



## **PRECOP-RF**

### **Protection of the Rights of Entrepreneurs in the Russian Federation from Corrupt Practices**

#### **Technical Paper on**

### **Regulatory and Supervisory Authorities in Council of Europe Member States Responsible for Inspections and Control of Activities in the Economic Sphere – structures, practices and examples**

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## Abbreviations

<b>BRDO</b>	Better Regulation Delivery Office
<b>CoE</b>	Council of Europe
<b>EU</b>	European Union
<b>FBO</b>	Food Business Operator
<b>HSE</b>	Health and Safety Executive
<b>OECD</b>	Organisation for Economic Cooperation and Development
<b>OSH</b>	Occupational Safety and Health
<b>SFBB</b>	Safer Food, Better Business
<b>SME</b>	Small and Medium Enterprises
<b>RUC</b>	Unified Inspections Registry [ <i>Registro Unico dei Controlli</i> ]
<b>UN</b>	United Nations

## TABLE OF CONTENT

<b>1</b>	<b>Executive Summary</b> .....	<b>5</b>
<b>2</b>	<b>Introduction</b> .....	<b>5</b>
<b>3</b>	<b>Structure of regulatory and supervisory authorities in CoE member states</b> .....	<b>6</b>
3.1	Structures of inspection functions .....	6
3.2	Relevant control functions .....	10
3.3	Objectives pursued by models of regulatory and supervisory activities .....	11
<b>4</b>	<b>Practices of governmental and non-governmental forms of control</b> .....	<b>13</b>
4.1	Overview of bad practices – in accordance with international experiences .....	13
4.2	Overview of good practices – in accordance with international experiences .....	15
<b>5</b>	<b>Implementation of the risk-based approach to inspections in EU countries</b> .....	<b>20</b>
5.1	Definition of a risk-based approach: overall relevance .....	20
5.2	Illustration 1: food safety in the European Union .....	21
5.3	Illustration 2: comparison of occupational safety and health inspection systems in Great Britain and Germany .....	22
<b>6</b>	<b>Examples of good practices from CoE member states</b> .....	<b>23</b>
6.1	Bosnia and Herzegovina .....	23
6.2	Great Britain.....	24
6.3	Italy .....	25
6.4	Lithuania .....	26
6.5	Slovenia.....	27
<b>7</b>	<b>Conclusion</b> .....	<b>28</b>
<b>8</b>	<b>Appendix 1: The Small Business Act for Europe</b> .....	<b>29</b>
<b>9</b>	<b>Bibliography</b> .....	<b>31</b>

## **1 EXECUTIVE SUMMARY**

This report provides a brief analysis of the structure of authorities in charge of regulating and enforcing inspections and control of economic activities in Council of Europe (CoE) member states within a given inspections system. It identifies the diverse existing approaches aimed at addressing the primary objectives pursued by regulatory and enforcement systems: ensuring public wellbeing/mitigating risks in an effective and efficient manner, economic growth as well as transparency and accountability of public services. Special attention is paid to the relevant control functions to be comprised within a valid inspection enforcement system. The report also gives a general overview of practices of governmental and non-governmental forms of control and determines bad and good practices in this field. In this context, the risk-based approach, based on the desire and need to ensure public well-being by reducing hazard and harms that might endanger the human integrity and health, the environment and other public goods, is to be considered as the most effective, efficient and rationalised enforcement model. Several examples from CoE member states illustrate this.

## **2 INTRODUCTION**

Regulations are essential to ensure that the economy functions effectively and sustainably, and they provide a foundation for the interaction of businesses, governments and the civil society. Their role is to ensure smooth operation of the economy, whilst respecting environmental, social and public concerns. Indeed, regulations are meant to build trust towards and between businesses and authorities, thus reinforcing the working of markets. They help to safeguard the rights and safety of consumers and citizens and guarantee the provision of goods and services in line with the public interest.

Inspections and control of activities in the economic sphere are, within this context, central tools to promote implementation of regulations, strengthen regulatory compliance and help ensure that economic activities do not endanger human and environmental safety. Credible inspections contribute to building the trust between actors that is necessary for a proper functioning of the market. To this end, inspections and control of economic activities should be based on sound principles of risk management and mitigation and risk proportionality.

Effective and efficient regulatory inspections require adequate planning and targeting of inspections and controls, good communication and coordination between inspection agencies, as key foundations. In addition, clear and precise information and guidance to regulated subjects (businesses, citizens) is a cornerstone for the good functioning of the system, since the primary responsibility for compliance remains with the regulated subjects. Such key components of an inspection system help avoid malpractices such as corruption and other unethical practices. Hence, an adequate regulation and supervision inspection system provides critical benefits to businesses and to society in general.

On the contrary, an inadequate system of inspection and control of activities has significant direct and indirect monetary and non-monetary costs for the state, businesses and society: international experiences show that such a system adds unnecessary administrative burdens (and cost) for businesses, reduces trade and investment and leads to corruption and abuses. Being inefficient, it combines a more significant enforcement cost both for the state (budget cost) and for businesses (regulatory burden), while failing to achieve policy objectives and diminishing businesses' and public confidence in the authorities and regulations.

This report provides, first, an overview of the structure of regulatory and supervisory authorities in CoE member states responsible for inspections and controls of activities in the economic sphere. The purpose of this section is to present and briefly analyse the various principal models of regulatory and supervisory activities, the principal control functions and the objectives pursued by the different

inspection systems. Following section discusses the practices of governmental and non-governmental forms of control and details bad and good practices as observed from international experiences. The next section identifies and describes the implementation of the risk-based approach to inspections. The report concludes with five examples of good practices from CoE member states.

### **3 STRUCTURE OF REGULATORY AND SUPERVISORY AUTHORITIES IN COE MEMBER STATES**

Institutional structures are unsurprisingly diverse across different countries, since constitutional, cultural, economic and other pertinent contexts differ from one country to another. International experience shows that different types of risks are limited in number and thus should form the basis for any inspection system and institution in charge of inspections and control of activities in the economic sphere. However, the structures in existence owe more to history than to careful planning. Control of activities already existed before the creation of modern inspectorates and were primarily created as a response to fears related to quality or safety (but not always corresponding to real hazards), or in order to protect trade from competition. Such control was either based on self-regulation or on supervision performed by public local authorities. Only later did the control of activities based on a model that included inspectors appointed by the central government come into existence. Workers' safety, for instance, only became a field of state control gradually, during the XIX<sup>th</sup> century. Enforcement aimed at dealing with health and safety issues in this area appeared gradually, in response to certain practices in large-scale industry that were considered as alarming (in particular children and juvenile labour conditions). The distant origins of institutions in charge of inspection explain to a large extent the existing structures and objectives, including their focus on issues of quality and techniques (and hence, strictly on compliance issues) rather than on ensuring public welfare and reducing risks that can be posed to human and environmental safety and health. Thus, an overview of existing structures does not mean that these structures are optimal – rather, we will try and point out in which ways different countries are trying to *reform* them to make them more risk-focused and efficient.

#### **3.1 Structures of inspection functions**

We can differentiate between four different dimensions of inspection structures, for each of which several types or approaches exist. The four key dimensions are: (1) how spheres of responsibility are allocated, (2) whether inspectorates are national or local, (3) the governance system for inspectorates and (4) whether some unifying or coordinating tools exist (and which ones). We will briefly consider each of these, and the different approaches taken by CoE Member States.

##### **3.1.1 Spheres of responsibility**

###### ***Specialised/fragmented***

Technical inspections focusing on compliance with regulatory requirements tend to be fragmented within many institutions. Inspection functions are divided into many specialised areas of competence. When spheres of responsibility are not clearly defined, the supervision of one enforcement area could face multiple redundancies, with adverse impact on state expenditure and business costs; as seen in the field of occupational health and safety in France, Italy or Germany, where several entities (national or local) have direct supervision responsibilities in the same area.

### *Consolidated in a few large institutions/domains*

Different inspection bodies are merged or combined under a single authority, which keeps specialised departments within a single agency that ensures a unified management. In most cases one single authority deals with one risk function, but exceptions can nevertheless be observed. Radical consolidation has thus occurred in the Netherlands (with the number of national inspectorates decreasing from 25 to 10) or in Slovenia (with a similar decrease). In Great Britain, where most inspections are conducted locally, inspectors are grouped into few large groups: trading standards, food safety, environmental health, etc.

### *Single inspectorates for several/most areas*

A centralised enforcement body is responsible for several or most inspection functions; this model allows for keeping the functions to a minimum and consolidating the number of procedures, the types of sanctions, the information management system, etc. An early example was in the late 1990s when Croatia established a State Inspectorate by means of two major laws, which assumed the responsibilities of 12 prior inspectorates. The model was considered in the Netherlands (but eventually not followed). Bosnia and Herzegovina adopted the same approach (and extended it to an even larger share of the country's inspection functions) in 2004.

## **3.1.2 Local/national structures**

### *Fully national with or without local branches*

National inspection bodies are mainly responsible for inspections and control of economic activities, with a network of local branches directly reporting to the national agency in many countries. This is the case e.g. in Slovenia (no local branches), Lithuania (some agencies with local branches), Poland (with local branches), etc.

### *National but with large autonomy of local branches*

Similar to the abovementioned form, national inspection bodies are mainly responsible for regulatory enforcement and supervision, but the local branches of these national institutions have large autonomy from the centre. This is e.g. the case in France.

### *Mix of national and local (with 'local' in large part being effectively autonomous)*

Both national and local bodies are responsible for conducting inspections and control of activities – with some inspection functions pertaining to local bodies, others to national ones, and some being split between both (with or without clear division of responsibilities). Local entities have specific technical departments for this purpose. In such model, local inspection bodies and national (central) inspectorates can coexist. For example, this is the case for the occupational safety and health inspection systems in Great Britain, where the **Health and Safety Executive** (HSE) is responsible for inspecting industries and high-risk facilities and, in parallel, Local Authorities are responsible for inspecting establishments considered as low-risk (see section 3.3 below). National agencies may have exclusive competence in very technical or sensitive areas of control, or concurrent competence on some topics, or may have a guidance role to help local inspection bodies implementing homogeneous practices, procedures, sanctions, and overall approaches. The Netherlands, Great Britain and Italy all have a mix of national and local inspectorates (majority local in the Great Britain, more balanced in the Netherlands, and majority national in Italy – but with local branches).

### 3.1.3 Governance

#### *Directly subordinated to political authorities (ministries or local authorities)*

In such a setup, the vast majority of inspection bodies are directly (or indirectly) subordinated to ministries (or to other political authorities, including regional governments, etc.). In this case, there can be direct influence from political office holders on inspection priorities, senior staff appointments, etc. The risk of this model is that direct instructions from the political level interfere with the day-to-day functioning of the agency, with proper risk-management and with professionalism. Such a setup also tends to lead to more instability. In good practice, it is appropriate for political decision makers to review and approve the strategic vision of an inspectorate, but they should not have influence on operational decisions.

#### *Independent/autonomous bodies with hands-off governance*

Keeping enforcement agencies at arm's length from political actors ensures a greater independence from political impact. This can be done by having strictly separate professional services for inspections in local authorities – or, with even stronger guarantees of independence, by having a system of management boards, as in Great Britain, for national inspectorates. Another option is having inspectorates report to Parliament (this is the case in the Netherlands, but inspectorates remain subordinated to ministers as well, which creates problems).

### 3.1.4 Unifying framework

#### *None*

There is neither a unifying legal nor institutional framework. Nevertheless, coordination and information sharing between different agencies can occur on an *ad hoc* basis. This is the least effective and efficient setup, but also the most common.<sup>1</sup>

#### *Common legal framework for all inspections – or common inspection procedures having impact on all inspections and control of activities*

In this case, a single law/regulation governs all or most inspections procedures. This unifying legal framework can cover mostly principles, or also operational guidance, and, in some cases the allocation of inspection powers. Important examples of such legislation are the Regulators Code in the Great Britain, the Law on Public Administration in Lithuania, enabling reform legislation in Italy, the Inspections Act in Slovenia, etc.

#### *Coordination body*

Another possible (and frequently followed) approach is the creation of an administrative structure, the central purpose of which is to ensure coordination, coherence and communication of inspections across enforcement bodies (all of them or, at least, a number of them) and hence, to guarantee that (at least some) information is shared between different inspectorates, that duplicated and overlapping inspections are avoided, and that practices are (to some extent) harmonised. Examples include the

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<sup>1</sup> A number of reforms have been carried out in the past years in order to improve the actual – often problematic – situations. The World Bank report entitled *Inspection Reforms; Do Models Exist?* (2011) identifies such reform approach as the “individual inspections approach”. Considered as a ‘bottom upwards’ approach, this model is based on regulations aimed at consolidating certain inspection functions, and, very often, merely introduces risk assessment and standards. Several inspections bodies exist, which are supervised by different ministries and agencies. In most countries, institutional structures have evolved focusing on one specific issue – or inspection function – at a time. Since more than one agency control and enforce regulations at the same time, this model entails a risk for including overlapping or duplicated functions; as a result, inspections and control of activities may also be duplicated.



Inspectorate Coordination Council established in Latvia in 2000 or the Inspection Council in Slovenia starting in 2002, or the Inspection Council of the Netherlands. In Slovenia, the coordinating body oversees all or key inspections activities. It is composed of chief inspectors and other officials and is positioned at a central level. The role of this body is to control inspections, particularly avoiding overlapping and/or contradictive visits and instructions on compliance. The institutional setting includes different ministries and agencies in charge of supervising the inspections bodies. Mostly this approach does not include a common legal framework establishing penalties or strict enforcement mechanisms. Moldova followed this model without establishing a proper coordination body: the coordination of inspections under the supervision of different ministries/agencies was strengthened by making the Ministry of Economy the coordinator of inspectorates at national and regional level<sup>2</sup>.

In practice, countries combine several of the aspects explained above. For example, in Great Britain enforcement functions (and responsibilities) are consolidated in a few large institutions, with both national and local bodies in charge of inspection activities. Moreover, inspection bodies are autonomous and are not directly under political influence. Local branches have nevertheless large autonomy. Moreover, inspection bodies are independent and are not directly under political influence. In Italy, the structures of inspections and control of activities are planned and conducted by a number of specialised and fragmented bodies (with a gradual trend towards a consolidation of competence in few large institutions), at both national and local level. Enforcement agencies are directly subordinated to political authorities (ministries) and, in general, there is a lack of clear unifying framework.

### ***Common database and information system***

Generally, common information systems are combined with other forms of coordination or consolidation – but in principle they can also be set up independently of such a reform. They can involve pooling and sharing the whole database of entities under supervision and all key parameters and inspection results, or only some of these, or just allow consulting inspection reports from other agencies. In some cases, they cover (nearly) all inspection functions, in some cases only a few. Interesting examples include InspectionView [*Inspectview*] in the Netherlands, the integrated IMS for the State Inspectorate in Bosnia and Herzegovina, the Unified Registry of Controls (Agriculture and Agri-Business) in Emilia-Romagna (Italy), or on-going work on data sharing in Great Britain.

### **3.1.5 Third-Party Inspections**

Some types of inspections (e.g. related to conformity assessment of non-food products or machinery safety, etc.) can be partly delegated to the private sector. This is for instance the case in EU Member States. Third-party (non-governmental) inspections have a number of advantages. They allow to manage large amounts of products/facilities to control, where state inspections may be seen as too costly and it is considered as inappropriate that taxpayers cover considerable costs. In the case of non-food products safety and machinery safety, the number of objects is too high – and often highly

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<sup>2</sup> Recent reforms carried out in CoE's member countries have refined this model and have led (1) to merger of agencies responsible for inspections or (2) to a centralised inspectorate. (1) This approach is aimed at consolidating related inspections, by merging different agencies or creating a single authority. The latter operated under the aegis of a ministry (or a specialised agency). Different ministries and/or agencies continue to have effective control over inspections, since they supervise the inspection body/bodies. Most often, a major law introduces this model. The objectives pursued by this model are to avoid duplications, to ensure the effective sharing of data, to improve the coordination of inspections and the systematisation of overall procedures as well as to enable the diffusion of better practices, etc. (2) This approach consists of establishing a centralised inspection supervisory/control body independent of the ministries or other governmental agencies. The operational policy, institutional organisation, procedures, sanctions, etc. are common for all inspections. As for model (1), can contain either all inspections or most of them; it can as well be set up as a centralised inspections supervision body.

specialised qualifications or sophisticated equipment are required. Third-party inspections also allow more easily to accommodate increasing trade volumes and the proliferation of inspection objects. In all cases, this kind of inspections need the support of a solid system able to certify the competence of non-governmental parties as well as to enforce their liability if needed. The system is, thus, difficult to introduce because of the complexity of necessary pre-requirements. It is most helpful and useful for assessing the conformity of activities in very technical fields, and only within an overall solid legal and institutional framework. In fact, third-party inspections should not be considered as an easier way to conceive inspections, but rather as a different way to do so. In addition, they are usually supplemented by “second-level” state inspections (e.g. Market Surveillance for non-food products) that ensure the integrity of the system.

### **3.2 Relevant control functions**

According to OECD *Best Practice Principles for Regulatory Policy on Regulatory Enforcement and Inspections* (2014), fundamental regulatory enforcement functions related to private business activities include (but are not limited) to:

- Food safety;
- Non-food products safety and consumer protection (food and non-food products safety can be dealt with by the same inspection body; nevertheless, it makes sense considering them as separate fields, as their respective regulations and issues differ);
- Technical and infrastructure/construction safety;
- Public health, medicines and health care;
- Occupational safety and health;
- Environmental protection;
- State revenue (even though most of the time this field is in practice essentially separated from the rest of the inspections fields, many of its areas and issues need the same tools and models as employed in the other cases);
- Transportation safety (including air safety, even though most often this field is dealt with separately);
- Banking, insurance and financial services supervision;
- Nuclear safety (because of the specificity and technical difficulty of the sector)<sup>3</sup>.

Identifying such functions is the foundational step that acts as the basis and starting point for setting up and reviewing existing structures responsible for inspections and control of economic activities, and thus, their budget allocation, resources (both financial and human), mandates, responsibilities, etc. Indeed, a clear and transparent vision of the risks to be addressed, and the institutional set up to cover them, is essential to avoid overlaps, grey areas, duplications and to ensure the coherence of the whole system.

In some cases, the selected core functions may be divided into more specific ones in order to allow for higher levels of specialisation in inspections and control of activities (for example, by splitting banking supervision, insurance supervision and finance control). This option enables governments to achieve better results in areas considered as risky or of high-risk. In other cases, governments may consider preferable to focus on coordination of information and resource sharing and hence, decide additional consolidation (for instance, by setting up a single inspection body composed of different

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<sup>3</sup> It is needless to mention that policy priorities vary from one country to another because of regional and/or national specificities, fields that need to be more strongly regulated within a certain context, etc. Identifying such functions is of paramount importance in order to comprehend and design improvements and modifications to existing institutional systems. However, the OECD document highlights that the listed functions are found to be essential in the vast majority of countries and recommends that the governments use them for the analysis, assessment and potential review of the institutional structure.

specialised departments for technical safety functions, which include technical and infrastructure/construction safety, occupational safety, etc.).

In all cases, governmental policies ensuring effective coordination and information sharing between regulatory/supervising agencies are fundamental. In this line, the existence or introduction of a common information system or a system interconnecting existing data and information is of paramount importance. This can only be accomplished if inspection bodies systematically (and automatically) share relevant information and inspection plans and by restraining re-inspection of the same issue by different inspection bodies. Moreover, regardless of the institutional approach chosen, an efficient model needs to ensure that inspected subjects know how inspection activities work and what they are aimed at, and how to comply with relevant regulation. In this context, harmonisation of practices and requirements between inspection agencies is of utmost importance (ideally through the publication of common guidelines).

Confusion amongst inspected subjects, overlapping and duplication of inspections, waste of resources (both material and human), as well as gaps in the implementation may occur when enforcement responsibilities for a given function are shared between national and regional and/or local authorities. It is thus essential that responsibilities and mandates of each structure are made clear and clearly communicated to regulated subjects. Again, the existence of a common information system or the active coordination between the different existing information systems plays a significant role in avoiding such dysfunctions.

### **3.3 Objectives pursued by models of regulatory and supervisory activities**

The fundamental goal of regulation and inspection activities is to increase public welfare by the prevention or mitigation of specific risks.

In order to achieve this goal, three specific objectives (however non-mutually exclusive) of inspection systems and models can be identified:

#### **3.3.1 Responding effectively and efficiently (in terms of cost-benefit ratio) to risks/threats presented by business activities**

- The main driver for achieving this goal is to design and plan inspections taking into account real risks on human, environmental and animal integrity, health and safety. The risk-based approach legitimates inspection activities to businesses and anchors inspection actions on a rational and ‘scientific’ foundation. Moreover, the risk-based approach usually ensures a more adequate and cost-efficient use of inspection resources. A business registry and the use of IT tools are key elements of the system, which would ensure the latter.
- Very often, the effort to achieve efficiency leads to merging inspection functions and (financial and human) resources. According to good practices, this objective can be achieved firstly by controlling the number, the frequency and the duration of inspections visits. Following this principle, a number of countries limit the number of days an inspection visit can last, as well as the frequency of inspection visits. However, the duration and number of visits can be radically reduced by appropriately coordinating inspections bodies and inspections actions (for example, through joint inspections) and by pre-planning inspection visits according to the risk level posed by the activity and the business.

#### **3.3.2 Fostering economic growth and employment, by reducing administrative burden and costs – related in particular to inspections and control activities – for enterprises (understood as a second instrumental goal)**

This approach involves:

- Information and communication to business on regulatory requirements and inspection and control processes and procedures;
- Inspections are aimed at assessing compliance and risk level, and therefore conducted following pre-established checklists, which ensure that businesses are treated equally and that inspection outcomes are predictable;
- Clear, simple and transparent inspection procedure, objectives, duties, rights and responsibilities;
- Inspections are carefully coordinated, not duplicated nor contradictive, even when they are performed by different authorities – different public authorities and inspection bodies are therefore coordinated;
- Confidentiality on commercial practices and sensitive information is respected;
- Inspectors are trained on the use of checklists and on technical and ‘soft skills’ knowledge required in order to conduct inspection visits and follow-ups.

### **3.3.3 Ensuring the transparency and accountability of public services and respecting the rule of law** – in particular ensuring the legal aspect of inspections and control of activities and appeal mechanisms (intermediate objective that aims at furthering the two instrumental goals)

In a number of countries (notably Spain<sup>4</sup>, Croatia and Bosnia-Herzegovina, among other countries), the regulator has anchored the inspection system and all inspection activities within a clear and coherent legal framework. These countries have thus lined inspection activities and procedures with a transparent and clear administrative framework, ensuring at the same time an appropriate access to courts. In the vast majority of cases, laws establish processes and procedures and provide detailed rules pertaining to the responsibilities of the inspector and the inspected subject. Certainly, one major objective of these laws is to fight corruption. Thus, countries like Romania have revised their internal inspection procedures to ensure due process in operations of inspection and control bodies, to institute mandatory checklists for conducting inspections and mandatory records of control visits and follow-up operations, ultimately to diminish discretion and bribe requests opportunities.

The means by which this goal can be met are:

- Ensuring the transparency and accountability of inspections. This involves the clarification of the mandates of inspection agencies as well as the role, rights and duties of inspectors. Some governments have also strengthened external and internal auditing of inspection bodies. For example, in Latvia, several inspection bodies host internal audit divisions.
- Setting clear standards, rights and obligations of inspectors and inspected subjects often achieves a reduction of excessive discretion, while setting precise standards that help business comply with regulation. This can be achieved by simple actions like introducing official identification documents and inspection orders. A valuable tool in helping reduce the risks of abuse is defining precisely the rights and duties of the inspectors and of the inspected entities through laws, or even through ‘soft tools’ like a Code of Conduct (introduced for tax inspections in Romania, among other countries). In addition to ‘soft measures’ that often lack strong sanctioning mechanisms, in countries like Latvia, inspection bodies have the obligation to adopt binding standardised procedures and principles, which cover inspection visits, tender/appeal procedures, etc. The ‘rule books’ are made available to the inspectors and the inspected entities by the inspection bodies, helping to improve the understanding of procedures by all interested parties and, therefore, also accountability and compliance.
- Manuals and checklists are important tools that help conduct the inspection visit in a transparent and accountable manner. They ensure that the inspection covers the regulatory

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<sup>4</sup> Law No. 30/1992 of November 26, 1992 on General Government and the Common Administrative Procedure (last amended by Royal Decree No. 8/2011 of July 1, 2011).

requirements and help avoid abuses of power by the inspectors. In a number of countries, the regulation requires the use of ‘inspection registration books’. These enable the authorities to maintain an official record of provisional measures decided by inspectors after an inspection visit and to control the frequency of inspection visits.

#### **4 PRACTICES OF GOVERNMENTAL AND NON-GOVERNMENTAL FORMS OF CONTROL<sup>5</sup>**

##### **4.1 Overview of bad practices – in accordance with international experiences**

###### ***Opacity of the inspection system:***

Experience has shown that lack of transparency leads to several problems, which most often are linked to abuses of powers and other forms of corruption. First, it allows individuals who are not empowered by the responsible supervising agency to conduct inspections. These individuals may either be public officials without inspection prerogatives, persons without any link to the supervising structure or inspectors who have retired or do not have a valid order to conduct the inspection visit. Second, in Eastern European countries in particular, ‘real’ inspectors perform many more visits than the responsible inspection body has entitled them to do. In general, it has been observed that in many cases inspectors do not show their documentation at the beginning of a visit, even in cases where the national regulation requires them to do so. This is a systemic issue that was observed notably in Italy, among other countries. It results from a lack of transparency of the inspection system combined with the general fear of the inspectors, who represent the supervisory authority and can impose sanctions.

***Excessive number of inspection visits – burden on businesses and overlapping/duplicated visits*** – linked with lack of risk focus/risk proportionality and the attempt to inspect/control permanently every single activity

When new regulations and, as a consequence, areas of competence and institutions responsible for inspections and control of activities are introduced without a prior review of the existing ones, there is a risk of overlapping and duplication in inspections. Indeed, in order to increase their power and their area of activity and influence, enforcement entities often interpret regulations broadly, so that they can claim to have a competence in a certain regulatory field. As a result, in practice, diverse inspection bodies conduct inspections on the same issues, which lead to overlapping and/or duplicated inspection visits. Such a situation has significant costs for the state (since often the decision to create a new inspection body or responsibility is adopted without a prior cost-benefits analysis) and for businesses, not to mention the significant and unnecessary administrative burdens. Lack of clear mandates and competencies goes hand in hand with lack of coordination between different supervising agencies. Moreover, this phenomenon can lead to gaps in inspection coverage (with no inspection body in charge of planning and conducting visits in a given field) and thus, leading to ineffective regulation and supervision.

###### ***Inspections lacking a public welfare goal / not aimed at mitigating risks<sup>6</sup>***

Frequently, the creation of an inspection agency following from a public discussion of a particular situation that has been considered as a problem by public opinion or the opposition happens without a real analysis of the existing parameters and the fundamental issues, such as, a prior cost-benefit

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<sup>5</sup> See Blanc, F. (2012), *Inspection Reforms: Why, How, and With What Results*, OECD and OECD (2014), *Regulatory Enforcement and Inspections*, OECD Best Practice Principles for Regulatory Policy.

<sup>6</sup> Both perspectives serve the same result: mitigating or reducing risks ensures the protection of the public interest and have the same goal as strengthening public good.

analysis; an analysis of existing institutions that would be able to assume the responsibility; definition of the actual purpose of the entity in terms of public good and risk.

#### ***Lack of coordination in national-local inspection model***

In number of countries, enforcement is predominantly the responsibility of local authorities, which may co-exist with national agencies that either have exclusive competences in given inspection areas, or provide guidance to the local authorities in order to ensure a coherent and homogeneous enforcement of the relevant regulations. The latter are entitled to adopt decisions on the allocation of resources and have departments specialised in the different technical inspection functions. Local inspections may suffer from lack of resources in some regions, and excessive means in others. In addition, the unclear allocation of responsibilities to both central and regional/local authorities may also lead to a lack of coordination and information sharing between institutions, as well as to overlapping and/or duplicated inspections. In such cases, the root of the problem lies in the fact that the decision concerning the enforcement functions has not been the result of careful analysis. Irrespective of the reason, as consequence there is frequently confusion among businesses (and inspection bodies themselves) about which agency is competent for conducting inspections in which field.

#### ***Lack of professionalism***

Recruitment rules, qualifications processes and procedures, training of inspectors on core inspecting skills, on compliance promotion and on reducing risks linked to the business activities, and the assessment of the performance of the inspectors (and inspection agencies) may not be well defined or developed in a coherent and homogeneous manner. Defining common basic skills and methods for all kinds of inspection areas is essential. In addition, improving relations with inspected subjects and reducing burden for businesses is also crucial.

#### ***Inadequate performance management***

This usually translates into an excessive number of inspections without this being justified and/or an excessive number of sanctions, which are seen as being appropriate (or as even one of the goals of the inspection system). Comparative research reveals that a high number of inspection visits neither ensures a better level of compliance with relevant regulations, nor a more effective safeguard of the public interest (the same applies to sanctions).

#### ***Use of inspections as source of budget revenue (linked to previous point)***

Regulatory enforcement work can be jeopardised if safeguarding public goods is in conflict with revenue generation (considered as another goal of the government structure). A problem arises when the revenue-generation goal is considered as a priority, resulting in enforcement oversights. This leads to major abuses of the system, and a breakdown in effectiveness and legitimacy. In order to avoid this conflict of interests, it is crucial to ensure that inspection agencies have clear mandates and that their activities are in line with their general mission in terms of preserving the public interest and mitigating risks.

#### ***Disproportionate sanctions / lack of proportionality and responsiveness***

If sanctions are considered as not sufficiently deterrent it is likely that some inspected subjects will continue committing the same incompliances, even after a first sanction. On the other hand, excessively heavy sanctions without proportion to the offence are economically inefficient, decrease legitimacy of public action and breed resistance to inspections and enforcement (and thus lower

compliance). Proportionality and risk-responsiveness means that the enforcement response to a violation, which is serious and may cause harm to human integrity or health or to other essential public goods or rights should be more coercive than for less serious breaches, which do not result in an imminent hazard. Consequently, the range of potential sanctions should be broad enough to ensure, on the one hand, that different behaviours are treated in a differentiated manner and, on the other hand, that they achieve in exerting effective deterrence.

#### ***No efforts to promote compliance, guide, advice, etc.***

A higher level of compliance and mitigation of risks is not likely to be reached if inspection agencies do not promote compliance (through the publication of guides, manuals, checklists or any other information, oral or written advices, and the improvement of the relationship between them and the inspected parties). This happens, in particular, when the main objective of the agency is revenue-collection.

#### ***Inadequate salaries and career perspectives***

This very often results in good staff (professional, qualified, educated, etc.) leaving the institution, while those who benefit from the system remain in office, doing so for the wrong reasons (because they are not qualified enough to find another job opportunity, they practice corrupt practices and acts of abuse of authority).

#### ***Absence of credible appeal possibilities***

When appeal possibilities are not outlined by the legislation/regulation, or when the conditions laid down for applying for a remedy are too difficult to fulfil, or when it is known that there is no actual appeal possibility, this results in a generalised lack of confidence in the public institutions (in particular in enforcement bodies and inspectors, and courts).

#### ***Absence of sanctions for bad behaviour of inspectors***

The lack of effective and deterrent penalties for inspectors who act against legal rules or norms of professional ethics lead to a lack of trust of the enforcement system by the regulated and to greater opportunities for abuse of power.

#### ***Undue influence***

“Execution of regulatory enforcement should be independent from political influence” (Principle 7, OECD [2014]). In some cases, even when legislation/regulation protects the staff of enforcement bodies from political interference, the management staff is still exposed to political influence (for instance, when it is replaced following political changes). In addition, inspection bodies could be under the direct influence of ministries, and are therefore exposed to the risk of altering some of their priorities based on political decisions.

## **4.2 Overview of good practices – in accordance with international experiences**

### ***Transparency of regulatory framework, procedures and structures***

Transparency is a key element in order to ensure an adequate enforcement of regulation on inspections. This principle applies to the legislative and regulatory framework (for example: the Regulators’ Code<sup>7</sup> in Great Britain; the Law-Decree n. 5/2012 – so-called “Simplify Italy” Decree,<sup>8</sup>

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<sup>7</sup> *Regulator’s Code* is available at [www.gov.uk/](http://www.gov.uk/)

<sup>8</sup> Law-Decree n. 5/2012 (so-called “Simplify Italy” Decree) is available at [www.funzionepubblica.gov.it/](http://www.funzionepubblica.gov.it/)

adopted by the Italian government in 2012 – that oversees delegation of powers to the government for the implementation of reforms), to procedures and practices related to inspection activities, as well as to structures and their mandates and responsibilities. This avoids confusion among inspected subjects and abuses of power, among other valuable consequences.

### ***Avoiding overlaps and duplications, improving efficiency***

In many cases, there is an excessive number of agencies responsible for inspections and control of activities, which leads to overlaps and duplications of inspections and to waste of (material and human) resources. Consequently, this situation entails a significant administrative burden on businesses and unnecessary costs for the state. Very often, CoE member states that have carried out reforms have considered the institutional reform as a leading objective and have tried, on the one hand, to reduce the number of agencies while consolidating their function and, on the other hand, to clarify the mandate(s) of each agency. All of the above models (see section 3.1) can achieve this objective, if the principles of the reform are respected. Nevertheless, successful consolidation experiences<sup>9</sup> suggest that it is of paramount importance to carry out a prior diagnostic analysis of the existing situation, and that framework legislation, coordination mechanisms and the willingness to reform structures must be part of the process. Also, avoiding overlaps and duplications and improving the efficiency of the inspection system also involves improving the articulation and coordination between national (central) and regional/local structures, as well as ensuring a systematic and effective information-sharing between agencies and coordination in the planning of inspections<sup>10</sup>.

### ***Risk-based regulation***

Risk-based regulation is essential, since it helps achieve public policy goals by targeting in an effective manner the establishments or businesses, which pose major risks: it allows a better use of public resources, by prioritizing the fields or inspections subjects that require the most stringent controls; it allows reducing unnecessary burden on economic operators. Risk-based regulation also involves adopting risk-proportionate approaches and tools for each issue, problem, and situation.

First, the main objective of risk-based regulation is to reduce the likelihood of an adverse effect on public welfare (taking into account the available resources). Risk-based regulation allows for a rational and data-driven selectivity, and could help direct government resources in a more efficient and effective manner.

Second, targeting the inspection system (and, in particular, inspection procedures) based on the risks economic activities entail to the integrity and safety of consumers, the environment society as well as to the whole society, is crucial. This principle has several advantages:

- It anchors the inspection system on a legitimate foundation;
- It makes the process more reasonable for the inspected parties;
- Risk-based planning ensures a more cost-efficient use of resources (both material and human).
- Risk-based focus, when well-designed and well-functioning, can lead to an improvement regarding to the confidence in high-risk businesses, as they are considered as complying with higher standards.

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<sup>9</sup> For instance, the gradual consolidation of state inspectorates in the Netherlands, which has allowed reducing their number from 26 of 10; or the consolidation of all agencies dealing with food safety into one single agency in many countries as part of the EU accession process; or following the example of Bosnia and Herzegovina, where government established a single State inspectorate covering all inspections (except fiscal and state services and structures inspections).

<sup>10</sup> See explanation and examples discussed in Blanc, F. (2012), p. 66 ff.



The introduction/use of precise data on businesses (for example, using an adequate business registry) and of IT tools is essential to make this development effective<sup>11</sup>.

Third, loose/more flexible regulatory requirements for businesses considered as posing a low risk can reduce their costs. Since low-risk businesses are the vast majority, lowering the burden on them could allow for a net diminution in economy-wide burdens.

***Sharing information for inspection planning – aimed at ensuring coordination (in particular, between national and local agencies)***

International experience has shown that effective information sharing helps reducing administrative burden, improving planning and ensuring cost-efficiency. However, this is only possible with both a consolidated IT system/tool and information on all objects subject to control. According to the report prepared for the OECD in 2012<sup>12</sup>, the IT system should ideally be created from a database including at least the following items: a list of all businesses and establishments; the parameters corresponding to risk factors for each establishment; a record of inspection visits; a list of the inspection results; automatically generated risk ratings for each business and establishment; automatically generated inspection visits selection and schedule. Even though some interesting/good practices examples exist<sup>13</sup>, more advanced systems are rare. However, despite obstacles – like the complexity of interconnecting different existing IT systems, the costs related to the introduction of the IT system, confidentiality issues, etc. – the crucial role of IT tools allowing information sharing between inspection bodies makes it a key element of a rationalised and efficient inspection system.

The tool “Inspection View” was introduced in the Netherlands in 2010 after a two-year pilot phase. This tool, whose primary goal was to ensure the exchange of information based on the improvement of information architecture, allows data-sharing between different inspection agencies, which have access to information on inspections and enforcement in certain businesses/establishments. “Inspection View” enables a certain centralisation of information on businesses (in particular, data on previous inspections, like inspection visits’ results), allowing each inspector to have a comprehensive view on a business. Even though it does not replace consolidated information tools in national inspection bodies, “Inspection View” facilitates the cooperation between national inspection bodies (about five). However, regional inspectorates can also access the application and are using it in some cases, where common supervision is the most important. The information available on “Inspection View” is to be used to target inspections in accordance with a risk-based approach in order to build a more effective inspection system. This tool also helps preventing duplications and overlaps. Used together with another informatics instrument called “Company Dossier”, both instruments have been recognised to diminish the regulatory burden on businesses. The tool Company Dossier, developed in 2011 by the business community and the Ministry of Economic Affairs, is to be used by the business, which can introduce information and data about its operations resulting from self-regulation and make them available for regulatory agencies (the latter can only access the information if the business has decided to share the data available on its “Company Dossier” with them). Both instruments used together help inspectorates and inspectors to focus on the issues that are considered as most

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<sup>11</sup> This issue will be addressed in more detail in the following section (4).

<sup>12</sup> Florentin Blanc (2012), *Inspection Reforms: Why, How, and With What Results*, OECD, p. 78.

<sup>13</sup> The Italian “Unified Inspections Registry” and the Inspection Management System introduced in Bosnia and Herzegovina (Republika Srpska) will be presented in a more comprehensive way in section 6).

problematic and to also on results. Moreover, they build/strengthen confidence in the regulatory and supervision authorities, which is favourable for supporting compliance.<sup>14</sup>

### ***Professionalism***

It should be the basis of any inspection activity. It involves both technical competences in the relevant areas and generic competences related to inspections (operational management, compliance promotion, ethical behaviour, risk management, etc.).

### ***Adequate performance management***

Performance management should reflect, on the one hand, the overall aims of inspection activities (mitigating risks, safeguarding the public interest) and the specific objective of each inspection function. Setting goals and objectives for inspectorates (and inspection staff) needs to be done in this perspective, i.e. so that positive outcomes in terms of compliance and safety are what is targeted, and not a high volume of inspections or sanctions. Large and increasing amounts of sanctions are particularly problematic because they suggest that compliance is bad (and worsening), i.e. they should never be understood to correspond to “good performance” by an inspectorate.

### ***Avoiding using inspections in order to generate revenue***

The inspection system should not aim at generating revenue, but at mitigating risks, and safeguarding the public goods and rights. Generating revenue should be banished as a goal for inspection agencies, since it may end up conflicting with the aforementioned instrumental and fundamental goals.

### ***The role and limits of adequate sanctions and liability in regulatory enforcement's effectiveness***

Research studies and articles have highlighted several issues related to this subject. First, excessive sanctions for violations considered as minor (according to the level of risks generated) are extremely costly of businesses, create opportunities for abuses of power and do not provide a satisfactory level of confidence in the public authorities. Also, sanctions that are not proportionate to the volume of profits generated by the incompliance and/or to damages<sup>15</sup> usually do not dissuade violation. Second, provisions on liability of businesses that are not adequately enforced often lead to insufficient sanctions and compensation and poor compensation for victims. It is therefore advisable that the legal framework provides for adequate sanctions for minor incompliances and criminal violations, as well as for a strong liability mechanism.

At the same time, sanctions cannot achieve compliance on their own. Indeed, it has been proven that dissuasion as a driver of compliance has important limitations. First, the effects of punishment are mediated by the inspected subjects' values: a stronger dissuasion effect tends to be experienced by subjects that already support compliance, whereas the dissuasion effect tends to be weaker for those who do not. Second, in practice, strong deterrence tends to have significant costs in terms of finances and personal and economic freedom and is, therefore, impossible to achieve in most cases. Third, procedural justice is most often negatively affected if regulated subjects feel that deterrence efforts are excessively intrusive (indiscriminate visits and checks, sanctions imposed regardless of the risk level, requirements that hinder economic initiative too significantly, etc.) affecting in this manner the strongest compliance driver. Since research and experience show that deterrence is a weak driver of

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<sup>14</sup> See Faure, M. (2015), p. 232-233 and the information contained on the following websites: [Gateway to all central government inspectorates of the Netherlands](#), available in English at [www.inspectieloket.nl/](http://www.inspectieloket.nl/) and Website of the PIM, Program Environmental Information Exchange [[Programma Informatie-uitwisseling Milieuhandhaving](#)], available at [www.informatieuitwisselingmilieu.nl/](http://www.informatieuitwisselingmilieu.nl/)

<sup>15</sup> In this case, according to the Hampton Review (2005), “regulatory penalties do not take the economic value of a breach into consideration and it is quite often in a business's interest to pay the fine rather than comply”.

compliance and that, on the contrary, legitimacy and values are far stronger, the emphasis of inspection activities should not be on deterrence through punishment, but on driving compliance in a positive way through trust, advice, guidance and constructive engagement. Sanctions should be used as a back-up for cases of continued reckless behaviour, for business operators that really act in a criminal way, etc.

### ***Guidance and information***

Promoting compliance rather than systemically imposing control and sanctions is considered as one of the most effective ways for enforcement agencies to improve public outcomes. It has been found, on the one hand, that very often SMEs do not know what to expect from inspection visits (thus, they fear inspectors and may react in hostile fashion during those visits); on the other hand, SMEs usually are unaware of all the regulatory requirements that apply to their activity and/or of the way to implement them. Providing clear guidance and hands-on advice to the inspected parties has demonstrated in many cases its effectiveness and benefits. Indeed, it helps improving compliance with regulations (and providing confidence that inspected subjects who comply have nothing to fear from inspection visits) and reducing the risks that economic activities pose to safety of consumers, the environment, and so on. In Great Britain “Safer Food, Better Business” toolkit has successfully helped businesses comply and reduce their level of risk to food safety<sup>16</sup>. Also, in Lithuania, mandatory use of checklists during inspection visits – which ensures that inspectors are focusing on the right things – has resulted in improvements of relations between inspectors and inspected parties and clearer requirements that ensure better compliance with regulations.

### ***Salaries and career perspectives***

Salary scales should be established following clear and transparent criteria such as qualifications, continuous training, seniority or performance (number of inspections performed and/or of sanctions applied cannot be performance criteria). Promotion opportunities should be offered to the civil servant on the basis of pre-established criteria inspired on the agencies’ goals (mitigation of risk, compliance promotion and safeguarding public good).

### ***Credible appeals***

Inspected subjects must be provided with clear information about their rights and duties during the inspection process. In particular, they must be informed on how to challenge and appeal the conclusions or report abuses if any. The legal framework should hence provide for those rights and duties, and guarantee the independence and effectiveness of courts, and other redress bodies. The public authorities should also publicise any new interpretation made by the courts; this ensures that the inspected parties have access to, and understanding of, their rights and obligations, as well as the possibilities of successful appeal and challenge of the relevant decision.

### ***Avoiding undue influence***

Best practices show that keeping agencies at an arm’s length from political actors is a key element of an effective and efficient enforcement system. However, the executive power can legitimately decide which hazards to prioritise and which actions (and, thus, enforcement agencies) deserve added efforts and the allocation of additional resources, provided that the decision is taken in accordance with a risk-based planning, and do not result from the so-called Risk Regulation Reflex<sup>17</sup>. In most countries, inspection bodies are – directly or indirectly – subordinated to ministers (this can be found, for

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<sup>16</sup> This example will be discussed in more detail in section 6.1.

<sup>17</sup> On this matter see Blanc, F., Macrae, D. and Ottimofiore, G. (2015).

example, in the Netherlands, where the Chief Inspectors are appointed by Ministers and, thus, report to them, as well as to the Parliament; in Bosnia and Herzegovina – Republika Srpska – the Head of State Inspectorate and their management team are appointed by the full Cabinet and report to it, thus avoiding direct interference from single Ministers).

## 5 IMPLEMENTATION OF THE RISK-BASED APPROACH TO INSPECTIONS IN EU COUNTRIES

### 5.1 Definition of a risk-based approach: overall relevance

Risk is an adverse outcome, which can harm human health, integrity and safety, the environment, animals, etc. It is defined in technical terms as *a combination of the probability, or frequency, of occurrence of a defined hazard and the magnitude of the consequences of the occurrence* (Great Britain Department of the Environment, 1995). The level of risk is proportional to the likelihood of the adverse outcome occurrence, to the severity of the harm and to the number (and vulnerability) of people involved. According to this approach, risk is a rationalised and measurable basis for an inspection system.

Risk-based targeting focuses on businesses and establishments where risk appears to be most significant. Consequently, high-risk establishments are to be inspected most frequently and thoroughly (in terms of time needed and of qualified inspectors, among other things) than others. The rating instrument developed for this purpose by expert practitioners based on practical experience, best international practices and data mining helps categorizing all businesses and establishments based on their level of risk (at least “high”, “medium” and “low”). Risk-based inspection planning needs to be performed by means of a risk assessment, which must take into consideration key information on the business: size of the business/establishment, prior inspection results, geographic and geologic area where the establishment is located, etc.

Risk categories: example

		Likelihood of Compliance				
		Very high	High	Medium	Low	Very low
Level of Hazard	High	LM	UM	UM	H	H
	Upper medium	LM	LM	UM	UM	H
	Lower medium	L	LM	LM	UM	UM
	Low	L	L	LM	LM	UM

Source: BRDO, *Common Approach to Risk Assessment*

As seen above in 4.2, risk-based regulation goes beyond risk targeting and provides a number of benefits for consumers, businesses and civil society in general. The first stage includes risk assessment, whose objective is to lower the probability of an adverse effect on public interest and to ensure safer consumer products, fewer cases of food-borne diseases, improve workplace safety, environmental protection, financial security, fair competition and compliance with relevant existing regulations. Moreover, risk-focus is likely to improve confidence in the regulatory and enforcement entities, as well as in economic operators and is a crucial tool to reduce burden on businesses and to improve enforcement efficiency and effectiveness.

International experiences show that the risk-based approaches actually deliver benefits such as better (and persistent) results in terms of compliance and reduction of risks, as well as cost-efficiency. Most importantly, while inspections level decreases (significantly for low-risk subjects), the level of safety appears to remain constant, or even to improve. Hence, the goals of inspections are better achieved and inspected subjects experience less burden from the enforcement system. In this sense, it can be said that the risk-based approach allows for “win-win” results. Risk is thus a fundamental principle to define what inspections are aiming at preventing or mitigating, to prioritise human and material resources, and to select the most appropriate activities and tools for interventions. However, a risk-based approach is not limited to planning inspections in a rationalised manner. It also involves in particular inspectors’ professionalism and behaviour during inspection visits for promoting compliance and confidence in the enforcement authorities, transparency and methods related to inspected subjects, information sharing and coordination between different agencies and/or between regional/local and national levels, clear competences of each structure involved in inspection activities and use of adequate IT tools.

## **5.2 Illustration 1: food safety in the European Union**

Food safety can be taken as an illustrative example of the development of modern inspection system based on risks. EU food safety set of regulations, known as the “Hygiene Package”<sup>18</sup> requires from all “Food Business Operators” (FBOs) to ensure traceability of products and applies to the whole food chain and to all operators. In addition, the regulations count on the complete liability of operators, who are responsible for any harm caused. The regulations also determine how a recall needs to be commanded in adequate detail. In doing so, the regulator has accepted, on the one hand, that it is impossible to reduce the risk of hazard to zero. On the other hand, it provides incentives for FBOs to initiate a recall if they become aware of a problem and if they do not perform the recall, their liability is engaged (but their liability can be mitigated if they mandate the recall as soon as they detect the problem). Operators are also required to put in place constant self-control systems, in order to ensure that food is continuously and consistently safe. Finally and most important from our perspective, the EU food regulations clearly formulate risk as the principle based on which regulatory tools are selected, resources allocated, and enforcement responses determined. The risk-based approach applies to inspections of operating businesses, but also to the pre-operation phase and governs official controls regulated by the “Hygiene Package” all over the EU’s territory. In this way, the EU regulation provides confidence that inspections are equivalent for all EU member countries.

As stated above, risk, risk assessment and risk proportionality are the core foundation of official controls on food safety. Regulation 882/2004/EU on official controls outlines in its Preamble that “the frequency of official controls should be regular and proportionate to the risk, taking into account the results of the checks carried out”. The Regulation states the use of risk-based planning, in accordance with broad guidelines aimed at promoting “coherent national strategies, and identify risk-based priorities and the most effective control procedures”. Article 1 of the Regulation clearly states that the objectives of official control are “preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment”. Article 3 of the Regulation defines the risk factors to be taken into consideration: inherent risk of the product or operation, controls’ previous results on compliance and internal controls and external data indicating cases of non-compliance. In addition, article 54 shapes a risk-proportionate enforcement approach to decisions on actions to take in case of non-compliance, while article 55 provides for proportionality of sanctions.

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<sup>18</sup> Regulations 852/2004/EU on General Food Hygiene, 853/2004/EU on Specific Hygiene Rules for Food of Animal Origin, 854/2004/EU on Official Control of Food of Animal Origin Intended for Human Consumption, and 882/2004/EU on Official Food and Feed Control.

Regulations dealing with UE food safety requirements have an operational objective and aimed at ensuring a uniform enforcement. This aims at ensuring coherence and equality of treatment across inspected subjects located in the EU's territory through procedures, allocation of adequate (in terms of number and quality) resources, coordination between central and regional/local authorities, between different agencies, and member states. Moreover, the regulation mandates that the Commission ensure the supervision of member states' inspection bodies.

### **5.3 Illustration 2: comparison of occupational safety and health inspection systems in Great Britain and Germany**

Outcomes of a risk-based inspection system can be highlighted through a comparison between the British and the German approaches of **occupational safety and health (OSH)**, and their respective development.

In Great Britain, the Health and Safety Executive (HSE) is responsible for performing inspections on industries and high-risk facilities (this used to include nuclear safety, which is now being excluded from the scope of competence of HSE); in parallel, the Local Authorities conduct inspections on service businesses and on facilities considered as low-risk. Even though HSE does not report the total number of inspection visits (proactive and reactive) anymore, data on inspections ratio can be estimated with a reasonable degree of certainty. These show that the average percentage of inspections over the period between 1 April 2013 and 31 March 2014 is 5.18%.

In Germany, OSH inspections are conducted by [*Gewerbeaufsicht*] (labour inspectorate) inspection bodies of the federate states, and mostly by [*gesetzliche Unfallversicherungen*] (mandatory insurance bodies for professional accidents). Unlike in Great Britain, inspection bodies of the German federate states tend to have other duties such as general labour law and in some cases market surveillance. Estimates show that the ratio of OSH inspections per business is between 4 and 5 times higher than in Great Britain.

Several effectiveness indicators can be compared, such as the number of non-fatal accidents, labour-related health statistics and fatal injuries. According to the latter, which is considered as the most reliable statistic, the rate per 100 000 workers for 2013 is 0.56 in Great Britain and 1.66 in Germany. The ratio of non-fatal accidents is roughly equivalent in both countries. Labour-related health statistics show a significantly higher level of effectiveness in the British approach. Higher rates of work-related accidents in Germany are in part caused by the fact that its industrial structure differs from the British one, resulting in structurally slightly higher rates of accidents. Fatal accidents are more frequent in Germany on mid/long-term average (ratio of 1.3 for recent years, 2008-2012; 1.5 for earlier years, 1998-2007<sup>19</sup>). Significant year-to-year variations exist in both countries; even though for some recent years the ratio is better in Germany, overall it can be said that fatal accidents statistics are comparable or significantly better in Great Britain, depending on the year.

As stated above, inspections are considerably less frequent in Great Britain. A range of factors can explain this trend:

#### ***Duplications***

First of all, whereas in Great Britain HSE and Local Authorities benefit from a clear distribution of responsibilities, this is not the case for entities performing inspections in Germany; as a consequence, the latter inspect several times the same object and do not share information found systemically, which leads to duplications.

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<sup>19</sup> According to statistics available at Eurostat, *Accidents at work statistics*, available at <http://ec.europa.eu/>

### ***Risk-based planning***

Even though Great Britain still needs some improvements in this field (for example, in databases), risk-based planning is far more advanced than in Germany. In addition, even though Local Authorities are less advanced in this field (OSH), they benefit from data sharing with other inspection services within Local Authorities and prove therefore to have targeting capacity. In fact, overall targeting is risk-based, which is not the case in Germany.

### ***Compliance promotion***

The British system emphasises on compliance promotion, guidance and support to businesses; statistics confirm the effectiveness of this approach.

Statistics show that the German OSH inspection system is improving its effectiveness – statistics improve, while inspections decrease – in parallel with a gradual introduction of risk-based targeting of inspections. However, the OSH inspection system in Great Britain remains overall more effective and even though the difference in rates is reducing, Great Britain continues to have among the best OSH results in the EU. In addition, it appears to be much more efficient and costs much less to the state than in Germany. These outcomes prove certainly the advantages of risk-based targeting, coordination between structures and emphasis on compliance promotion.

## **6 EXAMPLES OF GOOD PRACTICES FROM COE MEMBER STATES**

### **6.1 Bosnia and Herzegovina**

The experience of Bosnia and Herzegovina appears very interesting because of the comprehensive nature of the reform that was carried out, as well as because of the introduction of the IT Inspection Management System.

In 2004, following a “merging inspections model”, Bosnia and Herzegovina instituted a State Inspectorate responsible for all inspections (including food safety), except fiscal inspections and those exclusively applying to state services or structures. Because of the institutional complexity of the country, two entity-level structures were introduced – one for the Republika Srpska and one for the Federation of Bosnia and Herzegovina – as well as inspection entities at a regional level. In Republika Srpska, the Head of the State Inspectorate and all the management team are appointed by the Council of Ministers, to which they also report. Consequently, the State inspectorate should escape the influence of a single minister, while gaining prestige and a certain status.

The reform was not limited to the consolidation of inspection structures, but embraced the whole system of inspections’ planning and implementation, in particular through a partial renewal of staff and the adoption of a Law on Inspections for each entity. This legal framework specifies the mandate and competencies of the State Inspectorate and provides for new internal common procedures. In addition, the Law on Inspections introduced risk-based planning of inspection visits and the mandatory use of checklists by all inspectors.

The Law also provided for the creation of a unified IT system, which is often referred to as an example of best practice, as it is a fully integrated system with complete functionalities and involves the most sophisticated approach to risk-based inspection planning. Its establishment was a logical complement to the consolidation of inspection functions within a single regulatory and supervisory structure. Established between 2007 and 2009, the Republika Srpska Inspection Management System on inspections handles a number of key functions: planning of inspection visits based on risks, management of reports on inspections, management of inspections results, database of checklists, among other functions. The reformed information and planning system has resulted in a reduction of

overlaps and duplications. However, since registration and licensing are not included in the unified system, and therefore does not receive data from other sources, the central inspectorate is the only institution filing and updating the information on businesses and establishments.

## **6.2 Great Britain**

Regulation of inspection activities and structures in Great Britain are often and widely referred to while reporting on good practices. Some examples related to “assured advice” (or “guidance”), compliance promotion by clarifying regulations, risk targeting and governance can be briefly mentioned here.

GB “Primary Authority” has shown to be able to deliver “assured guidance” by, for instance, reviewing economic operator’s internal procedures or through better use of the competent authority. A business operating across more than one council boundaries is allowed to create a partnership with only one local authority in relation to regulatory compliance. If primary authority partnership is approved by BRDO (Better Regulation Delivery Office), it is then recognised by all local regulators. By working closely with the business the primary authority can apply regulations and at the same time provide detailed and reliable advice; the advice given by the primary authority is then be respected by all local regulators. This enables the business to operate with confidence, since the primary authority has validated its internal procedures, methods, etc. on the basis of relevant regulations. This system also ensures compliance, since internal businesses’ rules have in practice more “power” over employees – and employees know them better – than external regulations. Often, the primary authority develops a national inspection plan; by doing so, duplications may be avoided, and information can be shared in an adequate way. In case of problems, the primary authority can coordinate enforcement action in order to make sure that responses are proportionate to the issue. A primary authority can recover the extra costs resulting from the in-depth examination of the company’s processes, in issuing guidance and advice, etc. The system is therefore in part financed by businesses themselves.

“Safer Food, Better Business” toolkit (SFBB), which focuses on catering, restaurants, and other small businesses that prepare and serve food perfectly illustrates the way public authorities can help economic operators comply with complex regulations by making them clear. Often, food safety requirements are considered by SMEs in particular as impossible to comply with. SFBB is more than a clear guidebook; it illustrates that it is possible for the regulator to “translate” requirements into simple, clear steps and, at the same time, let businesses know that the same guidebook is binding (in practice, at least) for inspectors. The guide takes businesses through a series of steps that correspond in fact to EU requirements on food safety. A business that follows the guide step-by-step is, thus, consequently compliant with the EU legislation. The guide even includes illustrations, “right and wrong” questionnaires and has been translated into 16 languages.

The inspections conducted by HSE are a valuable example of risk-based targeting. Indeed, with almost no exceptions, HSE plans its inspections by focusing on the highest risk establishments and on establishments with a clear record of hazardous non-compliance. Inspections plans also target specifically those sectors involving the greatest numbers of incidents leading to deaths and injuries, such as the construction sector. In this field, in particular, HSE focused its efforts in mitigating risks rather than in controlling compliance and has included, to this end, guidelines in foreign languages to ensure that the prevention policy and explanations are made clear to the actual workers. Risk-based targeting and prevention efforts have led to low death and injury rates. In parallel, it is estimated that the number of inspections conducted by HSE have progressively decreased over the last decade from over 50,000 a year to less than 30,000 today.



The Great Britain governance model includes boards comprising of directors and dual Chairperson and Chief Executive Positions, which is interesting. The Chairperson is responsible for ensuring the strategic vision of the inspection body. This model could ideally be reinforced by reviewing the way appointments to the board are made (not only by the minister in charge, but also by other office holders – including the political opposition – or by stakeholders’ associations). However, the board of directors appointed by the ministry already represent diverse interest groups (labour, employers, etc.), as is the case for the HSE. National inspection bodies do respond to ministerial directives on topics related to strategic directions, budget allocation of institutional structure; nevertheless, the operational dimension (inspection activities) is usually protected from political influence.

### **6.3 Italy**

Following a diagnostic that relies on quantitative measurements based on business surveys, in year 2011 Italy started reviewing and reforming its inspections system. The goals of the reform are greater proportionality to risk, improved coordination between inspection structures and decreased bureaucracy. As a start, Article 14 of the Decree-Law 5/2012 on administrative simplification (called [*Semplifica Italia*]) requires the coordination and rationalisation of the whole system of control on businesses, aimed at simplifying controls and render them proportionate to risks. To this end, it gives the government authority to enact regulations on controls’ coordination and planning in order to avoid duplications and overlaps as well as to reduce burdens on businesses.

Within this framework, the Presidency of the Council of Ministers has adopted guidelines<sup>20</sup> aimed at serving national, regional and local authorities to improve their procedure and practices in line with Article 14 of the Decree-Law through specific recommendations:

#### ***Clarity of regulation***

Public authorities must inform businesses about their obligations and requirements imposed by regulations, respond to requests for clarification in a timely manner, ensuring the widest possible dissemination among regulated parties. In particular, the guidelines call for the development and adoption of checklists. These are aimed at making requirements more transparent and clearer as well as ensuring harmonisation among different structures’ practice. In addition, an inspector must in all cases present an official identification document during control visits.

#### ***Proportionality to risk***

Control activities must be planned based on the risk posed by the activity concerned; this allows allocating resources where they can be more effective. Previous risk analysis must be based on data and outcomes, that is, immediate/actual risk to the public and not only probability upon non-compliance.

#### ***Collaborative approach for relations with businesses***

Inspectors must establish a constructive relationship with the inspected subject. Hence, they need to consider that control activities are aimed at ensuring effective protection of the legal interest. In order to achieve this purpose, the guidelines recommend the development of checklists, that the inspectors announce their visit when possible, establishment of databanks and of compliance promotion mechanisms.

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<sup>20</sup> Presidency of the Council of Minister (24 January 2013), Act of the Conference [*Linee guida in materia di Controlli*], available at [www.arca.regione.lombardia.it/](http://www.arca.regione.lombardia.it/)

### ***Training and updating of personnel***

In order to fully understand this new approach, inspectors need to be trained at emphasising cooperation with businesses, acting in a transparent manner, collaborating with other public authorities and at promoting compliance.

### ***Publicity and transparency regarding the results of controls***

The guidelines ensure the establishment of incentive and disincentive mechanisms through the communication of inspection results and the creation of common databanks.

In Italy, most of the coordination in inspection activities is performed at the regional level. In this perspective, the Unified Inspections Registry [*RUC – Registro Unico dei Controlli*] is considered as the most promising initiative<sup>21</sup>. Such registries apply thus far to businesses in the agriculture and food production/processing sectors and are operational in some regions (Emilia Romagna, Lombardy and Tuscany). Such unified information tools are to be used by all inspection bodies and other public authorities dealing with this sector, and operating in the region. For each business, the registries record information on the inspections conducted such as list of inspection visits, and any other data related to the visit, information on inspected businesses, production, environmental compliance, etc.). In May 2015, the Ministry of Agricultural, Food and Forestry Policies informed of the future creation of a RUC at national level, in order to avoid duplication of control visits and make inspection bodies work more efficiently. RUC instituted by regions and the central RUC will constantly share data and work in close cooperation on updating databanks.<sup>22</sup>

## **6.4 Lithuania**

The reform process initiated in Lithuania in 2009 following the global financial crisis and the election victory of a new coalition introduced a new approach on business inspections and, thus, new mechanisms and tools aimed at ensuring its success. The first phase of reforms on inspections and regulation enforcement was part of the integration into the European Union. The EU accession has enabled assessing the outcomes of the novel inspection system in terms of social welfare. Such assessments show that the reform has had positive results, particularly with regards to food safety issues.

The revised Law on Public Administration – considered as among the best internationally for primary legislation on inspections<sup>23</sup> – has incorporated a comprehensive chapter on supervision, which is innovative in guidance and assured advice to economic operators. The law defines supervision not only as consisting of inspection visits, but also primarily of advice and consultation to economic operators, analysis of information and enforcement measures. The law sets forth a number of principles, which include burden reduction, proportionality of inspection and enforcement activities, risk assessment as the basis for inspection activities, obligation to provide assistance to businesses, functional separation between inspection and sanction in order to reduce abuses of powers. In addition, the new legal framework introduces significant changes regarding sanctions: first, during the first year of operation, it cannot be decided to suspend the operations of an economic operator; second, the number of imposed sanctions cannot be used as an indicator of performance of the inspectorates' activities; third, in case of minor legal violation, a fine cannot be imposed. Other

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<sup>21</sup> See OECD (2013), *Better Regulation in Europe: Italy 2012: Revised edition, June 2013*, OECD Publishing, p. 108.

<sup>22</sup> Press release of the Ministry of Agriculture, Alimentation and Forests (May 2015), *Simplification: approval of the single Register of Control* [*Semplificazione: Conferenza unificata approva Registro unico dei controlli*] available at <https://www.politicheagricole.it/>

<sup>23</sup> See OECD (2015), *Regulatory Policy in Lithuania: Focusing on the Delivery Side*, OCDE Reviews of Regulatory Reform, OECD Publishing, p. 111 ff.

positive provisions, which are worth being highlighted are the mandatory annual report on performance of inspectorates, the obligation for inspection structures to publish information on their web portal and the right of an inspected subject not to submit information they have already provided.

In particular, the Law on Public Administration oversees that providing guidance to businesses is a priority of the inspection system. Advice officially provided to economic operators is therefore considered as binding, that is, if a business acts in compliance with an advice provided by the inspection and enforcement body – personally or because the information has been published –, it cannot be sanctioned if the information ends up being incorrect. This provision on ‘secured advice’ has allowed the development and establishment of inspectorates’ call centres in order to provide guidance of consistent quality.

Over the first years following the beginning of the reform (until 2013), Lithuania showed its ability to achieve a number of important results in several directions, including: setting up and adoption of checklists for all major inspection bodies; introduction and/or consolidation of risk-based planning schemes for most important inspectorates; creation of call-centres in a number of major inspectorates and development of on-line services in the Tax Inspectorate; adoption of performance criteria for inspection structures.

Thus far, the reform in Lithuania has resulted in several positive outcomes and a number of examples of good practices (for example, in the case of the State Tax Inspectorate, which evaluates its own performance on the basis of compliance levels achieved, has a well-established centralized approach to information and guidance, and has been a pioneer in risk-based planning). The reform process was rapid over the early years, but has slowed down recently. However, compliance with new procedures (advance notification, use of checklists) is overall good and the reform awareness is slowly improving. In the area of food safety, EU assessments confirm that inspection and enforcement activities are effective and respect good practices. Moreover, the overall level of food safety is good (according to EU regulation and objectives).

## **6.5 Slovenia**

The reform process carried out in Slovenia is an example of good practice concerning in particular the consolidation of the inspection system and its functions, the coordination of procedures and processes and procedural norms. The first modification of the system in 1995 divided the public administration between the state (at a central and local level) and the municipal level. In parallel, inspectorates were consolidated as independent bodies, placed under the auspices of the relevant ministries and benefited from relative autonomy. Inspectors were given authority to take independent decisions. The systemic reform started in 2002 introduced major improvements, such as the creation of an inter-ministerial coordination body, the Inspection Council, in charge of ensuring coordination and cooperation between different inspection bodies, organising common inspections and strongly encouraging information sharing and legal aid. Inspection bodies are now separate and autonomous bodies (from a budget, human resources and professional perspective).

The Slovenian approach to consolidation is certainly the most important aspect of the reform, in terms of good practices. Law on inspections established an Inspection Council aimed at coordinating the inspection bodies and their activities and practice. It coordinates inspectorates with functions directly covering the private sector (such as the Financial Administration, the Health Inspectorate, the Market Inspectorate or the Administration for Food Safety, Veterinary and Plant Protection); inspection bodies with some minor coverage of the private sector (the Administration for Nuclear Safety or The Inspectorate for Internal Affairs) and inspectorates that deal solely with the public sector (Inspectorate for Defence and Inspectorate to the public sector). The Council is a permanent body composed by

principals of state inspection bodies. Since 2005, the Council has had authority to conduct procedures for minor offences, which were previously under the prevue of the courts.

The Slovenian model also allows for coordination of good practices. Indeed, article 7 of the Law on inspections foresees that the role of the Inspection Council is to achieve greater effectiveness of the operation of inspection services by coordinating the joint implementation of inspection duties, training in inspection services, and measures aimed at providing information support to inspection services. Further coordination of inspections has been made possible based on further reforms: the developments introduced in 2007 ensured regional coordination of inspectors and article 18 of the Law on inspections provided for coordination of food safety.

The new inspections system also introduced principles and procedural norms that can be considered as good practices. For example, based on the principle of proportionality, inspectors can interfere with the operation of inspected subjects only to the extent necessary to ensure an effective inspection; measure imposed must be the more favourable to the person liable if this achieves the purpose of the regulation and must take into account the gravity of the violation, the consequences for the public interest and the circumstances. The legal framework also innovated by introducing the principles of the preventive function of inspection activities (through tools, such as measures-warning) and of liability of the public administration for financial damage and by regulating job description and employment position of inspectors, with an emphasis on professional competence.

The overall reform has led to a reduction in the number of inspections and to an increase in the number of businesses (from 155.000 in 2007 to 187.000 in 2012). In addition, the inspection bodies are seen as having gained effectiveness. Data show that there is a significant decrease in the number of appeals against the inspectors' decisions and in presence of inspectors in the field.

## **7 CONCLUSION**

Valid structures and practices of regulatory and supervisory authorities dealing with inspections and control of economic activities are those which ensure (or tend to ensure) public wellbeing by reducing or mitigating existing hazards that may endanger public goods, such as health, safety or environmental protection, and, at the same time, foster economic growth and employment. So far, the risk-based approach has been identified as the most adequate model to efficiently and effectively address these objectives. Nevertheless, experience has shown that the implementation of a risk-based approach must go hand in hand with other fundamental instruments in this field, such as coordination between inspection agencies, information and data sharing, transparency and clarity of regulation and of appeal mechanisms, performance management, risk proportionality of measures and sanctions, and a collaborative approach for relations with businesses in order to promote compliance.

Concrete examples of international practice within the CoE provide solid evidence that, for different and diverse regulatory and enforcement approaches (or combination of models) to be valid (which also allow taking into account the historical and constitutional structure of each country), a number of essential principles need to be followed. Nevertheless, there are challenges that may cause practical difficulties in the implementation of a risk-based approach. For instance, risk-based enforcement needs good quality data and evidence, as well as a well-defined method of collecting and using them. Since some countries do not have access to good quality data and have difficulties in generating it other options for less solid information may be chosen. Also, the legal framework may not allow for enforcement, in which case, there will be will be a need to review or extend it to support the development and implementation of risk-based approaches.

## 8 APPENDIX 1: THE SMALL BUSINESS ACT FOR EUROPE

One of the key goals of improvements in inspections and enforcement is to support the development of SMEs, which tend to be disproportionately affected by poor inspection practices, because of their lower ability for legal recourses, their lesser access to expertise, and the higher proportion of their profits taken up by administrative burden (losing one day of an employee's work is a small cost for a large firm, a large cost for a small firm). Adopted in June 2008 by the European Commission and politically endorsed by the EU Council of Ministers in December 2008, the Small Business Act (SBA)<sup>24</sup> for Europe is a political document aimed at addressing the specific challenges of SMEs. Its primary objective is to anchor the "Think Small First" principle in policy- and regulation-making through 10 principles to be implemented and a series of actions to be performed by the European Commission as well as the EU member states. Based on the "Think Small First" principle, the SBA considers SMEs' recognition as an essential starting point and foundation for achieving better operational conditions for them.

The SBA aims at improving the general attitude to entrepreneurship in general and to SMEs in particular, and applies to all independent businesses that have less than 250 employees (i.e. the immense majority of enterprises operating in the territory of the UE). The SBA is a set of ten principles whose goal is to guide the conception of policies and their enforcement both at EU and at national level. This instrument reflects the European Commission's determination to recognise the role of SMEs in the economy by creating a wide-ranging policy framework for SMEs. The 10 principles set out by the SBA are:

- I. Create an environment in which entrepreneurs and family businesses can thrive and entrepreneurship is rewarded
- II. Ensure that honest entrepreneurs who have faced bankruptcy quickly get a second chance
- III. Design rules according to the "Think Small First" principle
- IV. Make public administrations responsive to SMEs' needs
- V. Adapt public policy tools to SME needs: facilitate SMEs' participation in public procurement and better use State Aid possibilities for SMEs
- VI. Facilitate SMEs' access to finance and develop a legal and business environment supportive to timely payments in commercial transactions
- VII. Help SMEs to benefit more from the opportunities offered by the Single Market
- VIII. Promote the upgrading of skills in SMEs and all forms of innovation
- IX. Enable SMEs to turn environmental challenges into opportunities
- X. Encourage and support SMEs to benefit from the growth of markets

Among these fundamental principles, several are of particular relevance to inspections and enforcement practices, in particular principles III, IV and IX. The requirement to "design rules according to the 'Think Small First' Principle" can be considered of particularly relevant, since it renders SMEs' involvement compulsory – at least for the European Commission – during the drafting/preparation of legislative or regulatory texts, and requires to think through the consequences for SMEs (in particular in terms of compliance costs, complexity, etc.) . Rules that are adequate for SMEs will have higher levels of compliance and thus most inspections will pass more smoothly. Indeed, principle III has been set out in response to the finding that compliance with regulations is the heaviest constraint on SMEs, which bear an unequal regulatory burden compared with big businesses; in fact, very often technical and administrative regulation does not take into account the specific needs and characteristics of smaller businesses. In order to address this problem and to ensure that

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<sup>24</sup> Commission of the European Communities [COM(2008) 394], "*Think Small First*": A "*Small Business Act*" for Europe, 25.6.2008, available at <http://eur-lex.europa.eu/>

regulations respect the “Think Small Principle”, the SBA obligates the European Commission and invites the Member States, in particular, to “rigorously assess the impact of forthcoming legislative and administrative initiatives on SMEs (‘SME test’) and take relevant results into account when designing proposals” and to “consult stakeholders, including SME organisations for at least 8 weeks prior to making any legislative or administrative proposal that has an impact on businesses”.

Based on principle III, all new legislative and regulatory (at European and national level) proposals shall be assessed through the SME test<sup>25</sup>, whose objective is to allow for an analysis of the effects of the proposal in SMEs – in particular, potential economic, environmental and social effect of draft regulation, by performing a cost-benefits analysis of a policy option as part of the impact assessment analysis. The SME test performed by the European Commission serves to highlight potential consequences on SMEs’ activities and helps find suitable solutions, which take their specificities into account. The SME test comprises a consultation with SMEs representatives, a preliminary assessment of businesses likely to be affected by the new regulation, a cost-benefits analysis and the decision of mitigation measures (such as simplified reporting obligations, information campaigns or tools, etc.) aimed at reducing the impact of the legislative/regulatory proposal on SMEs.

In addition, the European Commission has adopted certain measures in order to enable SMEs to speak for their interests through various mechanisms, such as SME panels – organised to consult SMEs about forthcoming legislation and regulation – or the SME feedback mechanism – which allows for retrospective collection of views and feedbacks on policies, programmes, actions, etc. Moreover, since involving SMEs closely when developing policy is considered as essential, the public consultation period has been increased afterwards from 8 to 12 weeks<sup>26</sup>.

In addition, principle IV requires public administrations to adapt their action to take into account SMEs’ particularities and issues, a point which, as we have seen, is crucial for good inspections practices. The idea to “turn challenges into opportunities” can also serve as important inspiration for inspections that are more supportive and emphasize guidance rather than punishments, to help SMEs overcome their compliance challenges and put in place best business practices.

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<sup>25</sup> See European Commission [SEC(2009) 92], *Impact Assessment Guidelines*, 15.1.2009 and European Commission, *Part III : Impact Assessment Guidelines*, 15.1.2009, available at <http://ec.europa.eu/>

<sup>26</sup> European Commission [COM(2011) 78], *Review of the "Small Business Act" for Europe*, 23.2.2011, available at <http://eur-lex.europa.eu/>

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