, the institutions and the tools for promoting effective compliance and the process of reforming inspection services to achieve results. They are also aimed at the prevention of corruption and at the promotion of ethical behaviour.

The OECD document addresses, in an across sectors and general manner, the way inspections are planned, their targeting, the communication with regulated subjects. The objective of the report is to present a range of key principles on which effective and efficient regulatory enforcement and inspections should be based. The ultimate goal is pursuing the best compliance outcomes and the highest regulatory quality. The report complements the 2012 Recommendation of the Council on Regulatory Policy and Governance⁴.

Enforcement activity is defined by the report in a broad sense, as all the activities of public bodies aimed at promoting compliance and reaching regulation's outcomes. Inspections are defined as any kind of visit or check conducted by authorized officials on products, or business premises, activities, documents etc.

The report provides eleven best practice principles, based on the two expert papers, presented to the OECD Regulatory Policy Principles at its 7th meeting in November 2012⁵, as well as on an extensive review of practices in OECD and non-OECD countries and on the

⁴ The OECD Regulatory Policy Committee, Recommendation of the Council on Regulatory Policy and Governance, 2012, available at: <http://www.oecd.org/governance/regulatory-policy/49990817.pdf>

⁵ J. MONK, *Reform of Regulatory Enforcement and Inspections in OECD Countries*; F. BLANC, *Inspections Reforms: Why, How and With What Results*, available at www.oecd.org

research that has been conducted on this topic over the past three decades. The principles have also been discussed in a public consultation with all the interested parties.

The principle of evidence-based enforcement and inspections

The first principle states that “regulatory enforcement and inspections should be evidence-based and measurement-based: deciding what to inspect and how should be grounded on data and evidence, and results should be evaluated regularly”.

The principle of evidence-based enforcement and inspections requires a regular evaluation of inspectorates’ actions and their effectiveness, against a set of well-defined indicators, based on reliable and trusted data. This principle requires data collection about the frequency of inspections, the number of entities subject to inspections, the length of inspections and the administrative sanctions that follow, in order to assess the quantity of the resources used and the burdens on businesses.

An essential element of evidence-based enforcement is the reliability of the data employed. The report suggests not using data that is directly the result of an agency’s processes in order to assess the compliance levels. This information may be directly influenced by the enforcement agency, and are based on the changes in the enforcement policy. Therefore, it is not considered an “independent” data which creates negative incentives. More broadly, any data that is recorded or produced by the agency should be treated with caution in terms of evaluation, because of the potential for conflict of interest. Indeed, the inspectorate may be incentivised to alter the data in order to improve its apparent performance.

The evidence-based principle stresses that it is crucial for governments to gather information on the main areas of enforcement activities and on the level of resources dedicated to them. It is also important to gain information on the opportunities of considering alternative and light handed approaches to promote compliance, such as civil suits and market mechanisms, on the potential use of risk assessment and management to design enforcement strategies, and on the possibility to remove overlap or duplication across different inspection and enforcement activities.

The OECD recommends a systemic and comprehensive approach for reviewing the way that regulatory enforcement works from the point of view of business in each sector. The governments' review of enforcement activities should draw on international experience to evaluate the merits of different organisational approaches to address common public policy goals. The report stresses that a specific agency should only be set up if there is a demonstrated need for this arrangement. Indeed, a very wide range of topics covered by regulation do not need an inspectorate to enforce the legal requirements and can be enforced through mechanisms of civil litigation, market forces and criminal law enforcement.

Enforcement and inspection agencies should have a clear defined mandate with regards to the outcome indicators that they aim to influence and they should be required to track and report on these regularly. To ensure the reliability of data used for evaluation, as far as possible, data used to evaluate an inspectorate's activities should be collected independently. The performance measurement approaches should balance the use of different indicators from various sources and consider the use of random, statistically representative surveys every few years in order to control the situation of business operators' compliance in critical areas.

Tracking the number of violations identified by inspectors and the value of penalties imposed may be useful for designing the indicators, but should not be used as performance indicators as it cannot reliably correlate with the performance of the agency. It is also necessary to track factors such as the perception of regulated entities on the inspectorates. There should also be strictly defined protocols which should bind the Agencies when collecting the data. In cases when data is produced or collected by the agency itself, it should be regularly cross-checked by independently conducted, representative surveys, or through the comparison with other existing sources of data.

The principle of selectivity

The second principle suggests that governments explore, whenever possible, the potential of market forces, private sector and civil society actions to support compliance and enforcement. It states that "inspections and enforcement cannot be everywhere and address everything, and there are many other ways to achieve regulations' objectives".

This principle denies that every rule issued by the state needs to have a specific enforcement unit following up on compliance by businesses. It stresses that, in a number of cases, there may be alternative mechanisms to ensure compliance, instead of assigning state resources to controls and enforcement actions. In particular, the principle suggests to rely on liability rules for suppliers, combined with adequate insurance requirements for one or both parties, when regulations apply to the provision of services and market relationships.

The document provides a number of criteria which should be followed by governments before deciding upon whether to assign inspection and enforcement resources to a specific regulation or set of regulations.

For example, it should be evaluated whether an ex-post remedy would be sufficient to repair or compensate the damage adequately or, instead, preventive action through inspections is essential to achieve the regulations' ends. Also, the type of action should be chosen according to the irreversibility and the magnitude of harm that the violation of the specific regulation may cause. Governments should consider the possibility to rely on market mechanisms and providers of conformity assessment services. Further factors to be taken into account are the level of asymmetries between market participants and of the convergence between public and private interests. Clearly, if complying with regulation is likely to be beneficial for business in terms of market share, revenue and profits, market-based mechanisms are more likely to be effective.

An alternative means to enforcement might be a mandatory insurance mechanism, which should be able to cover adequately both the potential liability in case of violation of regulations and the subsequent harm. Finally, enforcement of regulations through courts may also have the potential to deter serious violations.

In conclusion, all the aforementioned criteria should aim at driving state resources to alternative means, rather than inspections and enforcement, which are less costly and burdensome for regulated entities, such as information to businesses and consumers, and the promotion of voluntary certification schemes, or the use of rating schemes that distinguish best and worst performers. The document stresses that the primary responsibility for compliance lies with the regulated subjects, while inspectors and regulators have the different

role of assisting and promoting compliance, also through strong enforcement actions, if necessary, but not to actually implement regulations.

The report also considers the drawbacks of relying on market forces and court litigation, such as the lack of technical expertise of the courts and the uncertainty of the ex-post decisions. Moreover, it highlights that market mechanisms and direct regulatory enforcement by the government may be combined. For example, schemes such as certification and accreditation may be used to ensure compliance with less direct inspections and enforcement, but with a backstop of state-led enforcement to ensure the effectiveness and credibility of such schemes.

The principle of risk- focus and proportionality

The OECD recommends that all enforcement activities should be informed by the analysis of risks. The frequency of inspections and the resources employed should be proportional to the level of risk and enforcement actions should aim at reducing the actual risk posed by infractions. Therefore, risk assessment should cover all the activities and businesses.

Prioritisation in the allocation of resources is particularly important in inspection and enforcement actions. Indeed, governments cannot inspect each and every business or object and even attempting to do so would result in massive and unnecessary administrative burden.

The document defines risk as “the combination of the likelihood of an adverse event (hazard, harm) occurring, and of the potential magnitude of the damage caused (itself combining number of people affected, and severity of the damage for each)”. It stresses the need for a consistent definition of risk throughout all inspectorates and suggests that all enforcement agencies develops and collects criteria for risk assessment, data on business, planning and resource allocation based on the risk level, updating process, treating consistently-compliant business as correspondingly lower risk.

Governments should adopt legal provisions requiring all inspectorates to develop and implement enforcement policies based on risk-proportionality in order to review, analyse and rank the types of violations according to the potential risk they present and to provide

guidelines to inspectorate staff prescribing to always assess the actual risk level presented by each recorded violation or set of violations before deciding on a sanction. As a consequence, the sanctions should be proportional to the potential magnitude of hazard, ensuring deterrence in the most hazardous situations and, at the same time reducing burden for minor shortcomings.

Proportionality should be respected by governments also when drafting laws and executive orders concerning sanctions. Risk criteria, policies, guidance should be clearly communicated and explained to the public, and regularly reviewed based on results and available data, so that evolutions in hazards and threats are properly addressed.

Risk management should incorporate parameters based on information received by third parties, such as complaints, allegations submitted by workers, citizens, other business, to update the firm's risk profile.

Finally, the report highlights the need for a constant update of risk assessment and risk management resources and expertise, which should be ensured by governments. Every enforcement agency should thus be provided with a dedicated unit or team specifically in charge of risk management, with adequate resources to effectively perform their task.

Responsive regulation

The responsive regulation approach was first theorized in the early Nineties⁶ and, generally speaking, it suggests to differentiate the regulatory strategies according to the overall compliance behaviour of the regulated subject. More recently, it has been argued that a really responsive approach should take into account, not only the attitude of the regulated firm, but also the operating and cognitive frameworks of firms, the institutional environment and the performance of the regulatory regime, the different logics of regulatory tools and the interactions of regulatory controls, and the changes in each of these factors⁷.

⁶ See I. AYRES, J. BRAITHWAITE, *Responsive regulation: Transcending the deregulation debate*, Oxford University Press, Oxford, 1992

⁷ R. BALDWIN, J. BLACK, *Really responsive regulation*, in *The Modern Law Review*, 2008, 71, 59–94.

According to the OECD principles, this approach should be made public in order to provide an additional incentive for businesses to be as much compliant as possible and to cooperate with the regulatory enforcement agencies. A similar approach is the “persuasive enforcement”, which is aimed at showing regulated entities that compliance is in the best long term interest of business as it will ensure a positive relationship with the regulator.

In particular, the OECD suggests that a higher risk level is assigned to businesses that show a pattern of systematic and repeated violations⁸. These businesses are also showed no leniency when significant violations are found, and enforcement may immediately escalate to sanctions, and possibly suspension of operations, rather than just giving an improvement notice. Conversely, businesses which have a history of compliance should be rated as lower risk, and gradually inspected less often. By the same token, recently created businesses should be first given a chance to improve, rather than immediately resorting to sanctions, so as to promote a culture of openness on their side.

Enforcement should also be risk-responsive, meaning that, even if a violation is found in a business which is usually compliant, the enforcement should vary according to the seriousness of the hazard and to whether it poses a threat to essential public goods or rights. Lastly, an effective responsive regulation should provide a sufficiently broad and differentiated range of potential penalties in order to treat different behaviour in a proportionate manner and to exert real deterrence.

The principle of long-term vision

The fifth principle aims at designing policies on regulatory enforcement and inspections, setting clear objectives and a long-term road-map. Governments should have an official vision on enforcement and inspections and they should ensure continuity in goals and political support.

The advantages of long-term vision are twofold. On the one hand, it recognizes the similarities between all enforcement functions and structures, regardless of the sector, and thus it allows to address problems and issues in a consistent way, as well as to tackle overlaps

⁸ See R. BALDWIN, J. BLACK, *Really Responsive Risk-Based Regulation*, in Law and Policy, 2010, 181 – 213.

and duplications. On the other hand, it can be the basis for all inspection and enforcement reform initiatives in specific institutions and sectors and it helps to mobilise public support for transformations by lending more visibility to the topic.

Therefore, the regulatory enforcement policy should pursue both overarching goals, such as combining safety and economic growth, as well as specific objectives, such as improving efficiency, minimizing burdens, concentrating resources and efforts where they can deliver the most results, improving transparency and responsiveness. In each given jurisdiction the regulatory policies should address the issues that have been identified as particularly problematic, such as duplications of inspections on the same issue, unclear requirements, lack of information sharing, or problems of under-inspection in some sectors.

Governments should ensure that all relevant ministries, agencies and structures (regulators, inspectorates etc.) are involved in a co-ordinated manner and a strong political leadership. The resources should be allocated in a way that allows for long-term planning and are safeguarded from short term political or economic events.

Co-ordination and consolidation

The sixth principle states that “inspection functions should be co-ordinated and, where needed, consolidated: less duplication and overlaps will ensure better use of public resources, minimise burden on regulated subjects, and maximise effectiveness”.

The principle aims at removing duplications and suggests to restructure regulatory enforcement agencies. International experience shows that there is only a limited number of different types of risks, that should form the basis for restructuring. The document suggests some possible approaches, such as the “one risk, one inspectorate” model or to establish administrative arrangements to improve co-ordination, to ensure information is shared and inspections are not duplicated, without necessarily merging agencies.

The OECD provides a list of core functions which are deemed to be fundamental in all regulatory regimes that may be employed as foundation for reviewing the institutional structure. These are food safety, non-food products safety and consumer protection, technical and infrastructure/construction safety, public health, medicines and health care, occupational

safety and health, environmental protection, state revenue, transportation safety, banking, insurance and financial services supervision, nuclear safety.

It also stresses the trade-off between consolidation and specialisation, that needs to be taken into account in institutional reforms. The ultimate goal is not only to remove duplications, but also to improve co-ordination and focus, through a review of the resource repartition between enforcement areas. Moreover, in certain regulatory areas the hazard is particularly high and, therefore, an element of redundancy may build more robustness and resilience in the regulatory systems.

Among the approaches which may improve the institutional framework, the OECD suggests to create a unified information system, to merge most inspection structures within a “single inspectorate”; to set up a co-ordination council wherein most inspection agencies meet, harmonize practices and share information; to require all inspection agencies to systematically share with others all relevant data, and inspection plans; to limit re-inspection of the same issue by different inspectorates in the same business within a given time period, except if problems have been identified in the first visit, or if new evidence surfaces that indicates that a new visit may be necessary.

The principle also suggests, as an alternative to merging institutions, introducing “front-line inspectors”, with a wide mandate and a specific training who is able to spot issues concerning a number of regulatory fields. It also considers the possibility of concurrent enforcement between regulators and courts.

It is essential that governments pay great attention to clarify the respective responsibilities and mandates and ensure that information is shared effectively among agencies.

The principle of transparent governance

This principle aims at advising governance structures and human resources policies for regulatory enforcement to support transparency, professionalism, and focus on outcomes. Furthermore, it highlights the need for execution of regulatory enforcement to be independent from political influence, and of rewarding compliance promotion efforts.

Professionalism is understood not only as technical competence in the relevant field, but also as “generic inspection skills”, meaning the ability to conduct inspections effectively and promote compliance, ethical standards of behaviour, risk management, inter-agency cooperation and operational management. Therefore, human resources and training policies should ensure that management staff is recruited in a way that they have adequate professional management skills and experience, and not just technical competence. Furthermore, staff training should provide personnel a real understanding of what inspections and enforcement aim to achieve, how to interact most effectively with regulated subjects and foster compliance, how to assess and rank risk, as well as all relevant ethical standards.

The document emphasises in particular the need of regulatory enforcement agencies’ independence⁹. That is essential to ensure that inspectorates are free to set and follow their work priorities based on their professional expertise rather than on political instances. Agencies also have to pursue their objectives without fear of political interference in operational matters, or politically-driven management changes. Thus, political decision should only intervene at the level of the overall strategy and resource allocation.

In order to ensure the independence of the regulatory agencies, governments may establish mechanisms to ensure the stability of senior management of inspectorates, regardless of changes of the chief executives; the independent appointment of chief executives through an open process, based on appropriate professional credentials, and with the decision subject to a collegial review and open scrutiny; and the institutional distinction between inspectorates and ministerial department.

Moreover, the principle of transparent governance suggests that each inspectorate should develop and adopt human resources performance management policies in order to reflect the overall aims of enforcement activities and the specific goals of each agency.

⁹ On the independence of independent regulatory agencies from elected officials see M. THATCHER, *Regulation after delegation: independent regulatory agencies*, in Europe, *Journal of European Public Policy*, 2002, 954 — 972; See also M. THATCHER, *Delegation to Independent Regulatory Agencies: Pressures, Functions and Contextual Mediation*, in *West European Politics*, 2002, 125 — 147; M. EVERSON, *Independent Agencies: Hierarchy Beaters?*, in *European Law Journal*, 1995, 1, 180.

Therefore, the performance should not be based on the number of violations found or the sanctions issued. Conversely, staff that effectively promote compliance and work in line with principles of “responsive regulation” should be given appropriate recognition. The assessment of performance in terms of reaching regulatory outcomes and regulatory compliance should be made across teams or units, rather than individually.

A further factor to be considered is the change in cultures and behaviour of officials, business, operators and the public. Moreover, the OECD stresses how a cooperative approach may lead to regulatory capture and how government revenue that generates by issuing licences may conflict with other goals. Therefore, conflicts of interest should be avoided through institutional separation and a clear mandate to the regulatory enforcement agencies that any licence or permit they may issue are aligned with their general mission and not revenue-generating.

Information integration

The eighth principle states that “information and communication technologies should be used to maximise risk-focus, co-ordination and information-sharing, as well as optimal use of resources”.

Information sharing is essential as it allows inspectorates to have a much more accurate and updated assessment of the risk level of each business, without spending additional resources and enables them to avoid duplication of work. Therefore, common databases should be put in place by governments to be used by different enforcement agencies. Exploiting modern technologies in setting up a joint system for several inspection bodies, rather than procuring separate systems with largely similar specifications, is cost-effective and offers considerable benefits in terms of risk-management and co-ordination.

Thus, the OECD recommends that governments support the renewal of information systems for enforcement bodies, aiming at supporting effective risk-management, and give preference to shared systems across several inspectorates whenever possible.

Data sharing may be relatively more difficult in countries that have decentralised regulatory enforcement and inspection structures, or non-state regulators, with third-party

certification bodies, with private businesses. In these cases, it is suggested to gradually build systems which allows for greater data sharing and inter-operability between all these agents.

A problematic issue concerns information gathering in relation to privacy and data security legislation. The document provides some mechanisms to overcome these problems, including the possibility to introduce the principle that data from regulated entities can only be requested once and then state structures have to share it across agencies.

Finally, the document recommends that complaints should not always lead to inspections, but they should rather be integrated in the information system in order to assess the risk level of the product or business.

The principle of clear and fair process

An essential element for ensuring an effective functioning of the enforcement system is the clarity and coherence of rules and process for enforcement and inspections¹⁰. A good legislation to organise inspections and enforcement needs to be adopted and published, and clearly articulate rights and obligations of officials and of businesses.

The framework for enforcement and inspections, should thus be made clear and accessible by governments through appropriate legal instruments. Also a comprehensive list of bodies authorised to inspect, with their sphere of competence, should be officially published and updated when needed. Moreover, the whole inspection process should be organised according to regulations or legislation.

The document also considers the possible advantages of advance notification in appropriate circumstances (regular inspections, no suspicion of fraud or criminal behaviour). This could push businesses to check and improve their compliance.

Regulated subjects should be aware of their rights and obligations in the inspection process, of the means to challenge the conclusions, and of how to obtain compliance assistance, or report abuses if any. Therefore, governments should issue an official legal

¹⁰ On the importance of the quality of regulation see M. DE BENEDETTO, M. MARTELLI, N. RANGONE, *La qualità delle regole*, Bologna, Il Mulino, 2011.

document which summarises the rights and the obligations of regulated subjects in the inspection process.

The principle of compliance promotion

The last principle states that “transparency and compliance should be promoted through the use of appropriate instruments such as guidance, toolkits and check-lists”.

The complexity of the language and the “performance-based” way of the requirements’ description (i.e. that the process has to be safe, in such and such circumstances) may render difficult for business with less expertise to understand and meet the legal criteria. Therefore, enforcement agencies should develop and publish guidance notes or toolkits that help medium and small enterprises understand the requirements and how to comply in the most widespread situations and sectors.

It is also recommended to adopt tools, such as checklists, to improve consistency and predictability of what is expected by regulated subjects. All the checklists and guidance documents should be published on easily accessible internet portals, possibly unified, where business operators can find all the relevant requirements. These tools should include self-checks instruments to help business to improve their ability to comply. It should be also set up on-line support with trained staff to answer specific issues.

However, the document stresses that such instruments as toolkits or check-lists are often neither appropriate, nor helpful for larger or more complex businesses. These types of businesses require the possibility to request assured guidance from the regulatory enforcement agency, such as a consultation and review of the way the business works or purports to work, and a response on how the regulator considers that compliance can be ensured, which should bound the regulator. These mechanisms should enhance the environment for investment. Governments are thus invited to create the legal conditions for regulatory enforcement agencies to provide assured guidance, and encourage the development of such-schemes.

3. THE ITALIAN GUIDELINES ON REFORMING CONTROLS ON BUSINESS

Italian law has recently mandated the government to put in place measures to simplify and reduce the controls on business, on the basis on six principles¹¹. Those principles are: proportionality of controls and of administrative requirements according to the risk which the regulated activity creates to the protected public interest; elimination of unnecessary controls; co-ordination and planning of controls in order to avoid duplications and overlaps; collaboration with regulated entities; digitalisation of data and administrative procedures; rationalisation of controls.

The governmental department for the public administration has then issued a dossier and some guidelines in order to comply with the above mentioned rule.

The dossier¹² takes into account the OECD documents on risk regulation, the recommendations issued by the World Bank¹³, as well as the European laws on high risk sectors, such as food security and environment. It also refers to the UK Hampton review and to the Netherlands Inspection Simplification Programme of 2006. With that document, the Dutch government has proposed, *inter alia*, the “Inspection Holiday” principle, which essentially means to strongly reduce the burden of inspections for low-risk firms, for small and medium enterprises, and for firms which pose higher-risk but are consistently compliant. Then, the dossier refers to two pilot cases addressed by the World Bank (Tajikistan and Lithuania) and eventually gives some examples of risk-based regulation in Italy.

The dossier has also highlighted some of the main problematic issues concerning the inspections system in Italy. The fragmentation and the complexity of the normative system and the lack of co-ordination among enforcement authorities create overlaps and duplications in the controls on private enterprises. Simplification and transparency initiatives

¹¹ Art. 14, Law Decree 9 february 2012 n. 5, “Disposizioni urgenti in materia di semplificazione e di sviluppo”.

¹² Dipartimento della funzione pubblica, Ufficio per la semplificazione amministrativa, Dossier: i controlli, 3 settembre 2012

¹³ Investment Climate Advisory Services of the World Bank Group, How to Reform Business Inspections: Design, Implementation, Challenges January 2011

have been undertaken in some crucial fields, such as work security, tax, environment and food security.

The Guidelines¹⁴ provide a tool for the local authorities for conforming their enforcement activities to the principles of openness of regulation, proportionality to risk, collaboration, publicity and transparency of the inspections' outcomes. It proposes a modern meaning of "control on enterprise" as the activity aimed at verifying the substantial compliance to the legal duties by the regulated subjects, in conformity with the pursuing of the public interest. It also defines the word "risk" as the dangerousness of an event, calculated with regard to the probability of its occurrence, in relation to the seriousness of the consequences. Moreover, it distinguishes between the objective risk, linked to the type of activity, and the subjective risk, linked to the reliability of the enterprise and its compliance history.

The guidelines provide a number of principles that should drive the controls on enterprises, with the goal of coordinating and rationalizing enforcement tools.

The first principle is clarity of regulation. Information on obligations and duties for enterprises need to be easily accessible and understandable by the addressee. For example, the public administration should publish a checklist of legal requirements that firms have to comply with, as well as the answers to frequently asked questions (FAQ).

The second principle is proportionality to the risk which each activity poses to the public interest, and the probability of the occurrence of harm. The document contains a box which explains the method for risk assessment. The two main factors to be taken into account are the probability of non-compliance by the regulated entity and the potential impact of the violation on the public interest. The steps of risk analysis are: the analysis of the functions attributed to the office by the law; the identification of the probability of non-compliance with the legal duties; risk scoring, with regard to the type of activity undertaken (objective risk) and to the single firm characteristics (subjective risk). Based on this assessment, the administration classifies risks according to the degree of risk tolerance of institutions. Then,

¹⁴ Dipartimento della funzione pubblica, Linee guida in materia di Controlli art. 14, comma 5 del decreto legge 9 febbraio 2012, n. 5 convertito in legge 4 aprile 2012, n. 35, 24 gennaio 2013

there is the control planning and the simplification of legal duties pursuing the proportionality of intervention. Finally, it is suggested to undertake a periodical monitoring of the method adopted and of new risks arising.

The third principle is co-ordination of enforcement and control activities. This principle may be pursued through annual planning, common databases, agreements among administrations and the design of homogenous forms.

The fourth principle suggests a collaborative approach by public officers who exercise enforcement powers. They should attempt to reduce as much as possible the interventions which may interrupt or slow down the firm's business. Some of the tools endorsed to ensure this principle are: setting checklists, transparency of controls, technical equipment in order to immediately transmit the report of the inspection, providing clear indications on how to comply with the rules.

The fifth principle is training and updating of the officers. This should aim at dividing the phase of promoting of compliance to the phase of control.

Finally, the last principle is publicity and transparency of the inspections' outcomes. This should result in incentives for the enterprises to comply and in information available by the administration for further controls.

CONCLUSION

The recent proliferation of official documents on regulatory enforcement and inspections, adopted both at the national and international level, shows the increasing importance of these aspects of public regulation.

The recommendations adopted in the UK, the Best Practices published by the OECD, the piece of legislation and the guidance enacted in Italy, seem to converge in pursuing the ultimate goal of cutting unnecessary enforcement actions and inspections. Many of the principles stated in these documents are related to this issue.

For example, the need for rationalisation of controls, co-ordination among agencies, proportionality of the enforcement to the risk imposed by the regulated entities, are constantly emphasised by these guidance in order to avoid duplications and overlaps in the enforcement actions.

An element which is central in all the above mentioned studies is that of risk assessment. The aim of prioritising public resources on clearly identified objectives, linked to a technical analysis of the risk that each regulated entity poses to the agency's goal, is deemed crucial by all the bodies that issued works on regulatory enforcement.

A further aspect which arise from these works is the need for collaboration and communication with regulated operators. This element is linked with the transparency issue, as it requires public authorities to develop tools to enhance the accessibility and clarity of the rules and the requirements that the enterprises have to meet.

Furthermore, the independence of enforcement agencies from the political power also plays a fundamental role in increasing the quality of regulatory enforcement. As stressed especially in the OECD document, agencies need to be able to plan their activity with a long-term view, not being influenced by the political instability.

Finally, the centralisation and co-ordination of competences is also a factor of improvement of the enforcement mechanism. This principle implies a simplification of the institutional framework, with less specialised bodies, who share among themselves information on enforcement outcomes in order to better plan the future controls.

To sum up, all the principles recommended by national and international bodies aim at improving the regulatory enforcement and inspections tools by a rationalisation and co-ordination of existing mechanisms and institutions. The use of States' resources should be focused only on necessary actions, assessed by a proper risk analysis. Raising governments' awareness on these issues seems to be particularly urgent in times of crisis, when the need to effectively combat violations of regulations which undermine the possibility to achieve public interest goals should be addressed taking into account the limited resources of public administration.

Most of the above mentioned documents, however, take the form of soft-law instruments such as non-binding guidelines and criteria that governments are suggested to follow. These types of measures may not suffice to curb some of the criticisms pointed out by the OECD studies.

In order to give a concrete application to those principles and truly improve the effectiveness of the enforcement mechanisms and inspections at the national level, some hard law intervention seem to be desirable. Not only, principles such as proportionality and risk based enforcement action should be integrated in the relevant legislation, but also some structural reforms are needed. For example, the need for reducing the fragmentation of control responsibilities, improving the coordination and communication among enforcement agents, should be backed by a concentration and centralisation of the control functions. Moreover, precise rules should compel governments to follow an open procedure to identify the goals of the controls, their costs, the mechanisms for selecting who to inspect, and the outcome of the enforcement actions. These reforms seems to be necessary, in order to enhance both the accountability and the efficacy of the enforcement action.

In conclusion, the recommendations and principles for ensuring an effective regulatory enforcement and inspections are an important step towards a broader and substantial reform in the existing enforcement mechanisms at the national level. They should be followed by the adoption of new legislation, or the modification of the existing one, in order to introduce rules and structural reforms in accordance to the best practices emerged from the foreign and international experiences.