OECD Best Practice Principles for Regulatory Policy

Regulatory Enforcement and Inspections

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BETTER POLICIES FOR BETTER LIVES

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Foreword

Regulations are indispensable for the proper function of economies and the society. They create the “rules of the game” for citizens, business, government and civil society. They underpin markets, protect the rights and safety of citizens and ensure the delivery of public goods and services. The objective of regulatory policy is to ensure that the regulatory lever works effectively, so that regulations and regulatory frameworks are in the public interest.

The quality of the regulatory environment and the delivery of regulatory outcomes is not only based on how regulations are designed. In the last decade, OECD countries have been investing time and resources in examining the need for regulation and assessing regulatory options. Most governments have outlined their policy on improving the design of regulation through regulatory impact analysis and stakeholder engagement mechanisms, often with the support of central scrutiny for proposed new regulations. As well as improving the design of new regulation, nearly all OECD countries have searched for opportunities to remove unnecessary burdens on the business community and citizens.

Regulatory enforcement has been overshadowed by these initiatives in most OECD countries so far. Scarce attention has been paid to examining possibilities for improving the way regulations are implemented and enforced. Nonetheless, the delivery of regulatory outcomes cannot be effective without a proper enforcement of regulations.

Inspections are one of the most important ways to enforce regulations and to ensure regulatory compliance. Even though inspections are usually considered as sector specific, there are many core activities that inspections have in common and that are universal for all or most sectors where inspections take place.

The way inspections are planned, their better targeting, communication with regulated subjects, preventing corruption and ethical behaviour – these are just few examples of issues that can be addressed generally, across sectors and inspection authorities. The organisation of inspections and the governance of inspection authorities are other issues that could and should be solved through a cross-cutting policy.

Regulators in many countries are increasingly under pressure to do "more with less". While demands to better protect environment, health and safety of citizens have increased, the current economic crisis forces governments to reduce spending on public administration, including regulatory enforcement activities. In addition, inspections often create unnecessary burdens both for the state and those inspected. A well-formulated enforcement strategy, providing correct incentives for regulated subjects can help reduce monitoring efforts and thus the costs for both business and the public sector, while increasing the efficiency and achieving better regulatory goals.

The OECD has played a leading role in the international community to promote regulatory reform and the implementation of sound regulatory practices on a whole-of-government approach. The body of information and experience it has gathered is summarised in the *Recommendation of the Council on Regulatory and Policy Governance* (OECD, 2012).

The report *Regulatory Enforcement and Inspections: OECD Best Practice Principles for Regulatory Policy* complements the 2012 *Recommendation* and is intended to assist countries in reforming inspections and developing cross-cutting policies on regulatory enforcement. The principles seek to construct an overarching framework to support initiatives on improving regulatory enforcement through inspections, making them more effective, efficient, less burdensome for those who are inspected and at the same time less resource-demanding for governments.

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Executive summary

Regulation is a key tool for achieving the social, economic and environmental policy objectives of governments. Governments have a broad range of regulatory schemes reflecting the complex and diverse needs of their citizens, communities and economy.

Ensuring effective compliance with rules and regulations is an important factor in creating a well-functioning society and trust in government. If not properly enforced, regulations cannot effectively achieve the goals intended by the governments. Regulatory enforcement is therefore a major element in safeguarding health and safety, protecting the environment, securing stable state revenues and delivering other essential public goals. Inspections are the most visible and important among regulatory enforcement activities.

Regulatory enforcement and inspections is a relatively new and under-studied element of regulatory policy that has been gaining importance recently. The major challenge for governments is to develop and apply enforcement strategies that deliver the best possible outcomes by achieving the highest possible levels of compliance, while keeping regulatory costs and administrative burdens as low as possible. Only a few OECD member countries have introduced significant cross-cutting reforms in this area. Many other OECD countries are currently considering some reform initiatives and are seeking for guidance and good practice examples.

To fill this gap, the OECD believes that it is timely and useful to develop a number of key principles and guidance for organising and reforming inspections in OECD countries. These principles are based on a survey conducted among OECD countries in 2012, expert papers presented to the OECD Regulatory Policy Committee as well as on additional country information provided to the Secretariat on the voluntary basis.

The goal of this paper is to present a range of core principles on which effective and efficient regulatory enforcement and inspections should be based in pursuit of the best compliance outcomes and highest regulatory quality. The eleven principles addressing the design of the policies, institutions and tools for promoting effective compliance and the process of reforming inspection services to achieve results are:

1. Evidence-based enforcement;
2. Selectivity;
3. Risk focus and proportionality;
4. Responsive regulation;
5. Long-term vision;
6. Co-ordination and consolidation;
7. Transparent governance;
8. Information integration;
9. Clear and fair process;
10. Compliance promotion;
11. Professionalism.

The principles have an informal status of a guidance approved at the Committee level – they do not have the formal status of a soft law adopted by the OECD Council. They will serve as a complement to the 2012 Recommendation of the Council on Regulatory Policy and Governance. It can be used by member and non-member countries to guide their reforms. It will be also used by the OECD Secretariat when reviewing regulatory policies in member and non-member countries as a set of criteria for evaluation.

Introduction

Ensuring effective compliance with rules and regulations is an important factor in creating a well-functioning society and trust in government. It is a major element in safeguarding health and safety, protecting the environment, securing stable state revenue and delivering other essential public goals. This is critically important from a social perspective and as a foundation of economic growth. The challenge for governments is to develop and apply enforcement strategies that achieve the best possible outcomes by achieving the highest possible levels of compliance, while keeping the costs and burden as low as possible.

Box 1. **Definition of some key terms**

In this paper, "enforcement" will be taken in its broad meaning, covering all activities of state structures (or structures delegated by the state) aimed at promoting compliance and reaching regulations' outcomes – e.g. lowering risks to safety, health and the environment, ensuring the achievement of some public goods including state revenue collection, safeguarding certain legally recognised rights, ensuring transparent functioning of markets etc. These activities may include: information, guidance and prevention; data collection and analysis; inspections; enforcement actions in the narrower sense, i.e. warnings, improvement notices, fines, prosecutions etc. To distinguish the two meanings of enforcement, "regulatory enforcement" will refer to the broad understanding, and "enforcement actions" to the narrower sense.

"Inspections" will be understood as any type of visit or check conducted by authorised officials on products or business premises, activities, documents etc.

From the perspective of this paper, "regulatory enforcement agencies", "inspecting agencies" or "inspectorates" are all essentially synonymous (as in practice there is fluidity in the way they are called in various countries). The preferred wording adopted generally in the paper will be "regulatory enforcement agencies".

A well-formulated enforcement strategy is one that provides correct incentives for regulated subjects as well as appropriate guidelines for enforcement staff, and minimises both the monitoring effort and the costs for the regulated subjects and the public sector. To achieve this, any strategy needs to rely on a clear and sound vision of what the drivers of compliance are – both in terms of the effect of activities of the regulatory bodies, but also in terms of characteristics of the regulated businesses and of external factors (in particular market characteristics). An increasing number of OECD countries are coming to realise the importance of the enforcement phase in ensuring the quality and effectiveness of regulatory policy and delivery and for reducing the overall level of regulatory burdens imposed on businesses and citizens.

Increased attention is being given to the efficiency of the enforcement phase in the regulatory governance cycle and promoting proportionality in enforcement (*proportionality* being here understood both as allocation of resources proportional to the level of risk, and to enforcement actions proportional to the seriousness of the violation). Governments increasingly understand that this can help reduce burdens on business and citizens and release public resources for more productive tasks – while in fact improving the desired outcomes. Achieving efficiency improvements can follow from a review of the overall policies, the institutional framework and the tools used by regulatory agencies. It corresponds to a greater reliance on risk analysis and on a more targeted approach to the use of inspection and enforcement resources.

For most countries, relatively little focus has been given to consistently improve the way regulatory enforcement and inspections are organised and delivered. There is thus considerable potential for reducing regulatory costs on businesses and citizens through improving the efficiency and effectiveness of inspection services. Some OECD countries have launched reform programmes designed to ensure that inspection services are delivered efficiently and effectively, having regard to the costs for government in the delivery of inspection services and tailoring the organisation of inspection services to utilise changes in technology and social organisation to better attain regulatory objectives.

The processes of how regulations are designed and developed, how to improve them and make them "smarter", have been given considerably more study than the regulatory delivery mechanisms of inspections and other enforcement tools. Nonetheless, the latter is also crucial to understanding how the regulatory system affects businesses and the economy. Inspections and enforcement actions are generally the primary way through which businesses, in particular Micro, Small and Medium Enterprises[1] (MSMEs), "experience" regulations and interact with regulators. Inadequate

enforcement and inspection practices can mean that improvements to the design of regulations fail to realise their full benefits. Reform of inspections and regulatory delivery to make them more compliance-focused, supportive and risk-based can all lead to real and significant improvements for economic actors, even within the framework of existing regulations. Finally, the reform of enforcement and inspections is as much about changing methods and culture as it is about reforming institutions organisational mechanisms and legislation.

The main drivers for reform are generally to reduce the administrative burdens and other obstacles to business growth that stem from inspections (in particular regulatory uncertainty), to improve the effectiveness of enforcement practices and therefore improve regulatory compliance – and in some cases to increase efficiency and thus decrease budgetary costs to governments. Because situations are diverse, some principles may be more or less relevant to each context, and there are some trade-offs between different principles that may be decided differently based on the priorities in each jurisdiction.

In some ways, *ex ante* regulatory instruments such as permits, licenses and other approvals are also "regulatory enforcement instruments" in that they seek to ensure compliance and the achievement of given public goods. However, they are very specific, and differ from the ongoing work of supervision and enforcement in that they are used and administered before operations start. Because of this, and of their specific impact in terms of restricting access to markets, they have been the object of specific research and literature, and thus will not be covered in this paper, except incidentally in points which directly relate to the principles described here.

For reasons of size and complexity, the paper focuses on regulatory enforcement and inspections in relation to non-state operators, particularly private businesses. While many of the principles apply similarly to regulatory enforcement targeting other actors (state-owned enterprises or state institutions, NGOs, private individuals), there are of course certain differences. These are not discussed in the following principles.

Covering all regulatory enforcement fields in a single document has obvious advantages, because many issues and principles are common across all of them. There remain, however, important specificities in each field, and there may thus be points where the principles will need some adjustment in order to get adequately implemented in specific regulatory situations, for instance financial markets regulation (where the field's complexity, and the very powerful nature of many regulatees, calls according to many authors for increased regulatory discretion).

Box 2. Draft international best practice principles: Improving regulatory enforcement and inspections

1. **Evidence-based enforcement.** 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.
2. **Selectivity.** Promoting compliance and enforcing rules should be left to market forces, private sector and civil society actions wherever possible: inspections and enforcement cannot be everywhere and address everything, and there are many other ways to achieve regulatory objectives.
3. **Risk focus and proportionality.** Enforcement needs to be risk-based and proportionate: the frequency of inspections and the resources employed should be proportional to the level of risk and enforcement actions should be aiming at reducing the actual risk posed by infractions.
4. **Responsive regulation.** Enforcement should be based on "responsive regulation" principles: inspection enforcement actions should be modulated depending on the profile and behaviour of specific businesses.
5. **Long term vision.** Governments should adopt policies and institutional mechanisms on regulatory enforcement and inspections with clear objectives and a long-term road-map.
6. **Co-ordination and consolidation.** 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.
7. **Transparent governance.** Governance structures and human resources policies for regulatory enforcement should support transparency, professionalism, and results-oriented management. Execution of regulatory enforcement should be independent from political influence, and compliance promotion efforts should be rewarded.
8. **Information integration.** Information and communication technologies should be used to maximise risk-focus, co-ordination and information-sharing – as well as optimal use of resources.
9. **Clear and fair process.** Governments should ensure clarity of rules and process for enforcement and inspections: coherent legislation to organise inspections and enforcement needs to be adopted and published, and clearly articulate rights and obligations of officials and of businesses.
10. **Compliance promotion.** Transparency and compliance should be promoted through the use of appropriate instruments such as guidance, toolkits and checklists.
11. **Professionalism.** Inspectors should be trained and managed to ensure professionalism, integrity, consistency and transparency: this requires substantial training focusing not only on technical but also on generic inspection skills, and official guidelines for inspectors to help ensure consistency and fairness.

The fact that these principles aim to cover a wide range of issues pertaining to regulatory enforcement and inspections also mean that the depth in which each of them can be discussed is limited. This is particularly true of risk analysis and management techniques, but also of the details of compliance promotion and management approaches, inspection methods etc. These are covered in depth in other papers and publications, in particular in a number of OECD publications on risk management and compliance in the context of tax administration.[2]

The goal of this paper is to present some key principles on which effective and efficient regulatory enforcement and inspections should be based in pursuit of the best compliance outcomes and highest regulatory quality. The principles address the design of the policies, institutions and tools for promoting effective compliance – and the process of reforming inspection services to achieve results. Each of the principles listed in the box below is accompanied by explanatory text.

This revised version is based on two expert papers presented to the Regulatory Policy Committee at its 7th meeting in November 2012, an extensive review of practices in OECD and non-OECD countries and on the research that has been conducted on this topic over the past three decades. Public consultations on a draft of this paper were conducted in June – August 2013. The paper was adjusted accordingly, implementing most of the comments received during this period.

Notes

1. And MSMEs are also those for whom the experience can be the hardest, and the burden the heaviest, as they have less resources to deal with regulations, compliance issues etc.
2. See for example www.oecd.org/site/ctpfta/listofftapublications-bytopic.htm#comp.

Principle 1

Evidence-based enforcement

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.

Getting the policy settings right and deciding which regulatory enforcement agencies should exist, and with what mandate, is essential. To achieve this existing structures, budget allocations, human and material resources, mandates and functions of enforcement and inspecting agencies need to be reviewed systematically using a transparent set of well-defined criteria.

For most countries, the existing institutional structures and resources allocation have evolved over many years, incrementally through legislative and governmental decisions focusing on one particular issue at a time (often reacting to a particular emergency or event), without the benefit of a comprehensive perspective. As a result, government structures often have many overlapping or partly duplicating functions. Many regulatory enforcement agencies also have a mandate that corresponds to issues that may have come to present little risk, or where inspections are not an effective compliance strategy. This provides an opportunity for countries to learn from the experience of other jurisdictions in those cases where regulatory compliance has been found to be effectively promoted through other means.

Likewise, resource allocation is often based to a large extent on decisions taken long ago, in a different context. Institutions were set up with a given budget and staffing, and these evolve from year to year based on budget constraints and policy priorities – but the allocation across the executive branch, between different enforcement and inspection areas, is not

usually reviewed using a cost-benefit analysis and considering what hazards are being addressed by each structure, and at what cost.

A principle of evidence-based enforcement and inspections would require that regulatory enforcement agencies' actions and their effectiveness should be regularly evaluated, against a set of well-defined indicators, and based on reliable and trusted data. Collecting data on activities and outputs (e.g. how frequently an agency conducts inspections, how many entities are subject to inspections, how much time, private or public is taken up with inspections – and what are the administrative sanctions or criminal prosecutions that may follow) is important to assess resource use and burden on businesses. However, these should not be taken as a reflection of the effectiveness (or lack thereof) of an agency.

Comparative research has shown that a high number of inspections do not guarantee greater levels of compliance, and many sanctions do not necessarily safeguard the public. On the other hand a small number of checks or prosecutions do not mean that compliance is high, as it may just reflect a lack of inspection resources, or lax enforcement. It is acknowledged that properly assessing the effectiveness of enforcement and inspection agencies is difficult, because improvements or worsening outcomes (health, safety etc.) cannot directly be attributed to their activities because of the vast number of other, often more important, factors. Nonetheless, it remains crucial to monitor such outcomes in order to judge whether enforcement is having any positive contribution.

Associated with this, the reliability of the data used is of particular importance. As a rule, data that is directly the result of an agency's processes (e.g. number of prosecutions or sanctions, which is a number the agency can directly influence based on changes in enforcement policy) should never be used to assess compliance levels, because it is by no means "independent" data, and it 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 and there may be incentives for the inspectorate to alter the data so as to improve its apparent performance.

In developing a regulatory enforcement policy, governments should have an overview of the significant policy areas of regulatory enforcement, in order to gather information on:

- areas of enforcement activities and the level of resources dedicated to enforcement activities;

- opportunities for the effective use of alternative, and light handed approaches to promoting compliance, including through civil suits and market mechanisms;
- the potential for the use of risk assessment and management to identify and inform the design of enforcement strategies.
- any potential to remove overlap or duplication across different inspection and enforcement activities

Assessing regulatory enforcement agencies one by one and in isolation creates the risk of not having a comprehensive, systemic perspective, and to miss what is the real experience and perspective of regulated entities. Thus, reviewing what is the regulatory enforcement experience for businesses in a given sector is a necessary complement to investigating the relevance and performance of each given agency. Reviewing the way regulatory enforcement works from the point of view of a business rather than only looking at each agency in turn also enables to identify overlaps and duplication more clearly. Governments should conduct such systemic reviews and in particular look at the overall experience of regulatory enforcement from each sector's perspective, aiming at a more rational allocation of tasks and resources.

The review of enforcement activities should draw on international experience to evaluate the merits of different organisational approaches to address common public policy goals.

A review of a government's enforcement activities should be based on factors such as:

- Negative impact of the risk or issue addressed (looking at economic, human, environmental impact, as relevant – and basing this assessment on statistical data for past years),
- Existence or not of alternative enforcement mechanisms, and their effectiveness,
- Level of effectiveness of enforcement and inspection activities for each given risk (assessed looking at historical data, international comparisons, available research),
- Level of overlap between the activities of different inspection and enforcement structures (using also international comparisons to look at different organisational models).

Governments should not assume that wherever there is a legal requirement of some sort, a regulatory enforcement agency necessarily needs to exist to enforce this requirement. Requirements should be expected

to be enforced through the usual mechanisms of civil litigation, market forces and criminal law enforcement, if needed (see Principle 2) – and a specific agency set up (or empowered) to enforce a set of regulations only if there is a demonstrated need for this arrangement.

Governments should ensure that, when developing regulation, the priorities for the allocation of enforcement resources is informed by a cost-benefit analysis, based on effectiveness and efficiency criteria. This should include a consideration of whether compliance with the regulatory requirements can be expected to be achieved more efficiently through the mechanisms of civil litigation, market mechanisms and criminal law enforcement when needed (see Principle 2).

For each regulatory enforcement agency or structure mandated with the authority to conduct enforcement and compliance, governments should ensure that this mandate is clearly defined with reference to the outcome indicators that the agency aims to influence (e.g. number of preventable deaths and injuries due to specific hazards, etc.), and that the agency is 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 is collected independently. The improvements in the number of businesses that are "broadly compliant" with the requirements should be used only as a complement to outcome indicators. In addition, information on the efficient economic costs of inspection activities on an industry sector (administrative burden, satisfaction level of businesses relative to information provided by inspectors, etc.) should also be tracked and reported upon systematically as well as indicators reflecting on the internal process improvements (proportion of inspections planned based on risk analysis, share of resources allocated to consultation and advice, uptake of tools facilitating compliance, etc.).

Because regulatory enforcement agencies cannot (and should not) inspect each and every business operator under supervision, but rather should focus their inspection visits based on risk (see Principle 3), they cannot obtain statistically representative information on compliance based solely on their inspection activities – which may in some cases, if the risk-targeting models are effective, even show non-compliance to be higher than it really is. Governments should thus ensure that the performance measurement approaches balance the use of different indicators from various sources so as to minimise this bias in measurement – and, if possible, should consider the use of random, statistically representative surveys every few years so as to get a "reality check" of the situation with business operators' compliance in critical areas.

In designing the indicators, the numbers of violations identified and the value of penalties imposed should be tracked as reflecting information on the activities of the regulatory enforcement agency, but should in no case be used as performance indicators as it cannot reliably correlate with good (or bad) performance of the agency.

In addition, factors as perception of regulatees on the regulatory enforcement agencies, as well as views of other stakeholders, should also be tracked. Given the limitations inherent to data on a number of indicators, qualitative assessments are a necessary complement, and such perception information can contribute to comprehensive qualitative assessments. Governments should ensure that they take such a comprehensive view of regulatory enforcement agencies' performance, and that this is used to increase accountability.

Agencies should collect the data according to strictly defined protocols. In cases when data is produced or collected by the agency itself, it should be regularly cross-checked by independently conducted, representative surveys.

In all cases, governments should publish all the relevant information pertaining to indicators, how they were defined (and based on which assumptions and logic) and how they are measured.

Governments should not only require regulatory enforcement agencies to report on their performance, but also to provide their perspective on current safety issues (or issues with other public goods, as relevant), in particular whether they consider that any urgent action is required, even if such action is beyond the direct scope of their mandate or their powers, but is relevant to their mission. Likewise, if a significant incident takes place, governments should require inspectorates to analyse whether there are structural factors at play behind the incident, or whether it was just the result of an essentially unavoidable set of circumstances.

Principle 2

Selectivity

> *Promoting compliance and enforcing rules should be left to market forces, private sector, civil society actions and courts where it is possible and efficient: inspections and enforcement cannot be everywhere and address everything, and there are many other ways to achieve regulatory objectives.*

While regulations of economic activities have existed for a very long time, the emergence of specialised institutions tasked with verifying compliance and enforcing rules has only been a gradual process, and in many cases a relatively recent one. It should not be assumed that each and every rule issued by the state needs to have a specific regulatory enforcement agency following up on compliance by businesses.

In many cases, even if the regulation is both needed and cost-effective, there may be no need to assign state resources to actively control compliance and enforce it, because other mechanisms may be used for lesser cost and burden. In particular, when regulations apply to market relationships and services to be provided, it may be possible to rely on liability provisions for suppliers, combined with adequate insurance requirements for one or both parties. Governments, before deciding upon whether to assign inspection and enforcement resources to a specific regulation or set of regulations, should follow clearly stated criteria, such as:

- Would violation of these regulations potentially cause immediate, irreversible harm – or would there be possibility to later on repair or compensate the damage adequately, once violation is identified? Conversely, is *ex post* enforcement action through courts adequate to the issue the regulations aim to address, or is preventive action through inspections and other means of control essential to achieve the regulations' goals?

- Would violation of these regulations potentially cause, if not *irreversible* harm, extensive damage that would be extremely costly to remediate, whereas prevention of such damage would comparatively be feasible at low cost – and would the costs of damage, were it to occur, potentially put the business operator in a position where it can in no way compensate for it (default or equivalent), leaving the affected parties without recourse (or leaving the costs to the state)?

- Are there possibilities to rely on market mechanisms and providers of conformity assessment services, so that conformity can be verified by (adequately regulated and supervised) private sector entities, rather than directly by the state (and would this prove more cost-efficient for the state and for taxpayers)? What is the maturity and coverage of any existing and applicable market mechanisms?

- Is the asymmetry between market participants position very strong, in a way that would make market-based mechanisms unlikely to work? Do public and private interests roughly align (e.g. complying with regulation is likely to be beneficial for businesses in terms of market share, revenue, profits), in which case market-based mechanisms are more likely to be effective, or on the contrary are public and private interests in complete or partial conflict?

- Can the potential liability in case of violation of regulations *and* subsequent harm be adequately covered through a mandatory insurance mechanism?

- Does litigation (and prosecution) and enforcement of regulations through the courts have the potential to ensure an adequate level of compliance, and deter serious violations?

If the conclusion is that non-compliance would *not* immediately cause either irreversible harm or extremely costly damage that would make it impossible for the responsible operator to meet its liabilities, and alternative mechanisms are found to be applicable, governments should consider using market-based mechanisms rather than direct inspections and enforcement actions, or leave enforcement to litigation, public prosecution in egregious cases, and court decisions. Even when only some of these points are met, such mechanisms can be considered if, for instance, direct control by the state would pose an excessive burden on state resources or would result in major bottlenecks for the economy.

Likewise, if the harm that could arise from non-compliance with regulations is assessed to be very low, and regulations nonetheless exist (in cases where OECD principles would rather recommend *not* to use state regulation), inspections and enforcement resources should generally not be allocated.

In order to facilitate the enforcement of regulations through alternative means, and to allow citizens, consumers, civil society organisations and contractual partners to obtain redress in case of violations, governments should adopt rules that allow for class-action lawsuits (if appropriate in their legal system) or equivalent mechanisms to make legal proceedings easier (e.g. by allowing civil society organisations or business associations to be parties in such cases) in case of alleged violation of regulations.

At the same time, governments should ensure that significant resources are allocated to promote compliance by other means than enforcement, in particular through information to businesses and consumers, and through the promotion of voluntary certification schemes, or the use of rating schemes that distinguish best and worst performers. Such schemes, by changing the incentives for business operators, have the potential to effectively drive improved compliance in markets where the positive value conveyed by such certification or ratings is significant – but this requires that certification or ratings retain credibility.

It should be made clear, both in law and in practice that the primary responsibly for compliance and with safety lies with the regulated subjects. Inspectors and regulators are here to assist and promote compliance, but not to actually implement regulations – and they cannot be the ones ensuring safety, as they are not the business operators. Where appropriate and if this does not create disproportionate burden, this may also mean that requirements for self-monitoring and, in some cases, reporting can be introduced for certain operators which present a significant level of risk, so as to allow for less frequent inspection visits. These inspections can then focus on verifying how effective the self-monitoring and risk-management systems implemented by the business operator are, and whether they seem to work in practice and not only on paper. It is important to remember that such "system inspections" need to incorporate effective "reality checks" and not trust that systems always work as designed.

In areas where safety cannot be achieved without the end users or consumers being also involved (such as food safety), governments should similarly make this clear at the policy level, and mobilise resources to raise knowledge and improve practices of consumers and citizens overall.

Relying on market forces and court litigation is not an approach that fits every situation or jurisdiction, and like all public policy decisions it has its downsides. Relying on courts may have unintended side-effects: lack of technical expertise may mean courts take decisions that are less in line with technical innovation than a regulatory body would, for instance. Business operators may also prefer having a regulatory enforcement body as counterpart, if this institution is transparent and promotes compliance, issues clear guidance and shows proper attention to the specific circumstances of each business – as opposed to the uncertainty that can result from having to wait for a court decision to know how to interpret a given legal provision. In any case, if enforcement is left up to the courts, governments should support publication and dissemination of important case law.

In many cases, there may not be an "either, or" choice between market-based mechanisms and direct regulatory enforcement by the government, but rather co-regulation – where schemes such as certification and accreditation are 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. Governments should consider the applicability of such approaches in each regulatory area where private sector capacity is strong and private and public interests generally align, i.e. compliance with regulation is likely to be conducive to business profitability.

Overall, even though using market mechanisms and courts can be fully appropriate and efficient in some circumstances, and governments should always look for the possibility to do so, they should also monitor how the situation evolves and what the feedback from stakeholders is, and be ready to change the regulatory delivery mechanism if needed. Governments should also allocate resources to monitor the performance and results of the overall system of market-driven enforcement, and of any voluntary certification schemes (or any similar involvement of private entities in co-regulation) in particular, so as to spot any problems and be in a position to make appropriate changes if needed.

Principle 3

Risk-focus and proportionality

Enforcement needs to be risk-based and proportionate: the frequency of inspections and the resources employed should be proportional to the level of risk and enforcement actions should be aiming at reducing the actual risk posed by infractions.

All enforcement activities should be informed by the analysis of risks. Each activity and business should have their level of risk assessed. Enforcement resources should then be allocated accordingly. Each set of regulations should likewise be given a level of priority commensurate to the risks they are trying to address. Risk should be understood here 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). This means that typically the highest risk categories will comprise objects for which both probability and potential magnitude are high – but also in some cases those where probability is low, but magnitude of damage would be extreme, and much damage impossible to repair (e.g. major environmental disaster). It is important that risk is considered at all levels of decision making in relation to regulatory enforcement – from strategic prioritisation of resources to premise based targeting and proportionate sanctioning regimes. Governments should ensure that a consistent definition of risk is used throughout all inspectorates, and that it forms the basis for allocation of resources and for enforcement approaches.

Such risk-analysis should be used at all steps of the regulatory process – when designing regulation, enforcing it, and evaluating it. It is particularly important at the enforcement stage, because it is physically impossible for governments to inspect each and every business or object, and because even attempting to do so (while not being necessarily effective) would result in

massive and unnecessary administrative burden. Thus, because prioritisation in inspection and enforcement actions is indispensable, governments should make sure that it is done on the basis of risk-analysis and assessment of businesses' risk profile.

Assessing risks and prioritising on their basis does not need to mean complex data-mining methods – not all regulatory fields will have adequate data for this, and not all agencies will have the capacity – nor is it always necessary to use such techniques to achieve real improvements in targeting. In the absence of comprehensive and/or fully reliable data, regulatory enforcement agencies should rely on interpreting what data exists (at least to establish which sectors appear to generate the most damage), using international experience in the same field, as well as senior officers and experts' understanding of the field, to develop a risk-based categorisation of sectors, business types and objects of inspection. Risk-focus should not be seen as the opposite of relying on the expertise of enforcement officials, but rather a way to structure and orient such expert knowledge.

In practical terms, this means that governments should ensure that each regulatory enforcement agency develops/collects and uses the following:

- Criteria to assess the risk of individual businesses and rank them according to assessed risk level;
- Data on all (or at least most) businesses allowing to effectively assess their individual risk level;
- Planning and resource allocation mechanisms so that inspection visits are effectively planned based on the risk level, and resources are rationally allocated
- Updating process so that the risk-profile of each business is regularly updated to incorporate new information, and risk criteria are modified based on new statistical data on hazards, possible damages etc.
- In line with Principle 4, consistently-compliant businesses are treated as correspondingly lower risk, and inspected less frequently ("earned recognition").

In addition to the allocation of inspection resources, the follow up actions taken based on inspections findings, should also be proportional to risk. Governments should adopt rules requiring all regulatory enforcement agencies to develop and implement enforcement policies based on risk-proportionality so that:

- Types of violations are reviewed, analysed, and ranked according to the potential risk they present;
- Guidelines are given to inspectorate staff prescribing to always assess the actual risk level presented by each recorded violation or set of violations before deciding on a follow up, including sanctions;
- As a result of these steps, sanctions taken when violations are found are proportional to the potential magnitude of hazard – thus ensuring deterrence in the most hazardous situations but also reducing burden for minor shortcomings (in line with Principle 4, this can mean that for some minor violations and/or mostly compliant businesses no sanctions are imposed, but only improvement notice given).

Because sanctions (or at least the range of possible sanctions for a given violation) are to a large extent prescribed in legislation or regulations, governments should undertake to ensure that such principles are followed when drafting laws and executive orders, and that sufficient flexibility is left to enforcement and inspection officials to adapt their response in proportion to the facts on the ground, and in line with guidance issued by their agency.

Inspections provide opportunities for regulatory enforcement agencies to provide information and advice, suggest cost-effective remedies on site, increase the agencies' understanding of the businesses they regulate – and in this process, allow to develop trust relationships between regulators and regulatees. In addition, even well performing business operators may experience strong variations in compliance, due to a variety of internal or external factors. Relatedly, regulatory enforcement agency need some compliance (and compliance-related) information on all regulated entities – including regulatees with good compliance records – in order to monitor and measure regulatory compliance and performance in a comprehensive manner. This in turn allows tracking the evolution of risks, and whether their risk assessment models remain valid – and also to feed into the "responsive regulation" approach (see Principle 4). For all these reasons, governments should take care that the lower burden of inspections that is granted to good performers ("earned recognition") nonetheless leaves some opportunities for (less frequent, less burdensome) visits to these businesses.

Governments should ensure that risk criteria, policies, guidance, etc. are 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. Regulatory enforcement agencies should develop and track indicators that give "early warning" of changes in both the likelihood of occurrence and the magnitude of consequences. Moreover, the frequency of revisiting risk assessments should be linked to the agency's

understanding of differences in the likelihood that compliance risk may change over time, because some types of regulatory risk have greater inertia than others.

When assessing risks, inspectorates should take into account not only hazards (possible adverse effects on life, health, environment), negative impact on public goods, but also whether constitutionally or internationally recognised human rights could be jeopardised by the adverse effect.

Risk-focus and proportionality also means that governments should ensure that inspections and related enforcement actions are not allowed to fall too low, under what could be called a "threshold level" – particularly in budget restrictions contexts. There is no easy way to ascertain this level, and it will vary with the specifics of the regulation, industry and country. It has been nevertheless observed that when the percentage of business operators inspected each year is vanishingly small (e.g. less than 1% of supervised operators get inspected each year), a tipping point may be reached beyond which compliance decreases markedly. This is particularly true when business incentives run contrary to the requirements of the regulation, and thus market forces are unlikely to be a strong driver of compliance.

Proper risk-management also requires that regulatory enforcement agencies handle information received from third parties (complaints or allegations submitted by workers, citizens, other businesses etc.) in an effective way, so that it effectively allows to complement and update other sources of information, and to receive key information even in the absence of an inspection, but does not result in breakdown of the risk targeting system and excessive reactions by failing to discriminate sufficiently. It is essential that agencies filter first between complaints that clearly point to possible violations and those that just express some discontent with a business operator but without indication of a regulation being infringed, then between complaints that appear well substantiated and detailed and those that seem less grounded, between those that point to potentially major risks and others that only relate to relatively minor issues, and finally between repeated complaints from several sources and one-off allegations. Incorporating all these parameters will allow agencies to respond adequately – from a simple message indicating that the complaint was received but no action is required given its contents, through incorporation of the information to update the object's risk profile but without need for immediate action, up to the decision to conduct an emergency inspection if there is strong evidence of a major, imminent risk. Governments should ensure that regulatory enforcement agencies adopt procedures and processes to deal with complaints and allegations that are built along such lines.

Risk assessment and risk management require resources and expertise, and to be continuously updated using the results of inspections, monitoring, and analysis of all available sources of information on ongoing trends in the relevant field. This means that governments should ensure that regulatory enforcement agencies all have a dedicated unit or teams specifically in charge of risk management, with adequate resources to perform their task effectively.

Principle 4

Responsive regulation

Enforcement should be based on "responsive regulation" principles: inspection enforcement actions should be modulated depending on the profile and behaviour of specific businesses.

The "responsive regulation"[1] approach suggests that regulatory enforcement agencies should adopt a differentiated enforcement strategy based on the behaviour and history of the businesses they deal with. Used properly, responsive enforcement promotes compliance more effectively, while reducing the burden posed on the "best performing" businesses. Because businesses are informed about this policy, they have an incentive to improve their compliance and co-operate with regulatory enforcement agencies, because they know this will lead to less burdensome oversight. A similar approach is "persuasive enforcement": regulatory enforcement agencies should show that it is in the best long term interest of businesses to comply – because such compliance will ensure a positive relationship with the regulator, and on the contrary refusal to co-operate will result in heavy enforcement. Evidence shows that such combination of compliance support and deterrence with the right articulation between the two is the most effective and efficient approach. In this perspective, governments should promote the use of responsive enforcement approaches by regulatory enforcement agencies where possible and monitor their use.

The following approach is suggested:

- Businesses that show a pattern of systematic and repeated violations of regulations are assigned a higher risk level,[2] and accordingly checked more frequently;

- Businesses which commit repeated and systematic violations 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. Inspectors should also take into account the response of the business operator to the inspection and the identification of violations (e.g. whether the operator attempts to hide problems or is transparent about them, whether immediate corrective action is taken or on the contrary the operator seeks every possible way to hinder the inspection or challenge even the most obvious findings etc.);

- On the contrary, businesses which have a history of compliance should be gradually checked less often (their risk level being rated lower) – inspectors should also generally start with improvement notices or (in the case of lesser violations) verbal warnings, except in cases of major, imminent hazard;

- Recently created businesses should be similarly first given a chance to improve, rather than immediately resorting to sanctions, so as to promote a culture of openness on their side (except, once again, if violations are seen to be particularly dangerous and/or were clearly committed on purpose – in which case the regulatory enforcement agency should use sanctions as appropriate);

- Proportionality and risk-responsiveness mean that, even if a violation is found in a business which is usually compliant (or is a new business), but this violation is particularly egregious and poses very serious threats to life, health or other essential public goods or rights, the enforcement response should be stronger and more coercive than in cases where violations are relatively less grievous or do not create an imminent hazard;

- In order to be effective, the "responsive regulation" approach also requires that the range of potential penalties available to regulatory enforcement agencies be sufficiently broad and differentiated to really treat different behaviours in a proportionate manner, but also to exert real deterrence when needed – with penalties that clearly will impose higher cost than the violation may have brought in undue profits to the business operator, and a process for imposing sanctions that uses administrative penalties (and not prosecutions in courts) for at least a significant share of violations so as to ensure more rapid and predictable enforcement. If sanctions are insufficiently deterrent, there is a high likelihood that "rogue operators" will continue to commit major violations even after having been caught once (or repeatedly).

While the specifics of legal systems and of each regulatory area mean that it is impossible to consider the above steps as a "one size fits all", and in some particular cases there may need to be exceptions to the "responsive regulation" approach, governments should consider their applicability and, inasmuch as possible, adopt guidelines based on (or equivalent to) such an approach.

Notes

1. "Responsive Regulation" is an approach that was formalised in 1992 by I. Ayres and J. Braithwaite (but builds on considerable prior research and experiments) and suggests that the most effective enforcement strategy will be one that does not treat all regulated subjects in a uniform way, or all similar violations in exactly the same manner. Instead, differentiation should be based on the overall behaviour of the regulated subject (generally compliant, or ready to become so – or on the contrary unco-operative), on the pattern of violations (rare or repeated), etc. According to this approach, not only should each inspector deal with businesses it visits on this basis, but regulatory enforcement agencies should publicly announce this approach, because knowing this will provide an additional incentive for businesses to be as much as possible compliant, as this will also mean inspectors will be relatively more lenient if some problem or mistake does happen (cf. I. Ayres and J. Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate,* Oxford University Press, Oxford, 1992).
2. Compared to what their "inherent" risk would be considering their type of activity and scope, and thus to what the risk level of other businesses with a similar activity would be.

Principle 5

Long-term vision

> *Governments should adopt policies and institutional mechanisms on regulatory enforcement and inspections with clear objectives and a long-term road-map.*

Regulatory enforcement and inspections are functions that have a major bearing on regulatory effectiveness overall, on the intended effects of regulations in terms of public goods, and on the burden they pose to businesses and the economy. Thus, recognising them officially as a distinct priority is a first essential step. Transforming regulatory enforcement and inspections practices and processes requires time – and therefore it is essential to have as much as possible continuity in goals and political support. The breadth of issues and institutions involved also makes it necessary to establish an overall framework or mechanism to steer improvements and reforms across the board. Governments should thus adopt official policies on reform, oversight and continuous improvement of enforcement and inspections.

An official government vision on enforcement and inspections is important because: *i)* it allows to recognise the similarities between all functions and structures that deal with these issues, regardless of the sector, and thus to address problems and issues in a consistent way, as well as to tackle overlaps and duplications – *ii)* it can serve as basis and anchor for all inspection and enforcement reform initiatives in specific institutions and sectors. It also helps to mobilise public support for transformations by lending more visibility to the topic.

The policy on regulatory enforcement and its reforms should be based on clearly articulated overarching goals as well as specific objectives (e.g. improving efficiency, minimising burdens, concentrating resources and efforts where they can deliver the most results, improving transparency and responsiveness). The reform efforts should be regularly evaluated, and be updated where needed.

The objectives should aim to address the issues that have been identified in each given jurisdiction as particularly relevant or problematic. These are likely to include excessive numbers of inspections or of institutions covering the same issues (at least for some types of businesses and sectors), unclear requirements and expectations, insufficient focus of resources on risk, and lack of proportionality of sanctions to risk, lack of co-ordination and information sharing, limited (if any) provision of compliance supporting advice, evaluation systems treating outputs (inspections) as results, among the most typical problems. They may also include in some areas a problem of *under*-inspection, due to lack of resources, resulting in enforcement gaps in some critical areas (which resource reallocation and consolidation could help address) – or inspections may take place, but enforcement actions be insufficient or badly implemented and result in low credibility. Based on the analysis of the situation in their country, governments should developed detailed, specific objectives based on the OECD principles presented in this paper.

In addition, mechanisms are needed to drive the change process, evaluation framework and, if necessary, exert pressure. Governments should create an institutional set up that provides for co-ordinating and driving the change process, evaluation framework and, if necessary, exert pressure. This mechanism should ensure that all relevant ministries, agencies and structures (regulatory enforcement agencies etc.) are involved in a co-ordinated manner. A strong political leadership must be ensured as in case of all policy reforms. Adequate capacity is needed to promote improvements of regulatory enforcement and inspections. Governments should ensure that the institutions in charge of this work are appropriately staffed and resourced.

An important element for an effective, efficient, transparent and professional regulatory enforcement system is to have resources that are allocated in a way that allows for mid- and possibly long-term planning, and that are somewhat safeguarded from short term events, be they political, economic or otherwise. If analysis of the needs, risks and alternative ways to achieve compliance has been conducted as outlined in principles 1 and 3, and the need for state-led enforcement has been found clearly evidenced for a given regulatory field, it is essential that such enforcement be properly resourced, in a way that is commensurate to the risks being addressed, the technical complexity of the field, and the number of objects under

supervision. Governments, for regulatory enforcement areas the importance of which has clearly been demonstrated, and on the basis of a comprehensive assessment of the weight of relative priority fields, should strive to allocate appropriate resources for regulatory enforcement agencies, and with a level of stability that allows for proper planning, professional development and long-term improvements.

Considering the diversity of institutional, constitutional and legal frameworks, the form that the points above can take will inevitably be very varied, but governments should strive to create an appropriate framework to ensure long-term perspective and support to constant improvements of the regulatory enforcement system.

Principle 6

Co-ordination and consolidation

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.

One of the most important institutional changes to improve the efficiency of inspections and decrease the costs and burden they represent is to restructure regulatory enforcement agencies so that functions are consolidated, thus removing duplications and overlaps. Existing institutional structures are in many countries a result of *ad hoc* creations (when new legislation was adopted), or of policy changes focused on one sector but without a strategy or comprehensive perspective. Therefore, there are areas where more than one agency control and enforce regulations simultaneously, generally without co-ordination and in an inconsistent manner – and often with different sets of regulations. Governments should in this respect identify main areas of overlap and duplication among existing institutions authorised to inspect and enforce regulations with the aim to minimise those where necessary.

Institutional arrangements will inevitably be diverse, depending on constitutional and other contexts. However, international experience shows that there is only a limited number of different types of risks, that should form the basis for restructuring. One of the possible approaches is an institutional structure close to a "one risk, one inspectorate" model, which in most countries, if followed, requires considerable institutional changes, in particular mergers of agencies. Another valid approach is to establish administrative arrangements to improve co-ordination, ensure information is shared and inspections are not duplicated, without necessarily merging different organisations. This can take the form of each sector being assigned

a "lead agency", which can inform others of the results found on the ground, for instance (this approach can also be taken between agencies covering different regulatory areas). It is in any case fundamental to adapt to local political and institutional realities and priorities, and major institutional changes can be very difficult and costly, but in some contexts it is also known that inter-agency agreements simply do not work – thus governments should find the most appropriate mix between mergers and consolidation, and improvements within existing structures, so as to ensure that in the end results in terms of effectiveness and efficiency are really achieved.

In order to conceive and plan the required improvements to the institutional system, it is necessary to have an overview of what fundamental regulatory enforcement functions exist (focusing here on functions that relate to private business activities). Evidently, no comprehensive, generic list can be prepared, because policy priorities vary in each country, some activities that are left completely free in one jurisdiction are seen as vitally requiring regulation in another, some sector which is mostly left to private providers in one is covered by state institutions in another etc. However, it is recommended that governments take the following list of core functions, which correspond to those that are found to be fundamental in practically every regulatory regime, be used as a foundation for the analysis, and possibly for a review of the institutional structure:

- Food safety;
- Non-food products safety[1] and consumer protection;
- Technical and infrastructure/construction safety;
- Public health, medicines and health care;
- Occupational safety and health;
- Environmental protection;
- State revenue;[2]
- Transportation safety;[3]
- Banking, insurance and financial services supervision;
- Nuclear safety.[4]

It should be noted that there is a trade-off between consolidation (and thus rationalisation) and specialisation, which can help deliver better results in very narrow, high-hazard areas. Thus, governments may decide to split some of these core functions to keep some higher levels of specialisation (including e.g. between financial services, banking, insurance – or to keep

aviation separate from other transportation means). In other cases, the added value of resource-sharing and co-ordination may be deemed more important, and additional consolidation can take place (e.g. merging food and non-food safety, or even setting up a single inspectorate for most technical safety functions, with different internal departments looking at specific issues but under a joint management).

The aim of such re-organisation should be not only to remove duplications (thus decreasing costs and burden) but also to improve co-ordination and focus, and allocation of resources. Thus, the new structure should be implemented alongside a review of the resource repartition between enforcement areas (in line with principles 1 and 3). It should also be an opportunity to improve co-ordination and information sharing, and to improve governance (in line with Principle 7).

Because certain regulatory areas correspond to issues of particularly high hazard, and/or concerns such as potential regulatory capture or other abuses are important, there are situations where consolidation may not be helpful, but on the contrary retaining an element of redundancy may build more robustness and resilience in the regulatory systems. If such circumstances are found, governments should strive to ensure that information sharing and co-ordination between such duplicating structures is particularly effective. Otherwise this duplication will not result in increased reliability of regulation, but rather in more confusion and waste of resources.

Governments should put in place policies that ensure effective information sharing and co-ordination between regulatory enforcement agencies. The following approaches may contribute to the improvement and governments should consider which ones are relevant to their situation, or explore other solutions pointing to the same objectives:

- Creating a unified information system or otherwise strongly interconnecting existing information systems (in line with Principle 8);
- Merging most inspection structures within a "single inspectorate" (keeping specialised departments but within a single agency with unified management);
- Setting up a co-ordination council or other forum wherein most inspection agencies meet, harmonise practices and share information;
- Requiring all inspection agencies to systematically share with others all relevant data, and possibly inspection plans;

- Limiting re-inspection of the same issue by different inspectorates in the same business within a given time period (e.g. one year), except if problems have been identified in the first visit.

A valuable alternative to consolidating and merging institutions, for inspections of relatively simple objects (in particular Micro, Small and Medium Enterprises (MSMEs), and/or of objects of limited risk) is to introduce the practice to have "front-line inspectors" with a broader mandate, and a specific training allowing them to spot issues pertaining to a number of different regulatory fields. If and when these inspectors spot a problem, they can call upon to specialised inspectors working for different regulatory enforcement agencies, but otherwise their visit can substitute a number of more specialised ones. They effectively act as "eyes and ears" for multiple agencies. Governments should consider the applicability and feasibility of such an option to their situation.

When reviewing responsibilities and potential overlaps or duplication, governments should also pay attention to the role of courts in *ex post* enforcement and the way this interacts with regulatory enforcement agencies' functions. Though courts in principle can be seen as a place where regulators' decisions can be appealed, or where egregious violations can be prosecuted, in certain circumstances there can be in effect a sort of concurrent enforcement between regulators and courts, and governments should take this in perspective, in line with Principle 2 and the strengths and weaknesses of each type of enforcement.

Clearer responsibilities, improved focus of resources, better co-ordination all lead to improved effectiveness, and not just to higher efficiency and decreased burden. However, this higher effectiveness can only be achieved if inspectors operate in a consistent way, so that regulated subjects clearly know what to expect and how to comply. Thus, whichever exact institutional set up is selected, governments should ensure that agencies supervising related fields and spheres should harmonise their approaches and requirements, and publish joint guidance whenever possible.

An important source of confusion among regulatees, duplication of resources and controls, and potential enforcement gaps (because of unclear mandates and breakdowns in information transmission) arises when responsibilities for enforcement in a given field are shared between national- (or federal-) level agencies and local structures. Governments should pay great attention to clarify the respective responsibilities and mandates of different levels, inform regulatees about this, and also support the set-up of information systems that link the different actors in the enforcement "chain" so that critical information is shared in an efficient, effective and rapid manner.

Notes

1. Successful examples exist of agencies dealing with both food and non-food products safety but, because the set of regulations and issues differ, it makes sense to consider them as separate fields, even if they may be brought under one roof to optimise use of resources and information sharing.
2. All too often, state revenue agencies are excluded from broad Government programmes to improve inspections and enforcement. While there of course are important specificities in their work (as, even more so, in financial services supervision), there are many areas where the same tools and approaches are needed as in other inspections (risk management, compliance promotion etc.), and it thus makes sense to consider them as essential parts of the broad enforcement and inspections system.
3. Presented here as one function even though, in practice, countries usually have separate agencies looking at road safety and air safety – and possibly more. There are of course no overlaps between these because of the very clear specialisation.
4. Arguably could be under technical, OSH and environmental supervision. In most countries, however, the specificity and technical difficulty of the sector have led to a specific agency being in charge of nuclear installations when they exist.

Principle 7

Transparent governance

> *Governance structures and human resources policies for regulatory enforcement should support transparency, professionalism, and results-oriented management. Execution of regulatory enforcement should be independent from political influence, and compliance promotion efforts should be rewarded.*

Professionalism should be the foundation of regulatory enforcement agencies. This means not only technical competence in the fields relevant to the type(s) of risk(s) addressed, but also generic inspection skills (or “core inspection skills”) relating to how to conduct inspections effectively and promote compliance, ethical standards of behaviour, risk management, inter-agency co-operation – and operational management. Governments should establish human resources and training policies that ensure that:

- Management staff is recruited in a way that ensures they have adequate professional management skills and experience, and not just technical competence;
- Staff training results in operational personnel having, beyond technical skills, a real understanding of what inspections and enforcement aim to achieve, how to interact most effectively with regulated subjects (and in particular foster compliance), how to assess and rank risk – as well as all relevant ethical standards.

In some cases, even when civil service legislation generally means that the staff of regulatory enforcement agenesis protected from political interference, this does not fully apply to their management that tends to be more frequently replaced in line with political changes. Furthermore, even when even senior management is covered by civil service provisions, agencies in charge of enforcement and inspections are under the direct

supervision and influence of ministerial departments, and may alter some of their priorities based on political decisions. It is essential to ensure that inspectorates are able to set and follow their work priorities (which businesses to inspect, for instance) based on professional decisions and expertise, with political decision as much as possible intervening at the level of the overall strategy and resource allocation, but not in day-to-day operations and operational work. It is also essential that staff and management feel free to pursue the agency's objectives without fear of political interference or politically-driven management changes.

Thus, governments should consider establishing the following:

- Stability of senior management of regulatory enforcement agencies even when chief executives change (with careers governed by overall civil service rules and specific performance management policy, but not by external interference);
- Appointment of chief executives (and possibly of some other senior positions) through an open process, based on appropriate professional credentials, and with the decision made by consensus of a board/committee or of a cabinet meeting (or some other confirmation process), and not a simple ministerial decision – the possibility of time- or term-limiting chief executives may also be considered;
- Institutional identity of regulatory enforcement agencies as distinct from ministerial departments, so that they can clearly have their own strategic, objectives, activity planning etc., and also to accommodate the fact that many agencies have functions that cut across several ministries or departments – and with as much as possible distance from political decisions or interference.

Performance management policies for staff need to reflect the overall aims of enforcement activities and the specific goals of each agency, and in particular the performance indicators for the agency defined according to Principle 1. Thus, governments should mandate that each regulatory enforcement agency develops and adopts human resources performance management policies that align with principles exposed in this paper and ensure that:

- Staff that systematically aim to find the highest possible number of violations and issue the highest possible sanctions are *not* considered high performers;

- On the contrary, staff that effectively promote compliance and work in line with principles of "responsive regulation" are given adequate recognition;
- Overall, performance in terms of reaching regulatory outcomes and regulatory compliance is assessed across teams or units, rather than individually (as significant results in terms of compliance or safety improvement cannot be seen as the result of just one individual's work). Individual performance is then being assessed based on each staff member's participation in his/her team's work.

Improving the way regulatory enforcement agencies work involves not only changing structures, rules and incentives, but also in many cases changing cultures and behaviours (of officials, business operators and the public). Governments should pay attention to the fact that this means rapid breakthroughs will be difficult to achieve, important communication efforts will be needed, and reforms will have to be sustained over the long-term.

Regulatory enforcement agencies should engage with regulatees and strive whenever possible and appropriate to establish a co-operative approach, because only business operators themselves can ensure consistent, sustained compliance in their operations. Nonetheless, regulatory "capture" can also be a real danger, whereby some agencies become exceedingly close to regulated business operators, and end up being too lenient in the face of major violations or hazards, or possibly create an uneven playing field in favour of some operators. To avoid such problems, governments should make sure that governance systems for regulatory enforcement agencies ensure that stakeholders that stand to benefit from the regulation (e.g. workers, consumers etc.) are also represented, and that performance targets are strictly set and monitored that ensure that "regulatory capture", if it were to happen, would be promptly identified and addressed.

Another way in which regulatory enforcement work can potentially be put in jeopardy is when the regulatory enforcement agencies' goals in terms of safeguarding public goods (e.g. environmental protection, health and safety etc.) end up conflicting with other goals of the government structure they are part of, for instance revenue generation. Such a situation may arise when the same agency is in charge of issuing licenses (e.g. for the use of natural resources) that will generate considerable government revenue, while also being tasked with enforcing compliance with safety regulations for license holders. There is a real possibility that the revenue-generation objective will take precedence over other missions, and that may result in grave enforcement oversights. Governments should ensure that such conflicts of interest are avoided (preferably through full institutional separation, and at a minimum through strong "Chinese walls" within the

same institution, if full separation is not possible) and that regulatory enforcement agencies have clear mandates and that any licenses or permits they may issue are aligned with their general mission and not revenue-generating instruments that may interfere with their core mission.

As a support for improvements in professionalism, transparency and governance of regulatory enforcement agencies, governments should consider the appropriateness for them to follow the international standard (ISO/IEC 17020) for inspection bodies, and get accreditation against it.

Principle 8

Information integration

> *Information and communication technologies should be used to maximise risk-focus, co-ordination and information-sharing – as well as optimal use of resources.*

Information technology is essential in order to achieve major effectiveness and efficiency improvements in regulatory enforcement and inspections. It is the indispensable basis for risk-based planning, and for effective co-ordination of inspections. At the same time, if there is no comprehensive view of the information system across all types of inspections, the result can be duplicated expenses and work, incompatible systems, lack of information sharing. To ensure that information technology can deliver its full benefits, governments should develop and adopt a coherent vision of the development of information systems in enforcement and inspections – this vision should aim at ensuring co-ordination and data sharing.

Many regulatory enforcement agencies have partly similar focus, and thus a large amount of the information they need is similar. Findings by an inspector working for one of them can be directly relevant to other agencies. Being able to share data allows inspectorates to have a much more accurate and updated assessment of the risk level of each business, without spending additional resources. It also enables them to avoid duplication of work: if an inspection has recently been conducted by an agency, its findings being available to others mean that they can avoid another visit if the situation has been shown to be good. Governments should make sure that essential data from each inspection is made available to other agencies to serve for risk analysis and management.

As a substantial amount of the data used to build inspections information systems is common across agencies (business name and address, business location and size, etc.), it makes sense for several (or all)

regulatory enforcement agencies to rely on a common database. At a minimum, the structure and indexing of data needs to be the same in each separate database so that exchange of information can take place effectively. Governments should consider setting up a joint database to be used by multiple regulatory enforcement agencies, and at a minimum adopt common standards for information structure to ensure inter-operability.

Modern technologies allow to integrate many key processes of regulatory enforcement agencies into one system – inspections planning and scheduling, recording of findings, follow up and administrative sanctions, inspection tools such as checklists, even staff time management (at least in relation to inspection visits), data analysis and reporting. Setting up a joint system for several regulatory enforcement agencies, rather than procuring separate systems with largely similar specifications, is cost-effective in addition to offering considerable benefits in terms of risk-management and co-ordination, such joint systems (for several or most inspection bodies) should therefore be an option that is considered whenever possible. Governments should support the renewal of information systems for regulatory enforcement agencies, aiming at supporting effective risk-management, and give preference to shared systems across several inspectorates whenever possible.

In those countries that have partly or widely decentralised regulatory enforcement and inspection structures, sharing of data may be particularly important but relatively more difficult to organise, because of the number of decentralised bodies involved. A related problem is the need to share data beyond the circle of state agencies – with non-state regulators, with third-party certification bodies, with private businesses themselves (so as to avoid inspection visits when data can be obtained directly). Systems can and should be built gradually to allow for greater data sharing and inter-operability between all these agents. Governments should, as much as possible, promote adoption of shared systems for inspections at the local level – with either integration into a broader, national database, or effective mechanisms to share data between different localities and with central authorities. They should also promote mechanisms that allow data from non-state actors to be integrated into risk-management systems.

It is recognised that, in a number of situations, obstacles may exist to greater integration of information technology. These include legislation on data confidentiality and privacy, concerns about data security, difficulty and cost of integrating legacy systems, and operational difficulties when dealing with large and complex organisations. This means that governments in such circumstances should consider the following options:

- Introduce the principle that state structures should only request and collect data from regulated entities once, and then find ways to share this data across agencies that may require it (this may mean amending data confidentiality and privacy laws in the appropriate way, acknowledging the trade-off between more restrictions on data use, and higher burden and lower efficiency);
- Setting up of shared databases and systems across a limited set of regulatory enforcement agencies, or at the local or regional level;
- Creation of systems for information sharing which do not replace or consolidate existing ones, but come in addition to them, and where regulatory enforcement agencies (but also possibly private sector entities, e.g. the regulated business themselves) can contribute data in order to facilitate information sharing. Alternatively, systems can be set up that allow to register inspections and their results, so that all agencies involved in supervising a given business can see what other visits took place, and what were the findings. All solutions that involve creating such mechanisms on top of existing information systems are less optimal considering that they add a layer of complexity, often require additional work for officials, and generally result in less "real time" sharing of information – thus, they should only be considered if more integrated solutions are found to be impossible to implement.

Information systems that are geared towards enabling risk-focus in enforcement and inspections are also a key tool in helping manage the many complaints that regulatory enforcement agencies often receive. While initial screening of complaints (whether they deal with a legitimate legal issue or not, whether they appear substantiated and serious, are urgent or not) needs to be done by qualified staff, the proper use of complaints is mostly as an element in risk management. Except for the most urgent cases (where there is sufficient reason to believe an imminent danger may exist, and immediate reaction may be necessary), even complaints that pass the different screening filters should not lead to an inspection visit but rather be integrated in the information system. Repeated complaints about the same product or business should be a factor that markedly raises their risk level, which in turn will lead to inspections becoming more likely and frequent.

Principle 9

Clear and fair process

> *Governments should ensure clarity of rules and process for enforcement and inspections: coherent legislation to organise inspections and enforcement needs to be adopted and published, and clearly articulate rights and obligations of officials and of businesses.*

One of the difficulties that may harm inspection and enforcement in many cases is the lack of clarity. Who can inspect what? With which rights and authorities? What are the rights and obligations of regulated subjects? These are all points that are often unclear to many regulated subjects. This lack of clarity is frequently due not just to the lack of consolidated information, but to the lack of specific legislation on the issue. The exact way in which this can be addressed is of course country-specific – legislation, government decisions etc. can all be used to this purpose. Governments should aim at clarifying the framework for enforcement and inspections, through appropriate legal instruments.

A key element of such a legal framework is a clear list of institutions and the type of issues that can be inspected. This allows avoiding duplication and overlaps, confusion, and gives regulated subjects the possibility to protect themselves against abuses, and to know where to look for information. Governments should ensure that a comprehensive list of bodies authorised to inspect, with their sphere of competence, is officially published and updated when needed.

Other very important aspect of framework process regulations include ensuring proper organisation of inspection visits and establishing clear requirements for each step of the inspection process. This includes clarifying who has authority to appoint an inspection visit, which documentation an inspector should present upon inception, how the visit should be concluded, what the mechanism is for taking samples (and in particular who

compensates the costs), who has authority to impose sanctions. Inspections follow-up should also be covered, so that implementation of improvement notices and inspector recommendations are checked systematically – remotely (mail or phone) in most cases (limited risk or good prior compliance), or on site in higher risk cases. Governments should edict regulations or initiate legislation that organise the whole inspection process along these lines.

Except in specific circumstances, e.g. where imminent danger or fraud is suspected, experience has shown that advance notification of visits can help both regulated subjects and inspectors. By avoiding unexpected disruption of their activities, it alleviates the burden on businesses. Because these are prepared, inspectors find that documentation and needed specialists are more easily available. Advance notification also pushes businesses to check and improve their compliance, which should be seen as positive, not negative. Well trained and experienced inspectors will nonetheless be able to spot underlying issues and problems. Governments should allow and encourage the use of advance notification in appropriate circumstances (regular inspections, no suspicion of fraud or criminal behaviour).

Regulated subjects should be clearly informed of what rights and obligations they have in the inspection process, how to challenge and appeal the conclusions if relevant, where and how to obtain compliance assistance, or report abuses if any. Governments should ensure that an official legal document summarises rights and obligations of regulated subjects in the inspection process. They should also publicise any new interpretation made by the courts on these topics, so that regulated subjects have full clarity on their rights and obligations, and the possibilities of successful appeal and challenge of inspectors' decisions.

As appeal and challenge possibilities are often experienced by regulated businesses as insufficient, governments should review the range of options, consider expanding them if necessary (e.g. by introducing administrative appeal panels, that are not internal to the regulatory enforcement agency but function across several government functions, or creating hotlines for complaints), and most importantly ensure that business operators are made well aware of all options, and that access to these mechanisms is facilitated, including through the use of information technology.

Publicising information about the compliance level of individual business operators (as distinct from simply discussing average compliance levels in a given sector) is potentially a powerful tool to drive compliance improvements (as business operators' reputation is a very valuable asset in most markets), but also one that can be abused, e.g. if such information is disclosed although appeals have not yet reached their conclusions and the

information eventually is proven wrong, or if threat of going public is used by inspectors in an abusive way. Governments should ensure that there are safeguards that regulate how and in which cases regulatory enforcement agencies publicise such compliance information.

The most vulnerable subjects in the enforcement and inspection process, Micro, Small and Medium Enterprises (MSMEs) in particular, are generally the less well informed about it. Governments should actively disseminate information on the enforcement and inspection framework regulations through all available media and channels.

Principle 10

Compliance promotion

> *Transparency and compliance should be promoted through the use of appropriate instruments such as guidance, toolkits and checklists.*

For most regulated subjects, it is generally difficult to understand what they need to do to be in compliance with applicable regulations. There are many regulatory documents, generally in complex language, and the requirements they set forth are often described in a "performance-based" way – i.e. that the process has to be safe, in such and such circumstances. While this gives welcome flexibility on the exact methods to achieve safety, which is appreciated by larger, more advanced businesses, it often is very difficult to follow for Micro, Small and Medium Enterprises (MSMEs) or businesses with less expertise. Governments should require regulatory enforcement agencies to develop and publish guidance notes or toolkits that help MSMEs understand the requirements and how to comply in the most widespread situations and sectors – and ensure that these guidance documents are officially issued and there is assurance that inspectors will consider businesses that follow them to be compliant.

Lack of consistency between inspectors in the way they interpret requirements, and lack of predictability in what will be expected from the regulated subjects, are issues that not only create burden for businesses – but also result in lower compliance overall, as businesses are discouraged from trying to comply. Adopting tools that ensure more consistency not only alleviates these problems, but also helps inspectors know what to focus on, and thus helps inspectorates ensure quality standards among their staff. Checklists, that present key requirements in a straightforward way, are a good way to address this – though they are not the only way, and are not appropriate to every context. They need to be developed specifically for each type of inspection and of regulated subject (sector, activity etc.). They

also need to be risk-focused – i.e. not seek to include each and every requirement, but really focus on the essential ones, as much as possible. Finally, they should be regularly updated based on feedback from inspectors in the field, and from business representatives. Governments should encourage the development and use of inspection checklists, and consider whether it may be appropriate to make them mandatory at least for inspections of MSMEs, or for some widespread types of inspections.

Governments should require publication of all guidance material, checklists etc. on easily accessible internet portals, preferably consolidating them in "unified portals" where business operators can find all the requirements relevant to their business activity. Including in such portals as many "self-checks" tools as possible would be an important step to help business improve their ability to comply.

In some contexts, where regulatory officers are expected to exercise their professional judgement in making enforcement decisions, and where the level of professional competence and standards of the inspectors is agreed by stakeholders to be high, prescriptive checklists are not an appropriate mechanism for reducing inconsistency, and governments should instead encourage the adoption of guidance documents that, while clarifying what are the main topics and issues which should be checked (and how), leave more leeway to inspectors to follow their judgement.

Dealing effectively with questions from businesses is essential to increase compliance. Setting up hotlines and on-line support with well trained staff and thoroughly thought through sets of answers for specific issues is a cost-effective tool to achieve this.

For larger or more complex businesses, such instruments as toolkits or checklists are often far less useful (and possibly even, in the case of checklists, not always appropriate). What is needed is to have the possibility to request assured guidance from the regulatory enforcement agency – i.e. 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. The response should be "binding" for the regulator in the sense of providing assurance: as long as the business really adheres to the operational solutions endorsed by the regulator, it should be considered in compliance. This, again, can help to improve compliance considerably, while also making growth and development far easier for businesses. It provides a much more conducive environment for investment. Such services, because they can require quite significant resources (and because not all businesses will benefit from them to the same extent), could be provided on a cost-recovery basis. To support MSME development, since such assured guidance is extremely useful for them as well, regulatory enforcement

agencies could also extend such schemes to sector associations, allowing them to support their members through assured guidance on how to achieve compliance. Governments should create the legal conditions for regulatory enforcement agencies to provide assured guidance, and encourage the development of such-schemes.

Governments should also promote the following practices for regulatory enforcement agencies:

Adopt and publicise "service standards" that cover how the agency communicates with those it regulates, its approach to providing information and advice, its inspection and enforcement policy, its fees and charges (if any) and procedures for complaints and appeals;

In their guidance and information documents, raise awareness of the rights involved in the regulated activity, and clarify in which ways compliance relates to the respect of these rights by regulated entities;

When possible, publicise clear quantifiable indicators against which compliance will be measured, and be transparent about how these will be measured. Many important regulatory requirements cannot be assessed in such a way but, when possible, these are powerful and efficient tools;

Upon completion of an inspection, if serious non-compliances and in particular hazardous violations have been found, provide inspected businesses with clear indications on what the problems are and guidance on how to address them, both directly in the concluding discussion, and in writing.

Making inspections results public, for instance in the form of a compliance rating for each visited object, can be a powerful incentive for compliance, for it is likely to increase the reputation (and thus market share) of business operators that have a high rating, and conversely harm the profitability of businesses with very poor compliance. Subject to the risks of abuse and the corresponding safeguards required (see Principle 9), this instrument may be very useful for instance in regulatory fields where customers are at a strong information disadvantage, and where consumer choice can easily drive markets because competition is abundant, e.g. in retail trade, restaurants etc., where publicised food safety ratings have been found to be a powerful driver. These ratings system can only be successful, however, if the regulatory enforcement agency issuing them is trusted, and if updates are sufficiently regular to mean that ratings can be trusted, the latter being often quite a challenge given large number of regulated entities, frequent changes in operators at the retail level, etc. Governments should consider introducing such schemes in regulatory areas where they can be effective, and in a way that ensures fairness and reliability.

Principle 11

Professionalism

> *Inspectors should be trained and managed to ensure professionalism, integrity, consistency and transparency: this requires substantial training focusing not only on technical but also on generic inspection skills, and official guidelines for inspectors to help ensure consistency and fairness.*

To ensure that inspections and enforcement are effective and transparent, the professional competence of regulatory enforcement agencies' agents (inspectors in particular) is essential. Just as essential is that the way they are managed creates appropriate incentives, that support compliance promotion efforts. Governments should adopt human resources frameworks for regulatory enforcement agencies, including professional competence development plans and performance management guidelines that are in line with these principles.

Effective enforcement cannot take place without discretion – there are too many issues to be decided that require enforcement officials to make a judgement call, to interpret the regulatee's behaviour and intent, to decide on what they think will be the most appropriate course of action in a "responsive regulation" vision, to decide which points to investigate more in depth during an inspection, etc. All this means that discretion needs to be exercised within a clear framework (as per Principle 9), but clearly understood to be an inevitable part of the process. This in turn requires inspectors to have a high level of competence and professional standards.

A competency framework for inspectors would encompass not only technical skills (of course fundamental – ensuring that inspectors' specific knowledge remains current throughout their career), but just as importantly generic skills relating to their work as inspectors. This should include the understanding and analysis of risk, approaches to compliance promotion (communication, relationship-building, how to handle infringements), etc. It

is also important for inspectors to have some understanding of the key parameters of other inspection areas, so that they do not make recommendations that go directly against safety in another sphere, and are able to contact colleagues from other institutions if they spot what they deem to be potential major hazards in another area of competence. Inspectors also need to have a sufficient understanding of business logic, market forces and the role of consumers and other market players in driving business attitudes (including compliance). Conflict management skills are also important for them to handle often complex situations with businesses. Finally, investigative skills are key to finding out problems that may be hidden by businesses actively trying to fraud. While these are linked to technical knowledge, there is also an important dimension that goes beyond technical competence and is about asking the right questions and looking beyond the surface. Governments should foster the development of such competency and training frameworks across all regulatory enforcement agencies.

Developing inspectors' competence and autonomy, to enable them to handle complex situations and spot unforeseen problems, is important. It is just as essential, on the other hand, to balance this autonomy with greater coherence and consistency, so that regulated subjects are not confronted with excessive variations depending on which staff they are in contact with. Governments should ensure that regulatory enforcement agencies issue guidance to their staff on how to handle specific situations and how to interpret legislation in a consistent manner. This should include reference, where appropriate, to relevant court decisions and the applicable case law, so that inspectors can take into account the likelihood of a successful legal challenge to their actions.

Management of inspectors, be it at the operational or career level, should foster attitudes of responsibility, transparency, co-operative approach and compliance promotion, as well as of course ethical standards and attention to high risks. Performance of inspectors should be appraised based on standards that are in line with these principles. Governments should require regulatory enforcement agencies to develop and implement performance management approaches that foster risk-focus, proportionality and compliance promotion in inspecting approaches.

In order to support the development of the professional competency of regulatory enforcement officers, governments should consider adoption of a common approach to competency across all (or most) regulatory enforcement agencies, as well as an assessment tool to be used to evaluate the capacity and gaps of agencies as well as individual inspectors.

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