

# Actionable Regulatory Governance Indicators for EU Regions



**WORLD BANK GROUP**  
Governance



# Actionable Regulatory Governance Indicators for EU Regions

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## Foreword and Acknowledgements

This report responds to a request by the European Commission's Economic Analysis Unit of the Directorate-General for Regional and Urban Policy (DG REGIO) to the World Bank. As set out in an Administration Agreement signed in October 2015, the World Bank will help DG REGIO identify and develop three sets of actionable indicators of the quality and capacity of public administrations at the state and regional levels of the EU Member States. The three sets of indicators are (i) indicators on the Strength of Public Management Systems; (ii) Citizen-focused Governance indicators; and (iii) Regulatory Governance indicators. This report presents results of the third set of indicators. Separate reports summarize the results of the other two work streams.

Preliminary results and opportunities for continued work have been discussed on an ongoing basis with DG REGIO as well as with a steering group comprised of Directorate-Generals with interest in the topic. Meetings with the steering group took place in December 2015 and March 2017.

This report was prepared by a team of analysts from the World Bank led by Peter Ladegaard (Global Lead for Regulatory Policy and Management) under the direction of David Bernstein (Lead Public Sector Specialist) and the overall leadership of Adrian Fozzard (Program Manager for Europe and Central Asia) of the World Bank's Governance Global Practice. The project was co-led by Melissa Johns (until April 2017) and subsequently by Valentina Saltane, both from the Development Economics Department's (DEC) Global Indicators Group. The main authors included Peter Ladegaard, Valentina Saltane, and Elin Bergstein. Melissa Johns, Florentin Blanc, Joseph Antoine Lemoine, Petter Lundkvist, Nadia Novik, Dorina Georgieva, Radka Konstantinova, Margarida Soares Rodrigues, and John Arzinos also made significant contributions.

An earlier version of this report benefited from comments from Andreja Marusic and David Bernstein. Special thanks are extended to Lewis Dijkstra (Deputy Head of Unit of DG REGIO's Economic Analysis Unit) for his general guidance and leadership of the Actionable Regional Governance Indicators Project, and particularly for his input to this work stream.

## Executive Summary

The European Union's Cohesion Policy is its biggest investment instrument. With a budget of €351.8 billion for 2014–2020, the Cohesion Policy accounts for around one-third of the EU budget. The Cohesion Policy is implemented mainly through investments in EU regions and cities. Governance constraints have been identified as causing delays in the implementation of Cohesion Policy programs, and in reducing the impact of investments. The European Commission's 6<sup>th</sup> Cohesion Report stressed that "...it is of key importance for the efficient management of EU funding that a clear and stable institutional and regulatory framework is in place". This report focuses on regulatory governance constraints that may have an impact on the Cohesion Policy.

Deregulatory measures focusing on "fixing broken regulations" are a necessary and important element of investment climate reforms. Yet, regulation is an essential instrument to achieve policy objectives under the Cohesion Policy. The quality of regulation is critical not only for attracting productive investments but also for the multiplier effects and incentives it generates within a particular country or region. However, a lack of actionable indicators hampers implementation and monitoring of reforms. Current data and indicators for regulatory performance focus primarily on reforms of regulatory outputs at the national level rather than the quality of the underlying regulatory institutions and frameworks at the regional level. In light of these challenges, the primary purpose of the work described in this report was to develop and test a set of actionable indicators for regulatory governance in EU regions.

### ***Scope and analytical framework***

The analytical framework for the project employs a widely-accepted definition of regulatory governance: the systematic application of tools, institutions, and procedures that governments can use to make regulatory outcomes effective, transparent, inclusive, and sustained. Consistent with this definition, regulatory governance can be broken down into four dimensions or stages of the regulatory process: (i) design; (ii) coordination and oversight; (iii) delivery; and (iv) ex-post review. The explicit inclusion of delivery reflects a growing focus in recent years on regulatory governance mechanisms which can help close gaps between the rules on the books and actual implementation practices. The four dimensions of regulatory governance were operationalized into 11 sub-dimensions including access to regulation, use of regulatory impact assessments (RIAs), and use of risk-based approaches to inspection.

The project focused on governance practices in two specific regulatory domains—food safety and environmental regulations related to industrial emissions—in order to ensure a high degree of sector-specific relevance and operational insight. These policy areas were selected because of their importance for the European Union and the EU's Cohesion Policy, in particular, and because the domain-specific findings were considered good proxies for the whole-of-government regulatory governance features of the entire region. The final aspect of defining the scope of the pilot study involved the choice of EU regions in which to test the indicators. Key selection criteria included that the pilot regions represent a reasonable distribution of new and old members and have varying degrees of regional autonomy. The selected regions would also be less developed economically than other areas and thereby among the main recipients of Cohesion Policy funding and investment. After taking these considerations into account, the World Bank and the DG REGIO agreed to pilot the regulatory governance indicators in the Yugozapaden region of Bulgaria, the Campania region of Italy, and in Estonia (which in itself comprises one EU region).

### ***Design and rollout of the survey questionnaire***

The project conducted a comprehensive review of related indicator sets to leverage existing knowledge. It found that existing indicators—while providing a wealth of information regarding well-tested questions and approaches—lacked the necessary scope and geographical coverage from an EU regional perspective.

Further adaption and development were deemed necessary. Extensive internal and external consultations with regulatory policy experts, combined with a review of multiple previous data collection projects, suggested that administering questionnaires to public and private-sector respondents would be the most effective and reliable approach to generating a robust set of data. Key challenges to this approach included, among others: (i) applying regulatory governance indicators homogenously across EU regions; (ii) developing comparable indicators for regulatory delivery; and (iii) limiting questions to a reasonable number, given the expected challenges related to data collection. It was decided to create a new database with primary data collected as one, comprehensive dataset. Wherever possible, the questionnaire drew upon questions and formulations which had been tested through other indicator sets (primarily those of the World Bank Group and the Organisation for Economic Co-operation and Development, the OECD).

The questionnaire was administered to both regional and national regulatory agencies. Part of the questionnaire was also administered to private sector organizations to allow for the identification of regulatory overlaps and inconsistencies between different levels of government. A contributor database of 112 public-sector and 38 private-sector contacts was established using existing databases and World Bank Group offices. The data collection was conducted by email (with telephonic reminders) in the period from October 19, 2016, to January 1, 2017. In Campania—where responses were limited—data were collected through face-to-face interviews with the relevant authorities, and a total of 20 questionnaires were collected. The relatively small number of questionnaires is not, in itself, a concern; many agencies and ministries coordinated and consolidated responses before submitting, thereby decreasing the number of questionnaires significantly, while improving the quality and reliability of responses.

### ***Scoring methodology and survey results***

The project developed a composite regulatory governance index with scores from 0-4. The index is composed of scores from 0-1 on each of the four core dimensions of regulatory governance (design, coordination and oversight, delivery, and ex-post review). The composite score for the three regions are shown below (Table 1.1).

**Table 1.1 : Regulatory governance scores for the three pilot regions**

	<b>Regulatory Design</b>	<b>Regulatory coordination and oversight</b>	<b>Regulatory delivery</b>	<b>Ex-post regulatory review</b>	<b>Overall regulatory governance</b>
<b>Yugozapoden (Bulgaria)</b>	0.8	0.6	0.6	0.5	2.4
<b>Campania (Italy)</b>	0.3	0.5	0.8	0.4	1.9
<b>Estonia</b>	0.9	0.6	1.0	0.8	3.3

*Note:* The score for overall regulatory governance is not equal to the sum of the four sub-dimensions, since each of the nominal scores on the sub-dimensions are weighted equally (25%) in the overall score. For example, in the case of Yugozapoden region, the regulatory design sub-index is first calculated for food safety and then for industrial emissions sectors. Then, applying the weights of 25% the simple average is computed between the two to arrive at 0.8 points. The same is repeated for the remaining three sub-indexes. Finally, for each sector a separate total score is computed using equally weighted four sub-components and the overall regulatory governance score represents a simple average between the selected two sectors. For more details, please see section 6 of the report on page 27.

The scores reflect the regulatory governance practice *implemented* in the region, regardless of whether the practice is *executed* by a regional or national authority. The survey results suggest that Estonia has better regulatory governance practices on all four dimensions (although it ties with Yugozapoden on the regulatory coordination and oversight score), followed by Yugozapoden and Campania.

The survey findings confirmed that many aspects of regulatory design, ex-post review, and—to some extent—coordination are anchored more at the national level, and less so to the discretion of regional authorities (with some exceptions in countries with a high degree of decentralization or federalism, such as Italy). Delivery, however, is typically more heavily delegated to regions, both institutionally and in terms of execution. Regulatory delivery practices also showed significant variation among the surveyed regions.

The project also experimented with the construction of several additional composite measures, which could potentially provide insights into regulatory governance variations across regions. The three composite measures were: (i) overlap of regulatory authority (that is, how many different levels of government are assigned to conduct the same function?); (ii) sectoral variation (that is, are regulatory governance practices in one domain different from those in other domains?); and (iii) regional variation (that is, are regulatory governance practices in one region of the country different from other regions in the country?). The scores on these indexes consistently point to Campania as having the largest degree of regulatory overlap, sectoral and regional variation in regulatory governance practices, while Estonia has the smallest.

These results should be viewed as preliminary outcomes of a methodology which may be further revised, and which may have more actionable value when applied to a greater number of regions. The pilot measurements covering two sectors in three EU regions allow for a “proof of concept” regarding the indicator methodology, but not for a conclusive assessment of the regulatory governance capacities of the three regions in question. In other words, the indexes are likely to have only limited explanatory and operational value in the context of only three pilot regions but may be of relevance when larger cross-country and inter-regional datasets are collected.

### ***Quality tests and areas for improvement***

The analytical framework and data collection strategy are robust and demonstrate a feasible approach to collect and compare actionable regulatory governance indicators for EU regions. Implementation of the pilots uncovered a range of opportunities for more efficient data collection and analysis, including through improvements to the way respondents were identified and asked to provide contributions. These lessons have been documented and should be implemented in future rounds of data collection.

To better gauge important differences in regulatory practices, future surveys could expand coverage of how national-level regulatory impact assessments address issues of regional distribution and implementation, and how the implementation of EU regulation is managed. Slightly expanded coverage of “delivery” at the regional level could also be considered. Finally, future surveys could be adapted to better differentiate between regions with high or little regulatory autonomy.

### ***Next steps***

For the continuation and improvement of the survey instrument, the report recommends a modest expansion of the number of regions covered by the indicators. A first round could include 8-10 regions spanning 3-4 countries, facilitating both inter-regional and in-country benchmarking. Subsequent surveys could cover 15-20 regions on a rotating and bi-annual basis. If deployed to a broader set of EU regions, the indicators are likely to provide a sound baseline for comparisons and performance of EU regions. The surveys would be able to identify good regulatory governance practices, which can be replicated and adapted from one region to another and form the basis for peer-to-peer learning.

## I. Introduction

The European Union's Cohesion Policy is its biggest investment instrument. It supports the Europe 2020 strategy of smart, sustainable, and inclusive growth. With a budget of €351.8 billion for 2014–2020, the Cohesion Policy accounts for around one-third of the EU budget. The Cohesion Policy is primarily implemented through investments in EU regions and cities. Local and regional governments in the EU are responsible for more than half of all public investment.<sup>1</sup>

There is a growing focus on the importance of good governance to ensure effective implementation. The European Commission's 6th Cohesion Policy report notes that governance problems not only delay the implementation of Cohesion Policy programs but also reduce the impact of these investments. The report states: *"A lower standard of governance can affect the impact of Cohesion Policy both directly and indirectly. In the first place, it can reduce expenditure if programmes fail to invest all the funding available. Secondly, it can lead to a less coherent or appropriate strategy for a country or region. Thirdly, it may lead to lower quality projects being selected for funding or to the best projects not applying for support at all. Fourthly, it may result in a lower leverage effect because the private sector is less willing to co-finance investment."*<sup>2</sup>

The Cohesion Policy report highlights that the quality of governance is particularly low in those countries receiving the most substantial Cohesion Policy contributions and that there are significant disparities in the quality of governance at both the national and regional levels. To address these challenges—and to ensure that regulatory, administrative or institutional bottlenecks do not undermine the effectiveness of investment—the Cohesion Policy for 2014–2020 focuses on the importance of good governance. Regions and cities are required to fulfill several pre-conditions to receive Cohesion Policy funding, including implementing business-friendly reforms. The European Union will invest a projected €4.3 billion in institutional capacity building from 2014–2020 in support of such reforms.

Many reforms are constrained by a lack of actionable indicators, especially on regulatory governance. The fact that a comprehensive and comparable set of actionable regional governance indicators does not exist in the EU limits the identification and monitoring of governance reforms. This challenge is particularly pertinent in the area of regulation—an essential instrument to achieve policy objectives. The quality of regulation is critical not only for attracting productive investments but also for the multiplier effects and incentives it generates within a given country or region. When poorly conceived, regulations can pose obstacles to social and economic development. Poor regulatory practices and weak underlying governance arrangements can undermine the full implementation and success of Cohesion Policy investments. Current data and indicators for regulatory performance focus primarily on reforms of regulatory *outputs* rather than the quality of the underlying regulatory governance mechanisms.

The purpose of this report is to develop and test a set of actionable indicators for the regulatory frameworks of EU regions. However, gains from one-off initiatives aimed at cutting costs and procedures are often reversed if the responsible institutions, tools, and incentives are not changed. The connection between good regulatory governance, growth, and productivity is well documented in academic literature and empirical

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<sup>1</sup> According to the European Committee of the Regions, around 55% of total public investment in the EU-28 in 2013 was carried out by sub-national authorities (European Union 2015). The share of sub-national expenditure in total general government spending has increased in most EU countries over the past few decades (European Union 2015). It is important to note that responsibility for undertaking expenditure is not necessarily synonymous with decision-making powers. Although the autonomy of regions has tended to increase over the past few decades, there are still large variations in the degree of self-rule across countries. Most sub-national governments rely on transfers from the national government to fund their expenditure. This is especially the case in Bulgaria, Malta, the Netherlands, and Romania. In Austria, Germany, Spain, and Sweden, sub-national authorities mostly rely on local taxes, reflecting more regional autonomy in these countries.

<sup>2</sup> European Commission 2014a, p. 172.



studies (Box 1). This perspective is consistent with that of the Cohesion Policy, which emphasizes that “it is of key importance for the efficient management of EU funding that a clear and stable institutional and regulatory framework is in place.”<sup>3</sup> Reflecting these challenges, the purpose of this report is to support the strengthening of regulatory frameworks in EU regions by developing and testing a set of actionable regulatory governance indicators that measure EU regions’ capacity and practices to prepare, assess, consult, disseminate, and enforce high-quality regulation. Through this objective, the project aspires to contribute to the development of an assessment framework to identify and drive regulatory governance reforms in EU regions.

### Box 1 Regulatory governance, growth, and investment

Due to the complexity and multitude of factors that influence how good regulatory practices affect economic growth and prosperity, it is difficult to establish statistically clear causal linkages between the two. However, there is ample evidence of strong correlations—countries (or regions) with strong regulatory governance also fare relatively well in terms of growth, productivity, foreign direct investment, and investor confidence.

Regulatory quality has a positive and causal impact on economic growth. There is a statistically significant and positive causal relationship between economic growth, and: (i) regulatory quality, based on the regulatory burden on business of ineffective quantitative controls; and (ii) regulatory governance, based on the quality of public provision, competence of civil servants and credibility of government decisions.<sup>a</sup>

Improvements in the quality of regulatory management yield significant economic benefits. Improvements in regulatory management systems (regulation policies, regulatory institutions, regulatory procedures and regulatory tools) yield significant and positive impact on employment, GDP, and labor productivity.<sup>b</sup>

Political stability and regulatory quality tend to substantially influence FDI inflows. “Regulatory quality and political stability have significant impact on FDI inflows. This indicates that foreign investors are interested in political stability and regulatory quality in their choice of investment abroad.”<sup>c</sup>

Regulatory predictability is important for a good investment climate “Good governance, legal certainty and high-quality regulations are essential for a stable business environment ... strengthening institutional and administrative capacity, reducing the administrative burden and improving the quality of legislation underpins structural adjustments and fosters economic growth and employment.”<sup>d</sup>

a. See research on the World Bank’s Worldwide Governance Indicators in 215 economies by Jalilian, Kirkpatrick and Parker 2007.

b. See research in OECD countries by Jacobzone and others 2010.

c. See research on 20 developed and developing economies by Saidi, Yosra, Anis Ochi and Houria Ghadri.

d. European Commission 2014b.

The scope and organization of this report reflect its focus on development and testing. The project’s primary purpose is to *develop* and *test* a set of new regulatory governance indicators. In other words, the objective is not to conduct a representative survey, but rather to test the approach and methodology. Given these objectives, the rest of the report is organized as follows: Section 2 presents the analytical framework; Section 3 focuses on the questionnaire design; Section 4 outlines the data collection process; section 5 discusses several questionnaire quality checks, and section 6 reports on the main data results. Section 7 provides some reflections on continued development and scale-up of the indicators, possibly supported by capacity building initiatives.

<sup>3</sup> European Commission 2014a, p. 265.

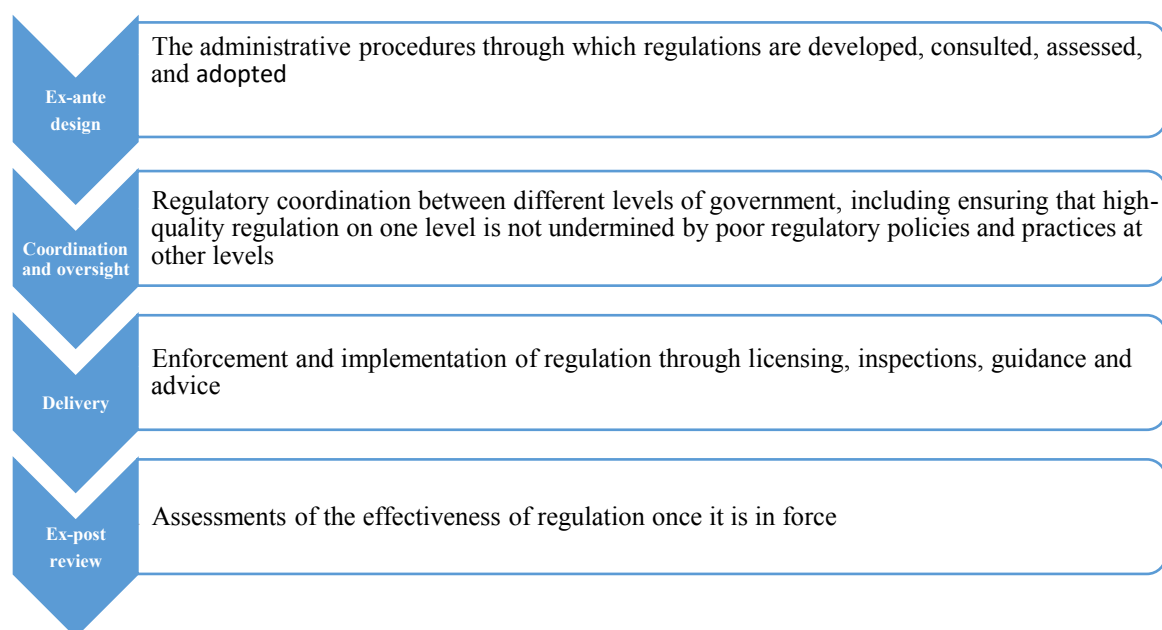
## II. Analytical Framework

This section presents the analytical framework which was developed to structure the identification of indicators and summarizes the rationale for the selected scope of pilot countries, regions and domains in terms their sectoral and geographical focus.

### Definition and core dimensions of regulatory governance

The analytical framework uses a widely-accepted definition of the term “regulatory governance”—that is, the systematic application of tools, institutions, and procedures which governments can mobilize to ensure that regulatory outcomes are effective, transparent, inclusive, and sustained.<sup>4</sup> Consistent with this definition—and broadly reflecting the regulatory process—regulatory governance is broken down into four stages: design, coordination and oversight, delivery, and ex-post review (Figure 2.1).

**Figure 2.1 : The four stages of the regulatory process**



The first stage covers procedures through which regulation is developed, consulted, assessed (regarding impacts), and adopted, and involves a range of measures related to transparency, access, and inclusiveness during the rule-making process. The importance of these features for regulatory quality are well established in the literature and observed in many comparative studies.<sup>5</sup>

<sup>4</sup> See, for example, World Bank 2010.

<sup>5</sup> Following international good practices, the design stage of regulations should involve active stakeholder engagements and consultations. As recent studies conducted in advanced economies (Diergarten and Krieger 2015; Gurin 2014) show, governments systematically consult citizens on proposed regulations before their adoption and implementation. Studies conducted in less developed countries (Adams and Atsu 2005; Denhardt and others 2009; Fishkin 2008) also indicate that the introduction of consultations into rule-making processes is beneficial for national economies. Constituencies that are directly affected by governments’ decisions should at least have an opportunity to comment on the proposed changes. This involvement is critically important as prominent studies (Abusah and Pingario 2011; Vallbé and Casellas 2014; Torriti 2007; Radaelli 2003; Fadaïro, Williams and Maggio 2015; Molster and others 2013) provide strong evidence that greater levels of consultation are associated with higher quality regulations. Practices of engaging affected parties in decision-making processes have been shown to increase the sense of “ownership” and lead to better compliance with regulations.

The second stage of the regulatory process focuses on strengthening coordination mechanisms between and within the national and sub-national governments (to ensure regulatory consistency and to avoid duplicate or conflicting regulations) and on the existence of a unit responsible for regulatory oversight or quality assurance. The importance of coordination between levels of government during the rule-making process, as well as the role of a regulatory oversight unit, is also well established in the literature and empirical studies.<sup>6</sup>

The third stage focuses on regulatory delivery, that is, “making regulation happen.” Systematic consideration of implementation issues has always been an important, yet often implicit, part of good regulatory design features. However, recent years have seen a growing focus on implementation gaps—discrepancies between (good) rules on the books and (poor and inconsistent) implementation.<sup>7</sup> In the context of the EU regions, the focus on “delivery” seems particularly pertinent given the various institutional and practical settings through which EU regulation and funding is implemented. The analytical framework identifies and focuses on a relatively broad range of practices pertaining to regulatory delivery to address this concern. These practices are: (i) transparency and communication of regulatory requirements; (ii) risk management and compliance promotion; (iii) accountability and independence of regulatory enforcement agencies; and (iv) institutional and functional integration of inspection functions.

Finally, the fourth stage of regulatory governance focuses on mechanisms and practices for reviewing existing regulations. Ex-post reviews enable governments to regularly update the regulatory stock by identifying bottlenecks, inefficiencies, and duplications and hence eliminating or amending regulations that cease to be relevant or do not yield the desired results. Ex-post regulatory review mechanisms are essential to ensure that regulations maintain their relevance and purpose. Under this category, the survey looks at government practices and methodologies to conduct ex-post evaluations, as well as feedback mechanisms from affected parties.<sup>8</sup> Figure 2.2 summarizes the analytical framework and the key dimensions of regulatory governance covered by the indicators.

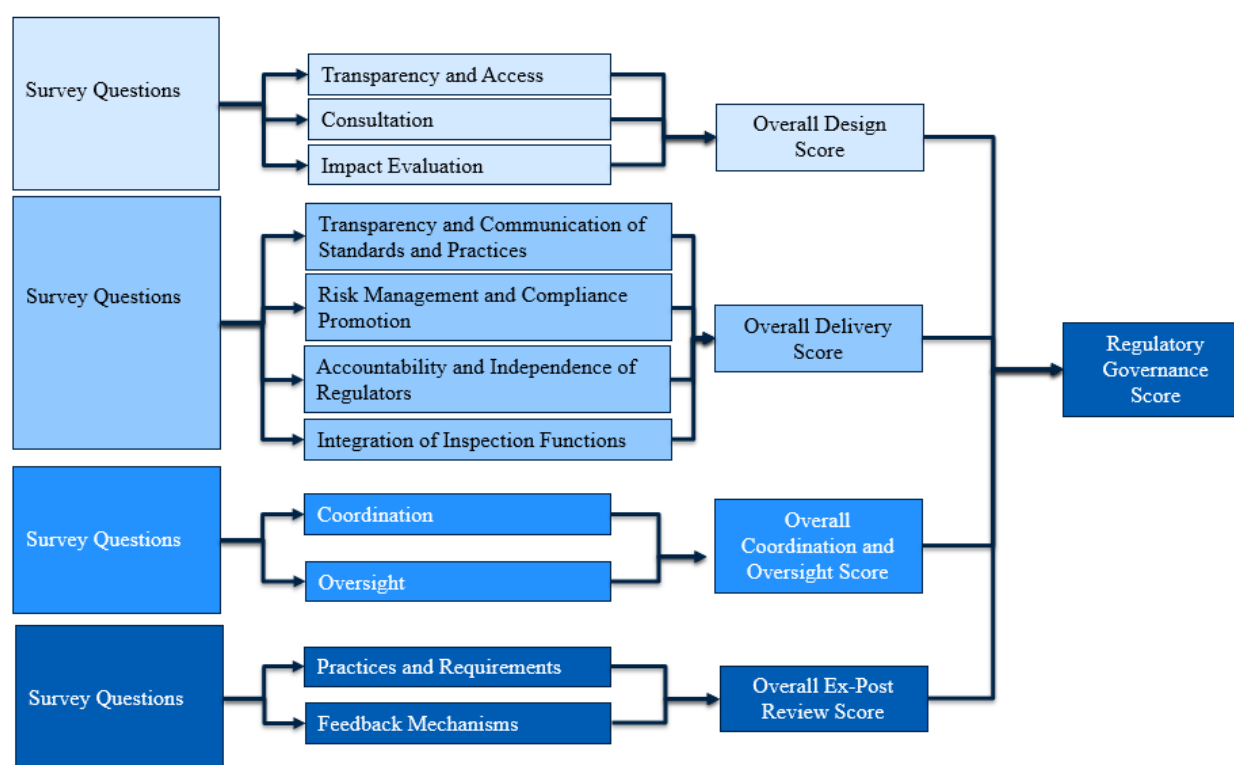
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<sup>6</sup> The coordination stage of the regulatory process is important for successful implementation and enforcement of regulatory policies. According to the OECD Recommendation of the Council on Regulatory Policy and Governance: “Where appropriate promote regulatory coherence through coordination mechanisms between the supranational, the national and sub-national levels of government. Identify cross-cutting regulatory issues at all levels of government, to promote coherence between regulatory approaches and avoid duplication or conflict of regulations” (OECD 2012).

<sup>7</sup> Regulatory delivery refers to all activities of state structures (or structures delegated by the state) aimed at promoting compliance and reaching desired regulatory outcomes, such as licensing, inspections, guidance and advice. It corresponds to a comprehensive understanding of “regulatory enforcement,” combined with all mandatory procedures implementing regulations, and compliance support. The “delivery” aspect of regulations has a direct impact on business development and growth (Netherlands, Bureau for Economic Policy Analysis 2004). As the OECD’s Regulatory Policy Outlook shows, “regulatory implementation and enforcement remain the weakest links in regulatory governance” (OECD 2015).

<sup>8</sup> Performance evaluation of regulations is another area of regulatory management receiving greater attention. Coglianese (2015) suggests that the performance of a regulation is based on the changes in behavior and outcomes and improvements stemming from that behavior. Evaluating regulations, therefore, entails an inquiry, after the regulation is put in place, into how it influences stakeholder behavior.

**Figure 2.2 Analytical framework: Key dimensions of regulatory governance**



*Source:* Actionable Regulatory Governance Indicators for EU Regions, the World Bank Group.

### Scope 1: Focus on whole-of-government features or specific regulatory areas?

With the project's analytical framework and key dimensions of regulatory governance established, a subsequent methodological consideration pertains to the *scope* of the indicators. Should the focus be on general, whole-of-government tools, approaches, and institutions supporting regulatory governance, or should the focus be on specific regulatory areas?

Both options have advantages and disadvantages. In favor of a whole-of-government approach are its broad, comprehensive coverage and the assumption that whole-of-government regulatory governance standards may, in many, cases be exhaustive for the regulatory governance standards in a particular regulatory area. In argument against this approach, findings and recommendations at a whole-of-government level may be less actionable and provide fewer insights into regulatory governance constraints in particular regulatory areas.

Focusing on specific regulatory areas provides indicators which would be more likely to include detailed and actionable information on the particular regulatory area in question. More specifically, if carefully selected to be representative of a larger regulatory framework, many of the regulatory governance requirements for a particular regulatory area—such as regulatory coordination and oversight—would be applicable across all or most regulatory areas, making it a good proxy for a region's overall regulatory governance performance.

These considerations led the team to develop an approach focused on specific regulatory areas. In doing so, it also decided to include the role of national-level institutions involved in the regulatory process in the selected regulatory areas. The team anticipated that a focus on policy—rather than on regional institutions

exclusively—would help capture more aspects of regulatory quality assurance mechanisms affecting businesses in a given region.

## Scope 2: Focusing on regulatory “sectors” or “domains”?

The next step in identifying the scope of the regulatory governance indicators entailed a determination of how to operationalize “regulatory areas.” In consultation with DG REGIO, the World Bank team decided to focus the indicators on regulatory domains rather than on sectors (Box 2).

### Box 2 Defining sectors versus domains

A *sector* is an area of the economy in which businesses share the same or a related product or service. Businesses operating in a given sector are regulated by both sector-specific regulations as well as laws and regulations within cross-cutting regulatory domains.

A *regulatory domain* refers to a set of laws or regulations within a particular area that governs the way a business can operate within that domain. Examples of regulatory domain include environmental rules, products safety norms, occupational safety, and health rules, and so on. Laws and regulations within a given regulatory domain affect business and citizens across different business activities.

A sector approach entails focusing on several sectors with high levels of Cohesion Policy spending (such as transport, energy or education) and assessing regulation affecting a given sector. An advantage of this approach is the targeting of spending areas with high relevance for the Cohesion Policy, while its disadvantages are both conceptual and practical. It is difficult to define “sector regulation” exhaustively. A sector is affected by a broad (and diverse) set of regulations. When applied to road transport, for example, sector regulation could include specific road regulations, safety regulations, environmental regulations, regulations for market access, and labor regulations. Such an approach would require a large number of survey respondents. Furthermore, indicators would only be actionable for selected sectors and may not be suitable proxies for overall regulatory governance. Finally, to be operational, a sector approach would require a selection of regulatory domains, since examining all of the regulations affecting a sector would not be feasible.

A regulatory domain approach measures regulatory governance in a selected regulatory domain or regime such as business registration, food safety, land acquisition, and so on. An important advantage of this approach is that since multiple types of businesses would be subject to regulatory governance standards in a particular domain, the measurements could provide not only “sector-specific” performance but also serve as a good proxy for how regulatory governance arrangements in general affect the growth opportunities, market access and investment decisions of a typical business. Similarly, it is assumed that possible reforms related to improvements of domain-specific regulatory governance shortcomings in the areas of design, coordination and ex-post review would also have a whole-of-government effect since regulatory governance features along these three dimensions are relatively uniform across regulatory domains.

Finally, development of the analytical framework required selection of specific regulatory domains which would be subject to the indicator pilot. Key criteria included: (i) the relevance of the selected areas to the European Union, and the Cohesion Policy in particular; (ii) the extent to which domain-specific findings could be proxies for regulatory governance features in the overall region (whole-of-government); (iii) where the regulatory domain affects businesses (and, by implication, the multiplier effect of Cohesion Policy investments); and (iv) the availability of data and in-house expertise in the World Bank (to ensure quality and reduce costs). An overview of some of these criteria, and the associated assessment of several regulatory domains (pre-selected for relevance to EU policies), are set out in

Table 2.1.

**Table 2.1 Selection criteria for pilot regulatory domains**

Regulatory Domain	Selection criteria			
	Good proxy for “whole-of-government” capacities?	Key regulatory domains affecting business?	Easily available information/ existing in-house knowledge?	Low reputational risks and limited intra-organizational constraints ?
Environmental regulations	Yes – core domain subject to standard regulatory governance procedures, handled by large institutions	Yes - most business affected by a number of environmental statutes and regulations	Yes	Highly diverse set of regulations may complicate analysis
Occupational Safety and Health (OSH) regulations	Yes – core domain subject to standard regulatory governance procedures, handled by large institutions	Yes – all businesses affected by general OSH provisions, some sectors more heavily regulated (construction workers, health care workers, etc.)	Yes	Limited risks
Product safety regulations	Yes – core domain subject to standard regulatory governance procedures, handled by large institutions	Yes - 75% of trade in the EU is in goods => lion share of EU economy affected by product safety regulations	Yes	Limited risks
Food Safety regulations	Yes – core domain subject to standard regulatory governance procedures, handled by large institutions	Yes – all sectors of the food chain, including feed production, primary production, food processing, storage, transport and retail sale are affected	Yes	Limited risks
Employment (labor regulations)	Yes – core domain subject to standard regulatory governance procedures, handled by large institutions	Yes – affects all business as it determines who can be employed and under what conditions	No	Potential risks due to the politicized nature of area
Banking regulations	Yes – core domain subject to standard regulatory governance procedures, handled by large institutions	One among other factors that could affect access to credit. However, uncertain if access to credit is a problem in the pilot regions (if yes, uncertain whether the problem is regulation)	No	Potential risk due to intra-organizational constraints
Land regulation	Yes – core domain subject to standard regulatory governance procedures, handled by large institutions	Important for businesses who need to set up facilities to start operations, but less relevant once a business is up an running	No	Potential risk due to area being highly technical and lack of strong consensus on what is ‘good’

*Source:* Actionable Regulatory Governance Indicators for EU Regions, the World Bank Group.

Following discussions with DG REGIO, a decision made to focus on the regulatory domains of food safety and environmental regulations related to industrial emissions. These two regulatory domains are politically and economically important, and they are not country specific (they can be studied in each EU Member State). They are also characterized by a high level of EU competence and represent types of regulation and regulatory interactions that affect businesses, particularly SMEs. Finally, anecdotal evidence suggested that there are considerable variations in regulatory quality across regions and countries—including additional regulatory requirements, procedures, and so on—despite a high level of EU harmonization of rules.

### Scope 3: Selecting pilot regions

The final aspect of defining the scope of the pilot study involved the choice of two to three EU regions in which to test the indicators. According to the current nomenclature of territorial units for statistics (NUTS 2013) classification, there are 276 regions at the NUTS 2 level in the European Union.<sup>9</sup> The regions are a mix of administrative and purely statistical entities which, as such, do not necessarily correspond to functional labor markets, functional economic urban areas or political jurisdictions. The World Bank team and DG REGIO agreed that the selected pilot regions should represent a reasonable distribution of new and

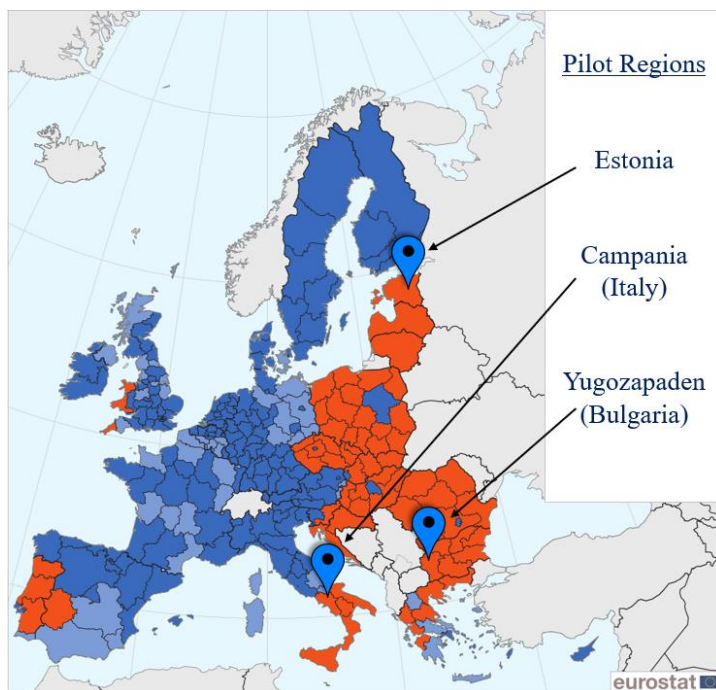
<sup>9</sup> The regions are a mix of administrative and purely statistical entities, which as such do not necessarily correspond to functional labor markets, functional economic urban areas or political jurisdictions. Eligibility for funding differs across various categories of regions. The EU Cohesion Policy places regions into three categories depending on their GDP per capita relative to the EU average: “more developed” (with GDP per capita over 90% of the EU average), “transition” (between 75% and 90%), and “less developed” (less than 75%). For more information, see Eurostat’s [overview](#).



old members, should have varying degrees of regional autonomy,<sup>10</sup> and have relatively high levels of business activity (to be affected by the selected regulatory domains and thereby ensure capture of relevant data). It was also agreed that the selected regions should be economically less developed (with a per capita GDP less than 75% of the EU average), and thus eligible for and among the largest recipients of funding and investment under the Cohesion Policy.

To this end, it was decided to choose from regions representing new Member States (Bulgaria and Romania, for example), the southern European Union (Greece, Italy, Portugal, and Spain), and the Baltics (Estonia, Latvia, and Lithuania). Among these, the Yugozapaden region of Bulgaria, Campania region of Italy and Estonia were selected as the best representative options for the study (Figure 2.3).

**Figure 2.3 Geographical coverage of the pilot project**



Source: EUROSTAT

The key features of the selected pilot regions are included in Table 2. 2. Bulgaria is a relatively new member of the European Union and its Yugozapaden region lags behind in terms of economic development and growth. While this region has a low level of self-rule, it also has a high level of business activity in the selected regulatory domains of food safety and industrial emissions. Italy is characterized by being an “old” EU member and, unlike Yugozapaden, its Campania region exhibits a high degree of self-rule coupled with the highest level of business activity among the less developed regions in the two selected domains. Estonia is a relatively small economy with only one administrative region where most of the legislative power is concentrated at the national level.

<sup>10</sup> The implications of regional and local regulatory governance on the Cohesion Policy vary significantly across countries, depending on the role of their regional and local governments. Decision making and regulatory delivery often take place at the local or municipal level, instead of the regional level.

**Table 2. 2 Key features of the selected pilot regions**

	<b>Yugozapaden, Bulgaria</b>	<b>Campania, Italy</b>	<b>Estonia</b>
<b>“New” or “old” member</b>	New	Old	Relatively new
<b>Level of regional development</b>	Less developed	Less developed	Less developed
<b>Level of regional self-rule</b>	Low	High	None (the country constitutes a region)
<b>Level of business activity (food service and industry)</b>	High	High	High



### III. Questionnaire Design

This section describes the process, methodological considerations and choices related to the design of the survey questionnaire. The challenge was to develop questions that would provide insights into the practical regulatory dimensions and sub-indicators of regulatory governance using the analytical framework summarized in Table 3.1.

**Table 3.1 Regulatory governance data to be captured by the questionnaire**

Dimension	Sub-indicators	Data to be captured by questionnaire
Design	Transparency and access	<ul style="list-style-type: none"> <li>- Existence of online database of existing laws and regulations</li> <li>- Advance public notice on the introduction of new amendments of old regulations</li> <li>- Publication of draft legal texts before adoption</li> <li>- Publication of text before enactment</li> </ul>
	Consultation	<ul style="list-style-type: none"> <li>- Pre-consultation practices</li> <li>- Methodology and practice for consultations on proposed regulations</li> <li>- Requirements and practices for responding to feedback</li> <li>- Use of feedback</li> </ul>
	Impact evaluation	<ul style="list-style-type: none"> <li>- Methodology and practices for impact evaluation</li> </ul>
Delivery	Transparency and communication of standards and practices	<ul style="list-style-type: none"> <li>- Provision of guidance on interpretation and implementation of regulatory requirements</li> <li>- Publication and communication of enforcement decisions and inspection results</li> <li>- Publication and communication of methodologies and approached used for enforcement</li> <li>- Feedback mechanisms (inspection)</li> </ul>
	Risk management and compliance promotion	<ul style="list-style-type: none"> <li>- “Gold-plating” at lower levels of government</li> <li>- Use of risk-based approach</li> <li>- Use of statistical data to determine risks</li> <li>- Range of compliance and enforcement measures available to regulators</li> <li>- Training of enforcement staff</li> </ul>
	Accountability and independence of regulators	<ul style="list-style-type: none"> <li>- Practices of performance reviews</li> <li>- Independence (institutional/staff/budget)</li> </ul>
	Integration of inspection functions	<ul style="list-style-type: none"> <li>- Institutions involved in enforcement</li> <li>- Coordination across inspectors</li> <li>- Integration of information management across inspectors</li> </ul>
Coordination	Coordination across levels of government	<ul style="list-style-type: none"> <li>- Existence of formal coordination mechanisms</li> </ul>
	Oversight and control	<ul style="list-style-type: none"> <li>- Existence of oversight units</li> <li>- Practices of quality controls</li> </ul>
Ex-post review	Practices and requirements	<ul style="list-style-type: none"> <li>- Methodology</li> <li>- Practical application</li> </ul>
	Feedback mechanisms	<ul style="list-style-type: none"> <li>- Feedback mechanisms (existing regulations)</li> </ul>

The questionnaire design was based on the identification of related indicator sets that are complementary to existing datasets.

#### Summary and scope of existing indicators

A considerable portion of the pilot project’s design stage was devoted to a comparative analysis of various existing datasets related to regulatory governance. The primary objective of this exercise was to ensure that the proposed indicators would leverage insights from previous efforts covering similar terrain. A particular focus was placed on the coverage of different stages of regulatory processes by the existing datasets. The significant value-added of this project is the mapping out of the regional regulatory environments, as well as the interactions between distinct regulatory sectors. Capturing these interactions—between the national

and regional tiers of government as well as between different regulatory domains—allows for the creation of indexes such as the Regional or Sectoral Variation Indexes or the Overlap of Regulatory Authority Index.

### *Design*

Several existing databases touch upon the design stage of regulatory processes, yet only at the national level. Stakeholder engagement and regulatory impact assessment, for example, are captured by the World Bank's Global Indicators for Regulatory Governance and the OECD's About Indicators of Regulatory Policy and Governance (iREG) projects. Many additional indicators that focus on measuring the cost of regulation on business (the World Bank's Doing Business project, for example) include some elements of the design dimension, such as days to obtain an operating license, number of procedures for starting a business, license and permit systems and administrative burdens for corporations. These latter examples mostly capture the “outputs” of regulatory processes as opposed to the quality and design of the underlying mechanisms.

### *Coordination*

The closest proxy among current indicators is the Bertelsmann Stiftung's Transformation Index, specifically its indicators for policy coordination and regional coordination. However, none of the datasets focus specifically on regulatory coordination. In particular, they do not provide any information on the availability of formal regulatory coordination mechanisms that help ensure regulatory consistency and avoid duplication or conflict of regulations between national and sub-national governments. Also, existing datasets do not contain information on specific efforts of countries and regions to reduce regulatory overlaps between different levels of government. Furthermore, none of the reviewed indicators measure the existence, quality or effectiveness of regulatory coordination mechanisms at the sub-national level. In general, methods used to avoid overlapping responsibilities are not evaluated in a manner that is systematic and comparable.

### *Delivery*

Many of the World Bank's Doing Business indicators—including starting a business, registering property, dealing with construction permits, paying taxes, trading across borders, enforcing contracts and resolving insolvency—include elements of regulatory delivery. However, these indicators are intertwined with issues strictly pertaining to the specific regulatory instruments in question, such as fee amounts, number of procedures, and tax rates. Measuring regulatory delivery is a relatively new domain in regulatory management, and there is currently no comparative set of indicators that comprehensively covers this dimension of regulatory governance. It is necessary to collect more detailed data to get the “delivery” angle. Specifically, it is important to measure four components: (i) transparency and clarity of delivery mechanisms; (ii) risk management and compliance promotion; (iii) accountability and independence of regulatory enforcement agencies; and (iv) coordination of inspections and oversight.

### *Ex-post review*

The dimension of the ex-post review is covered by the OECD's iREG indicators and the World Economic Forum's Global Competitiveness Report. However, like most of the other data sets referenced above, the indicators are only applied to the national level with limited coverage. Furthermore, the indicators mainly capture government-driven approaches to reviews, as opposed to feedback mechanisms provided to businesses and citizens.

The World Bank team identified a total of 14 datasets covering relevant aspects of regulatory governance (Table 3.2). Each has some relation to, or effect on, regulatory governance, whether measuring the cost of doing business, competitiveness, social elements, or public accountability. For more details on the datasets, please see Annex 4 (pg. 61).

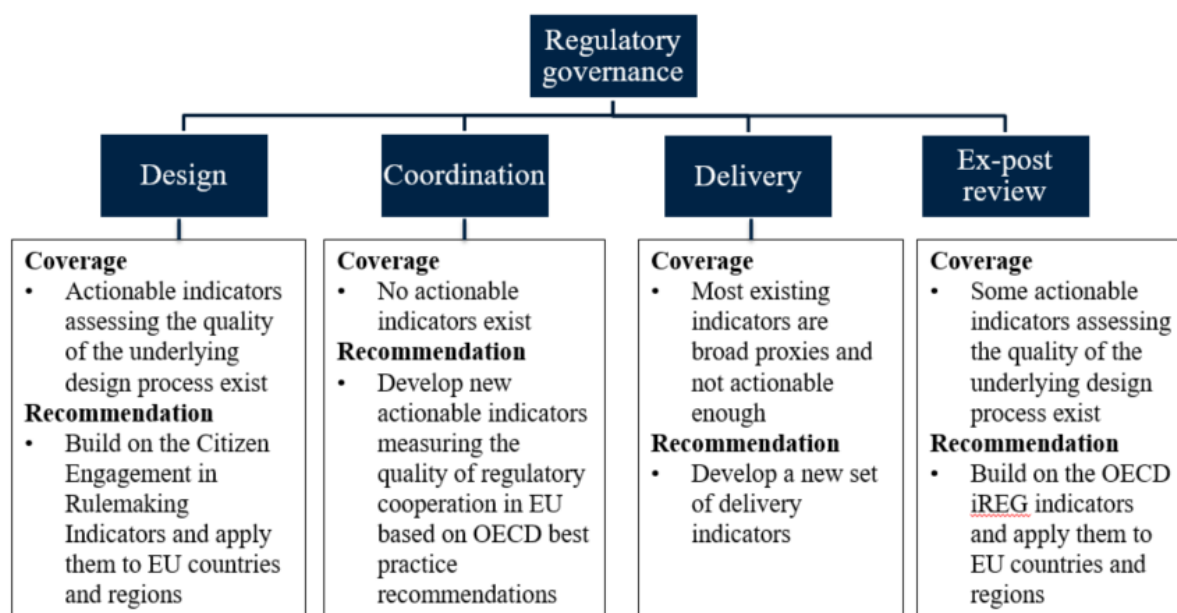
**Table 3.2 Overview of relevant data sources**

Database	Summary
<b>Bertelsmann Stiftung's Transformation Index (BTI)</b>	Analyzes whether and how developing countries and countries in transition are steering social change toward democracy and a market economy in 129 states
<b>Doing Business indicators, the World Bank</b>	Measures regulatory cost of carrying out business activities in 190 economies
<b>Enterprise Surveys, the World Bank</b>	Includes a broad range of business environment topics, such as access to finance, corruption, infrastructure, crime, competition, and performance measures in Eastern Europe and Central Asian economies; known in Europe and Central Asia as Business Environment and Enterprise Performance Survey (BEEPS)
<b>Global Competitiveness Report, the World Economic Forum</b>	Assesses the competitiveness landscape, providing insight into the drivers of productivity and prosperity in 144 economies
<b>Global Indicators of Regulatory Governance, the World Bank</b>	Evaluates experiences of citizens and firms in learning about new business regulations and engaging with the government on their content and how governments assess the possible impact of new regulations, including economic, social, and environmental perspectives in 185 economies
<b>Global Integrity Index, Global Integrity</b>	Measures both design and performance of public accountability frameworks; scorecards take into account both the existing legal measures on the books and de facto realities of practical implementation in 33 economies
<b>Index of Economic Freedom, the Heritage Foundation</b>	Represents an overall indicator of the efficiency of government regulation of business; the quantitative score is derived from an array of measurements of the difficulty of starting, operating, and closing a business in 186 economies
<b>Indicators of Regulatory Policy and Governance, OECD</b>	Covers three principles of the 2012 Recommendation: stakeholder engagement, RIA and ex-post evaluation in 34 OECD member countries and the European Commission
<b>Indicators on Regulatory Management in Network Sectors, OECD</b>	Measures regulatory management practices (governance of the bodies that design, implement, and enforce these regulations) in six network sectors: electricity, gas, telecom, railroad transport infrastructure, airports, and ports in 35 OECD and 22 non-OECD economies
<b>Product Market Regulation Indicators, OECD</b>	Measures the degree to which policies promote or inhibit competition in areas of the product market in 34 OECD and 22 non-OECD economies
<b>Quality of Government Index, EU</b>	Assesses perceptions and experiences with public sector corruption and the extent to which citizens believe various public-sector services are impartially allocated and of good quality in the 28 EU Member States, Serbia and Turkey
<b>Rule of Law, the World Justice Project</b>	Measures how the rule of law is experienced in practical, everyday situations by ordinary people in 102 economies
<b>Worldwide Governance Indicators, the World Bank</b>	Assesses regulatory quality based on perceptions of the ability of the government to formulate and implement sound policies and regulations that permit and promote private sector development in 215 economies

## Creating a new database with primary data for regulatory governance in EU regions

The review of existing datasets revealed that they include many of the dimensions of regulatory governance also identified as relevant for EU regions. However, several noteworthy gaps related to EU regions were identified. First, and most importantly, none of the identified indicator sets covered EU regions (with the exception where an EU region is identical to a nation state, for example Estonia). Second, the existing datasets lacked a regulatory governance “delivery” dimension. Finally, the number of questions (data points) collected under the various existing indicator sets varied significantly and would be either too limited or too expansive to replicate in the context of a pilot conducted in EU regions. Figure 3.1 shows how the proposed indicators identify and measure national and regional regulatory governance practice.

**Figure 3.1 Coverage of the project’s regulatory governance dimensions by existing indicator sets**



*Source:* Actionable Regulatory Governance Indicators for EU Regions, the World Bank Group.

Although existing indicators provided a wealth of information regarding well-tested questions and approaches, further adaption and development were required. The primary challenges were applying existing indicators to EU regions, developing (better) indicators for regulatory delivery, and focusing the questions to a workable, limited number, given the anticipated hurdles to data collection.

### Box 3 Breaking new ground: Creating indicators for regulatory delivery

Regulatory delivery is currently a hot topic in regulatory management discussions. However, there have been only limited attempts to develop and operationalize comparable indicators. There are several good reasons for this. First, the concept itself has not fully reached a level of common understanding among experts and practitioners, having only recently emerged as a way to cover the “implementation” side of regulation. Secondly, the delivery stage of regulation is inherently difficult to capture through standardized, simple indicators, because it presents considerable variations in practice—with far larger numbers of officials and institutions involved compared to the design stage of regulation. Third, the quality of delivery is hard to measure without considering the actual interactions with stakeholders, since this is the stage at which regulation becomes translated into practice. Developing indicators for regulatory delivery is difficult; capturing data for such indicators in a reliable way is even more challenging. Until

recently, only practice-focused data existed, through ad hoc surveys conducted to capture the inspections or licensing burden in various countries (in the European Union, Greece, Italy, Lithuania and the Netherlands conducted such exercises).

The development of indicators for regulatory delivery faced several constraints. First, there was a need to keep the number of questions and data points to a minimum so as not to end up with a survey instrument that would be excessively burdensome and complex. Second, it was challenging to rely on earlier studies or models; that the few that existed had a very different focus (more on practice than on systems). Third, the high level of heterogeneity in practices meant that it was difficult to devise indicators that would prove adequately reliable.

Based on existing literature and discussion among peers and experts, it was decided that the study would focus on the following dimensions of regulatory delivery: (i) transparency and clarity of delivery mechanisms; (ii) management and compliance promotion; (iii) accountability and independence of regulatory enforcement agencies; and (iv) coordination of inspections and oversight.

Based on the above gaps and weaknesses, the World Bank in collaboration with DG REGIO opted to create a new database with primary data collected in one dataset. Wherever possible, the resulting questionnaire drew upon questions and formulations tested through other indicator sets (primarily of the World Bank and the OECD). Annex 9 (pg. 75) includes the full version of the questionnaire.

## IV. Identification of Respondents and Data Collection

### Contributor identification

Due to the diverse regulatory structures and varying degrees of regulatory authority vested in regions, the questionnaire was administered to both regional and national regulatory agencies. Even though the indicators do not focus on regulatory outputs directly affecting the private sector, part of the questionnaire was also administered to private sector organizations. This approach was intended to allow for identification but also perceptions of regulatory overlaps and inconsistencies between levels of government.

Potential respondents were identified from among the relevant government bodies and private sector actors. For the public-sector respondents, relevant bodies included authorities responsible for the design, delivery, coordination, and ex-post review of environmental regulations and food safety regulations (Box 4). For the private sector respondents, relevant actors included business associations and industrial federations (such as food business operators, industries regulated under the Industrial Emissions Directive (IED), chambers of commerce, and so on.)

#### Box 4 Potential public-sector respondents

- Central regulatory oversight/coordination body
- Ministry of Environment
- Ministry of Health
- Ministry of Agriculture
- Departments of regional decentralized administrations for environment, health, and agriculture
- Inspectorates responsible for environmental business licensing under the IED
- Inspectorates responsible for food safety
- Networks/associations of environmental regulators and food safety regulators
- Networks/associations of environmental/food safety rulemaking agencies

A comprehensive database was compiled with potential respondent information including full name, title, email, phone number, physical address and website of the applicable agency. The database, which was created on the basis of desk research, also drew upon information provided by local World Bank offices and existing government contacts of the World Bank's Governance Practice and the Global Indicators of Regulatory Governance (GIRG) project.<sup>11</sup> This allowed the project to gather preliminary information on regulatory structures and to identify some of the relevant agencies from the two regulatory domains.

The finalized contributor database included 112 contacts from the public sector (spanning 40 different ministries and agencies) and 38 contacts from the private sector. The data collection exercise revealed that the consolidated contributor database covered most of the relevant agencies at the national level; few additional national-level contacts were added during the data collection phase. However, at the regional level, limited publicly-available data—as well as insufficient points of contact—resulted in initial contributor lists that were not exhaustive and did not consistently provide the correct entry point, necessitating extensive follow-up and additional research.

A lack of in-depth knowledge of the regulatory systems in the three regions and language barriers also complicated the process of identifying suitable respondents. Local World Bank staff and consultants helped to mitigate these challenges. Identifying specific individuals within the appropriate agencies with insights

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<sup>11</sup> Desk research consisted of exploring all the relevant ministries' websites to identify correct departments and respondents within those departments. However, many calls still needed to be made to agencies to obtain contact details of specific respondents.



(and incentives) to respond to the questionnaire also proved difficult; this was resolved through perseverance—multiple emails and phone calls.

Having a precise list of potential contributors significantly aids the process of data collection. All efforts vested in this task certainly facilitate questionnaire distribution and increase the rate of response. In-depth screening of regulatory agencies is desirable for a smooth data collection process. For future surveys, it would be preferable from the outset to have local regulatory experts mobilized to improve respondent pre-selection.

## Data collection

In preparation for data collection, a joint letter from DG REGIO and the World Bank (Annex 9 (pg. 75)) was sent to relevant agencies to inform them about the survey and stimulate their interest in responding. The questionnaires, the glossary and the distribution emails were translated from English to Bulgarian and Italian. As Estonia is a relatively small economy with a high percentage of English-speakers, the decision was made not to translate Estonia's questionnaires.

Data collection took place in the period from October 19, 2016, to January 1, 2017. During the data collection period, emails were sent to each of the 150 contacts on the distribution list and over 750 follow-up phone calls were placed. Individual follow-up took place on a case-by-case basis, as the team sought timely answers from respondents.

When the Bank team received the completed questionnaires, they were bookmarked by an IT specialist in order to extract and process the data. The IT specialist developed two separate Excel data processing programs—one for food safety regulations and one for environmental regulations—to capture the questionnaire answers from the national, regional and private contributors.

During the three-month data collection period, the Bank team received a total of 20 questionnaires (Table 4.1). Contributors at the national level submitted at least one questionnaire from each sector. In the case of private contributors, questionnaires were received from each sector (except for food safety in Italy). In general, obtaining responses from private sector organizations proved more difficult than from public sector agencies.

**Table 4.1 Number of questionnaires received per country**

	Bulgaria		Estonia	Italy	
	National	Regional	National	National	Regional
Public sector	1 (industrial emissions) 1 (food safety)	1 (IED) 1 (food safety)	1 (industrial emissions) 1 (food safety)	1 (industrial emissions) 2 (food safety)	1 (industrial emissions) 1 (food safety)
Private sector	4 (industrial emissions) 1 (food safety)		2 (industrial emissions) 1 (food safety)	1 (industrial emissions)	
Total	9		5	6	

The relatively small number of questionnaires is not in itself a concern since many agencies and ministries coordinated and consolidated responses before submitting the final answers, thereby significantly

decreasing the number of potential questionnaires but improving quality and reliability.<sup>12</sup> Data collection in the Italian region of Campania was particularly challenging. After requests by email and phone failed to result in the submission of questionnaires, data collection was conducted through on-site visits by World Bank staff and consultants. In-person interviews, though costly and resource consuming, yield better quality data due to the interviewer's ability to ask direct follow-up questions and clarify answers.

There are several areas where future data collection exercises could be improved. First, data collection could have been facilitated by reaching out to local regulatory experts even before sending out the questionnaires. Doing so would allow for the pre-selection of relevant experts and increase the likelihood that they would voluntarily participate in the project. Second, to better identify respondents and coordinate responses, a complementary strategy could involve the distribution of questionnaires via the respective Permanent Representations to the EU of pilot countries.

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<sup>12</sup> The completed questionnaire for food safety in Estonia, for example, was received by the Bank team from the Ministry of Justice in coordination with the Food Safety Department of the Ministry of Rural Affairs and the Veterinary and Food Board. Three weeks later, the same answers were received again from the Ministry of Rural Affairs, illustrating a high level of coordination.



## V. Checking Validity, Comprehension and Relevance of Questions

### Feedback from respondents

The Bank team contacted contributors for feedback at the end of the data collection cycle. For the most part, respondents at the national level found the questionnaire to be user-friendly and easy to follow. Respondents indicated that it took them anywhere from 20 minutes to one full day to provide the required answers. Coordination and collaboration among various regulatory agencies took the most time. Across all levels and sectors, few answers were left blank. One national-level contributor from Estonia indicated that the questionnaire could be challenging to understand for an official not directly familiar with the EU regulatory practices.

The contributors generally agreed that the questionnaires were well designed and accurately captured relevant aspects of regulatory processes in each of the sectors. Although some respondents noted that the questionnaires were too long, most contributors found the questionnaires an easy and effective method of data collection. The glossary proved useful by helping respondents to understand nuanced technical terms not commonly used in their legislation.

The questionnaires gave regulatory agencies and ministries an opportunity to coordinate and consolidate their answers. Two contributors from the private sector noted that in-person follow-up meetings would have aided and complemented the data collection process. Another two contributors also suggested that the process could have been easier had the questionnaire been web-based. One public sector contributor from Estonia mentioned that translation of the questionnaire into Estonian would have been helpful. Feedback from face-to-face interviews in Campania also suggested that a more detailed explanation of the survey and the use of the intended questionnaire would have been useful. Additional tailoring and background information would have to be weighed against the value of a consistent approach across countries and regions.

### Qualitative analysis of the answers

#### *Internal consistency*

A means of gauging the quality of the questionnaire was to explore variations in the details of responses and the comprehension of questions across regions and sectors. Overall, contributors provided sufficient evidence to substantiate their answers, including websites and references to laws and regulations. No particular region stood out, and no major differences were observed in the quality of answers between the two sectors covered. Contributors from both sectors appear to have taken similar care in completing the questionnaires.

Most respondents contributed coherently on individual questionnaires. The Bank team rarely found illogical answers (contradictory answers within one section, for example) suggesting that most experts understood the general logic of the questions. Each section of the questionnaire was completed with similar care across economies, with the notable exception of Italy (where the RIA and ex-post review sections were not filled out through in-person interviews).

## Box 5 Insights from in-person interviews in Campania

After initial attempts to connect with previously-identified contact points in Campania's regional authorities were unsuccessful, the team chose to employ an alternative approach: two Italian-speaking team members were dispatched to Naples to meet in person with the relevant officials in the office of the regional president.

These visits gave the team the opportunity to provide clarifications on some of the survey questions, but also revealed a reluctance on the part of respondents to answer the questionnaire—they were unsure of its source, the degree to which responses would be official, and whether they were authorized to “represent” the region.

Once the purpose of the data collection exercise was fully understood, officials in Campania were forthcoming and shared several insights and good practices with relevance for other regions. In the food safety domain, for example, Campania has put in place a cutting-edge integrated information management system, together with risk-based planning tools (see section 7).

While dispatching a team of experts for face-to-face interviews may not be feasible for an EU-wide survey, it is a useful tool that can be mobilized when there are significant obstacles to data collection or when a review of survey answers suggests potential good practices deserving of further examination.

### *Consistency across contributor categories*

The quality of the questionnaire can also be gauged by exploring variations in the substantive responses. In most cases, private sector contributions confirmed the answers received from the public sector at the national level (see Annex 5 (pg. 64)). While the number of returned questionnaires is lower than expected, this comparison suggests that all the questions were well-understood by the respondents. There were, of course, some exceptions. In the case of Italy only one contribution from a private sector respondent was received (and it was of questionable quality).

Regarding regional versus national level responses, the information provided was mostly similar (see Annex 6(65)). However, some interesting variations were observed, both in terms of which level of government has the regulatory authority for a particular function and the regulatory quality requirements in a particular regulatory domain. In the context of insights from other survey processes, these variations were not seen as reflecting a misunderstanding of the questions, but rather as reflecting discrepancies among agencies regarding awareness of roles and requirements.

### *Consistency with comparable data sets*

The quality of the questionnaire was tested by conducting cross-examinations of regulatory governance scores and rankings in similar datasets. These cross-examinations show that the answers collected at the national level are of satisfactory quality (no other database covers the regional level). The data points shared with the World Bank Global Indicators of Regulatory Governance—including access to laws and regulations, publication of forward regulatory plans, public consultation, and regulatory impact assessment—are all consistent. However, cross-checking the data with the OECD 2015 Indicators of Regulatory Policy and Governance provided mixed results: the results are fully consistent for Estonia, but there were some inconsistent data points found for Italy (the OECD indicators do not cover Bulgaria).

### *Scoring and composite measures*

All core questions and sub-questions received specific scores. Based on the codified data, four main indexes were created for each country: design, coordination, delivery and ex-post review. The regulatory governance composite index was then computed using these indexes. The proposed methodology also allows for the computation of three complementary indexes, namely the overlap of regulatory authority index, the sectoral variation index, and the regional variability index (see Annex 1 (pg. 47) for details on scoring methodology and index computation).

## VI. Survey Results

This section summarizes and compares regulatory governance practices across the three regions surveyed. The results are presented along the four main regulatory governance dimensions as well as through the overall regulatory governance index and the three additional indexes attempting to capture regulatory overlaps, variations between sectors and regional variations within countries.

The primary purpose of this project was to *develop and test* a set of regulatory governance indicators for EU regions, not to present robust and fully actionable findings. The results should be seen as preliminary outcomes of a methodology, which may need further revisions, and will likely have more actionable value when applied to a bigger set of regions. In other words, the results reported below provide examples of the kind of information that can be extracted from the survey tool. The preliminary results reported below portray novel findings and provide interesting insights on the studied regulatory practices and domains.

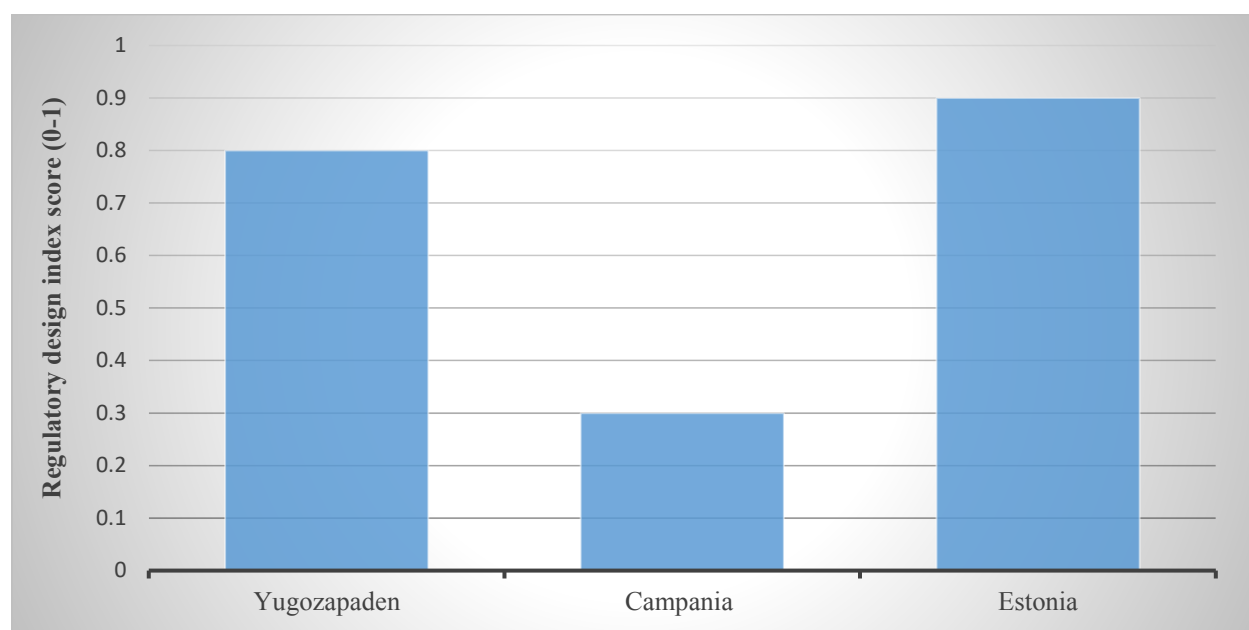
For all dimensions of regulatory governance recorded for this survey, the results reflect the regulatory governance practices exercised *in* the region in question, *regardless* of whether the practice is delivered or exercised *by* the regional or national level of government. In many EU regions, for example, practices for regulatory design (RIA, consultation, and so on) are prescribed by and implemented through nationwide requirements. Conversely, a larger number of practices for regulatory delivery are both prescribed and implemented by regional (or sub-regional) entities.

### Regulatory design

Regulatory design includes practices related to: (i) public availability of laws and regulations; (ii) advance notice of regulations to be issued over the next six months or longer (forward planning); (iii) consultation practices; and (iv) the use of impact assessment for new regulation supplemented with guidelines for implementation of EU regulation (Figure 6.1).

Among the three regions, Estonia has the highest score (0.9) for regulatory design, reflecting observation of good practices in all aspects of regulatory design. Yugoapaden follows with a score of 0.8, reflecting minor gaps in guidelines for implementation of EU regulation. Campania lags with a score of 0.3, reflecting opportunities for further improvements in forward planning, consultation, impact assessment, and guidelines for implementation of EU regulation.

**Figure 6.1 Estonia scores highest on the regulatory design index**



*Source:* Actionable Regulatory Governance Indicators for EU Regions, the World Bank Group.

### Laws and regulations online

All three regions have free-of-charge online databases with all the relevant laws and regulations from the two sampled domains. In Yugozapaden and Estonia, food safety and industrial emissions laws—including EU regulations—are available from national-level websites. The Estonian authorities maintain a publicly-available online [database](#) where all the laws are easily accessible. The contents of the website is available in English, which is helpful to potential foreign investors. In contrast, citizens and businesses in Yugozapaden must consult several different websites to get a full picture of existing regulation. In the food safety domain, the Ministry of Agriculture and Food and the Ministry of Health (together with the Agency for Food Safety) publish their respective regulations on electronic platforms. The Ministry of Environment and Water and the Environment Executive Agency publish regulations on the industrial emissions domain. Several examples of Bulgarian legal databases are [Ciela](#), [Apis](#) and [Lex](#). The Bulgarian Parliament and the Council of Ministers have a unified legislative portal, PRIS.

In Campania, the authorities responsible for the two domains surveyed maintain online databases that include not only regional regulations, but also regulations and guidelines issued at the national level. In Italy, national-level ministries and regulatory authorities maintain a publicly available online database of current laws and regulations. However, the central database only covers regulations issued at the national level. There are separate databases for each region (including Campania). While the main, national-level “official bulletin” website is difficult to navigate, the food safety and industrial emissions domains have specialized websites where all key national-level regulations are publicly available.

### Forward planning

Practices for early notification of forthcoming regulation (over the next six months or longer) vary between the three regions. For Yugozapaden and Estonia, national-level authorities publish a separate plan of regulations to be prepared, modified, reformed or repealed over the following six-month period. For

Yugozapaden, as well as other regions in Bulgaria, there is no separate regional regulatory plan. No forward planning practice is reported for Campania or Italy at the national level.

### *Consultation practices*

All three regions report extensive use of consultation practices. Consistent with variations across other jurisdictions, practices differ according to how consolidated or centralized consultation processes are, whether feedback is published, and whether agencies reply to comments received during the consultation process.

In Yugozapaden, consultation practices are mandated and executed at the national level and channeled through a unified portal, [Strategy](#). The Law of Normative Acts establishes the requirement for consultations on a national level, which applies uniformly to all regions. Article 26.1 stipulates that “each draft legislation should respect the principles of transparency, usefulness, subsidiarity, proportionality etc.” In other words, each agency responsible for draft laws should publish them online, along with the justification for the issuance of the legislation and the relevant impact assessment. The minimum time allowed for proposals and comments during the public consultation phase is 30 days (or 14 days in the case of expedited legislation). As per article 26.5, after the public consultation period has ended the respective agency must publish online the summaries of received proposals and comments. For the industrial emissions domain, these comments are distributed in summary form. While the legislative bodies are legally required to respond to all queries, some survey respondents indicated that they have insufficient information to assess the actual implementation of this requirement.

In Campania, agencies with responsibility for regional food safety and industrial emissions regulation conduct online consultations through their respective websites (there is no consolidated website for regional-level consultations). Regional authorities report that they also conduct targeted consultations with business associations and other stakeholders, as well as public and sectoral roundtable engagements (*tavoli di filieria*), which include experts from both the private and public sectors. Interestingly, while national authorities report that there is no specific regulatory guidance on how to conduct national-level consultations, regional authorities in Campania have issued guidelines for regulatory consultation in the food safety domain. Regional agencies do not (systematically) provide any responses to feedback received during consultations, whereas national-level authorities report that they commonly reply to feedback through one consolidated response, which is published online.

In Estonia, regulatory agencies hold consultations with both the general constituency and targeted stakeholders. However, written guidance on how to conduct public consultations exists only in the food safety domain. Regulatory authorities process all the received input and, in the case of industrial emissions, respond in a consolidated form as well as through personalized answers to each of the comments received. All of the answers are published online and can be accessed by any interested party. In the case of food safety, authorities follow the same procedures, but they do not publish the responses online. There is a certain degree of variation in responses to feedback, depending on the stage of regulatory design, since the ultimate authority to decide on how to respond to feedback lies with the regulatory agency in charge of the regulation in question.

### *Impact assessment*

All three regions conduct regulatory impact assessments (RIAs) of new regulation, although practices seem to vary considerably regarding scope and consistency.

In Yugozapaden, given the limited authority of Bulgarian regions to issue new regulation, requirements for impact assessments are issued at the national level and are executed by national-level authorities. According to the Bulgarian Law on Normative Acts, the impact assessment of legislation should be both preliminary

and ex-post. The preliminary assessment measures the expected outcomes against the set objectives and applies uniformly to all regions unless a particular region is subject to a separate impact assessment process. The studies are published on the [Strategy](#) portal alongside an opinion from the Modernization of Public Administration unit within the Council of Ministers (in accordance with the provisions of the Ordinance on the Structure and Functioning of the Council of Ministers) and the draft legislation itself. In the case of both industrial emissions and food safety, impact assessments study a variety of factors including the economic impact, the impact on the environment, and the impact on the private and public sectors. Impact assessments have been required for industrial emissions regulation only since the enactment of the Industrial Emissions Directive in 2013 (which resulted in Bulgaria's Environment Law). Since 2013, impact assessments are required whenever legislation is amended; they are published online on [Strategy](#) in the same folder as each piece of draft legislation.

In Campania, impact assessments are conducted by national authorities for national regulation and by regional authorities for regulation developed for and applicable to the region only. National-level RIAs assess economic and environmental impacts, impacts on regional development, and potential impacts on the private and public sectors. On the regional level, RIAs assess similar areas but exclude environmental impacts. There is national-level guidance on how to develop RIAs across all regulatory domains. Additional guidance has been developed for RIAs in the industrial emissions regulatory domain. Completed RIAs are not made publicly available; they only serve as internal documents.

In Estonia, draft food safety and industrial emissions regulations are subject to general RIA requirements applicable across sectors. RIAs cover potential economic and environmental impacts, impacts on regional development and impacts on the public and private sectors. Public health impacts are also considered for food safety regulation. Estonia has published RIA guidelines and all impact assessments are made publicly available.

### *Implementation of EU regulation*

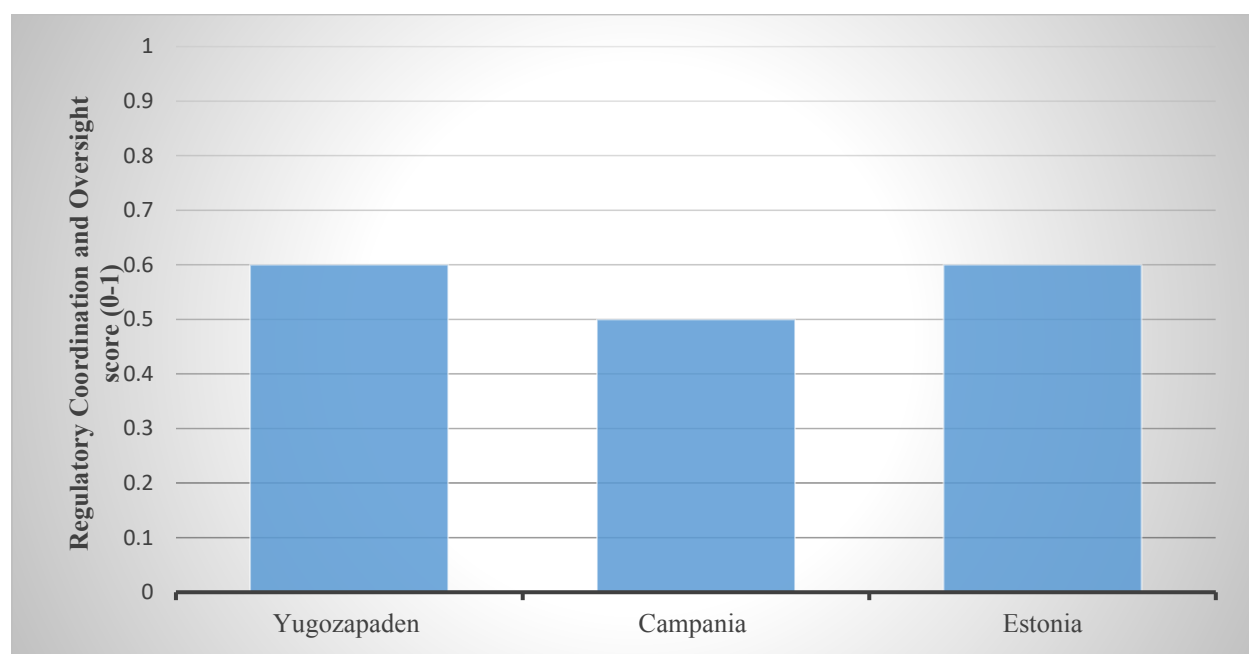
The EU is a unique economic and administrative space owing to the presence of regulations voted upon at the supranational level which then have to be implemented and incorporated at the national and regional levels. Depending on the type of regulation, on the subnational level, these could enter into force either automatically or require action by the national parliament or regulatory authority.

Regarding guidelines for implementation of EU regulation, practices vary considerably between Estonia on the one hand, and Yugozapaden (Bulgaria) and Campania (Italy) on the other. Estonia has national-level guidelines on how ministries and regulatory agencies must implement EU legislation, which includes an obligation to justify any regulatory requirements beyond the EU's minimum standards. In the industrial emissions domain, no such guidelines have been reported. Bulgaria reports to have these guidelines only in the food safety domain; no such guidance is reported to exist in Italy.

### **Regulatory coordination and oversight**

The regulatory coordination and oversight dimension of regulatory governance explores: (i) the existence of formal regulatory coordination mechanisms between the national and sub-national governments; (ii) the existence at the country or regional level of unit(s) responsible for regulatory oversight or quality assurance; and (iii) institutional integration and coordination of inspection functions. On this sub-indicator, Estonia and Bulgaria both score 0.6 while Italy scores slightly lower at 0.5 (Figure 6.2).

**Figure 6.2 Estonia and Bulgaria receive the highest scores on regulatory coordination and oversight**



*Source:* Actionable Regulatory Governance Indicators for EU Regions, the World Bank Group.

### *Coordination*

Both Bulgaria and Italy have mechanisms in place to support regulatory coordination between the national and subnational levels of government in the two surveyed regulatory domains. Because it is *one* region, Estonia is not included in this score.

In Bulgaria, the National Committee for the Coordination of Controls is the coordinating body in the food safety domain. The Committee, which includes representatives from various levels of government, is reported to have a role in ensuring consistency between national and regional regulation, avoiding regulatory overlap, planning, and implementation of inspection and enforcement, information sharing, and dissemination of innovative regulatory practices. Quality assurance and regulatory oversight are national competencies which apply uniformly to all regions. In the industrial emissions domain, a network involving representatives from different levels of government functions as the primary mechanism for the coordination of regulatory consistency.

As a control question for the activity, urgency, and results of coordination efforts, the surveyed officials were asked to list any specific efforts to reduce regulatory overlaps between levels of government in which they had been involved in the previous three years. In Bulgaria, no record of such efforts was provided by either Yugozapaden or the national government.

In Italy, the State-Region Conference, a coordination committee with representatives from different levels of government, is charged with ensuring regulatory consistency and avoiding inefficiencies associated with regulatory overlap. In the food safety domain, this committee oversees and ensures consistency between national and regional regulations and specifies and monitors responsibilities across different levels of government. It also coordinates inspections and enforces planning and implementation. In the industrial emissions domain, the committee disseminates innovative regulatory practices across jurisdictions.



## *Oversight*

Since Bulgaria does not have an agency to ensure regulatory oversight and quality assurance on the national level in the industrial emissions domain, Bulgaria loses points in the coordination and oversight index. In this category, Bulgaria receives a score of 0.5 across the two domains.

Estonia has one administrative region and, as a result, all regulatory processes occur at the national level, without the need for coordination between different levels of government. The Legislative Division of the Ministry of Justice, located in Tallinn, is responsible for regulatory oversight and quality assurance. Its duties include quality control of impact assessments and legal drafts, monitoring of regulatory reforms, and reporting to Parliament. On this index, Estonia receives the maximum score of 1 in both the food safety and industrial emissions domains.

In Italy, which receives the maximum score of 1 on the oversight indicator, there are different provisions for regulatory oversight and quality assurance across the country. National-level regulatory bodies charged with such tasks include the Presidency of the Council of Ministers, the Constitutional Court, the State Council, and Parliament. These bodies focus on the quality control of impact assessments and legal drafts and provide targeted staff training. On the regional level, quality assurance and consistency are monitored by the Legislative Office of the Regional Advocacy.

## *Institutional integration and coordination of inspection functions*

Primarily due to the centralized structure of the regulatory system, in Bulgaria there is no explicit coordination and integration of inspection functions across different agencies. In both regulatory domains, only one central agency is responsible for safety inspections, although there is some coordination with regional directorates. The agency responsible for carrying out inspections in the industrial emissions domain, for example, operates on both the national and regional levels with little coordination across the 16 regional directorates. It is responsible for planning and targeting; methods, practices and enforcement decisions; information sharing and guidance as well as feedback and appeals case management.

In Italy, the organization and coordination of inspection functions mirror the country's federalized constitutional system; they also owe more to long-term legacies than in the other two pilot regions. Still, major consolidation efforts were completed in the environmental sphere (where only one agency is in charge of industrial emissions at each level—with three tiers of institutions: national, regional and provincial) and in food safety (where the 1992 creation of the *Aziende Sanitarie Locali* means that most inspections are done by these institutions, though the consolidation was less complete and national-level structures remain). The interaction between the different levels differs in the two domains, with food safety being primarily a regional competence, and industrial emission being led at the national level (though mostly implemented regionally). Significant efforts have been made to improve coordination between the various agencies active in food safety by the Campania region (for example, through a unified information system; see Annex 2 (pg. 53)). Many other elements of good practice are in place and coordination institutions continue to work on ensuring a sound national-regional dialogue.

Since multiple agencies are involved in the enforcement of regulations at both the national and regional level, a formal structure is in place to coordinate inspections. Cross-regulatory level coordination is mostly based on planning and targeting in the area of food safety, and methods, practices, enforcement decisions, information sharing and guidance in the area of industrial emissions. This coordination is carried out through the Integrated National Plan for Official Controls (*piano nazionale integrato dei controlli ufficiali*) and consultation structures gathering national and regional authorities in each domain.

In Estonia, two agencies—the Veterinary and Food Board and the Consumer Protection Board—are charged with carrying out food safety inspections. However, there is no formal structure to ensure coordination



between these two institutions. Conversely, in the industrial emissions domain, there is only one agency responsible for all inspections. Estonia has a unified database and information system for inspection planning and record keeping.

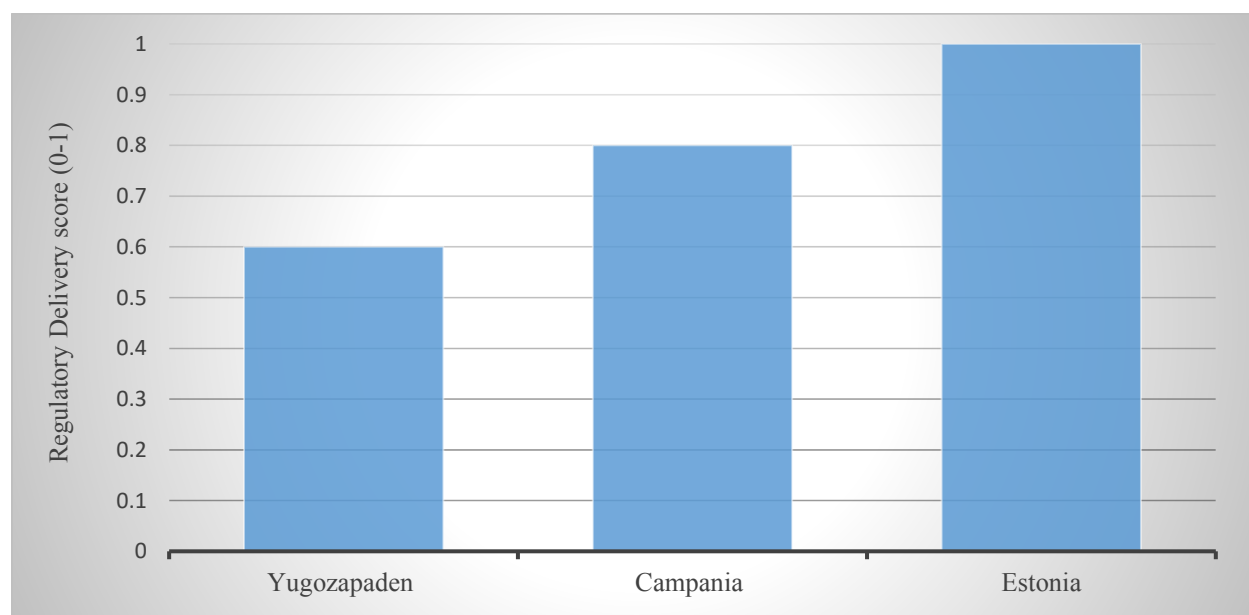
### Regulatory delivery

The regulatory delivery dimension of regulatory governance includes the systems and activities that are intended to translate regulations into practice and to achieve the “real-life” implementation of regulatory norms and objectives. The survey captured regulatory delivery aspects related to planning (and use of risk management), compliance promotion and transparency measures, enforcement decisions, and appeals and performance management.

The results highlight a sharp contrast between the regulatory delivery structures of Bulgaria and Estonia on the one hand, and Italy on the other. Bulgaria and Estonia are relatively new members of the European Union that enjoy a high degree of consolidation of institutions in charge of inspections and enforcement (particularly for food safety); this was, in fact, a pre-requisite to EU accession. Italy, by contrast, is a founding member of the European Economic Community and, as such, was not required to enact similar pre-accession reforms. Italy’s institutional structures had existed for decades, before new approaches to food safety had been developed (nonetheless, in 1992 Italy conducted a significant consolidation of institutions active in public health, including food safety). Italy also introduced federalism through changes to its constitution in 2001, increasing the country’s already-high level of decentralization. As a result, while environmental issues continue to be managed at a national level, food safety is primarily tasked to regional bodies (with national authorities retaining their mandate to define the overarching food safety framework for the entire country). Some differences identified in the survey responses are the result of these varying national contexts.

All three regions have undertaken significant efforts to improve methods, planning, and coordination of regulatory delivery. In Bulgaria and Estonia these reforms formed part of the national EU accession process; in Campania, reforms were the result of both national and regional initiatives. Still, there is ample room for additional improvement in the scores (Figure 6.3).

**Figure 6.3 Estonia scores highest on the regulatory delivery index**



Source: Actionable Regulatory Governance Indicators for EU Regions, the World Bank Group.

Bulgaria's regulatory delivery system for both food safety and industrial emissions consists of national agencies with regional (subordinate) units conducting the bulk of the fieldwork. One ministry, the Ministry of Environment and Water, is in charge of the entire industrial emissions domain. Consolidation in the food safety domain is not complete; the Ministry of Health still conducts some inspections in parallel to the Bulgarian Food Safety Agency. Based on the survey answers, the level of transparency, information, and risk-based planning appear mostly adequate in both regulatory domains.

Italy's regulatory delivery structures mirror its federalized constitutional system. Significant consolidation was achieved in the environmental sphere, where only one agency is in charge of industrial emissions at each level—national, regional, and provincial. Consolidation in the food safety domain took place in 1992 with the creation of local health authorities (*Aziende Sanitarie Locali*, or ASLs). Most inspections are now carried out by ASLs, although some national-level structures remain. The interaction between the various levels differs in the two domains—food safety is mainly treated as the responsibility of the regions while industrial emissions are regulated at the national level (although mostly implemented regionally). Campania has made a significant push to improve coordination between the various food safety agencies active in the region, including the establishment of a unified information system for use by both ASLs and national institutions (see Annex 2 (pg. 53)). Many other elements of good practice are in place, and coordination institutions are working to ensure adequate regional-national dialogue.

In Estonia, the regulatory delivery system for both food safety and industrial emissions is executed by national, unified agencies, each in charge of an entire domain. Based on the survey results, the level of transparency, information, and risk-based planning in both domains are mostly adequate. Importantly, the food safety and environment agencies are guaranteed operational autonomy from political interference, among other features.

### *Planning and use of risk management*

In Yugozapaden (and Bulgaria in general), the Agency for Food Safety and its 28 Regional Directorates, along with the Regional Health Directorates of the Ministry of Health, are the central bodies responsible for food safety inspections. At the national level, the Ministry of Agriculture and Food and the Food Safety Agency publish a multiannual control and inspection plan, which is communicated to the European Commission. This process is specific to the food safety sector and applies uniformly to all regions of the country. In the industrial emissions domain, the chief enforcement bodies in charge of inspections are the Executive Agency of the Ministry of Environment and Water and its 16 Regional Inspectorates. The Inspectorates are responsible for carrying out the inspections on installations located in their respective regions. The national government issues guidelines for enforcement agencies regarding their operational planning, processes, and reports. However, these are not publicly available.

The preparation of inspections in the food safety domain includes the pre-population of checklists on issues to be inspected. However, methodological guidelines for inspections are not available in a unified document. The choice of which businesses to inspect is based on a combination of risk factors associated with the sector, taking into account business category, activity type, company management structure, scale/turnover, past audit results, and notifications in the EU's Rapid Alert System for Food and Feed (RASFF) system. Complaints, past infractions, and accidents are also factored into the decision on whether or not to perform a food safety inspection.

In Campania, inspection plans are developed based on a risk assessment methodology that takes into account information on business operations (intrinsic risk) and past inspection records, as well as prior complaints and incidents (operator risk). Each regulatory domain has a set of specific additional parameters. In the industrial emissions domain, for example, the vulnerability of a potentially impacted ecosystem has to be considered. The Campania region has separate inspection planning practices for the food safety

regulatory domain, while it follows national practices for the industrial emissions domain—in line with the fact that food safety is constitutionally a regional competence, whereas environmental protection is a national one.

While there is no prohibition of re-inspections by different inspectorates, information sharing between agencies attempts to limit inefficiencies and repetitive inspections. Information sharing mostly takes place through the Integrated National Plan and is uploaded to specific websites. For food safety, Campania has introduced an innovative integrated information management system, *Gestione Integrata Servizi e Attività* (GISA), that not only allows inspectors to translate strategic plans into operational plans based on available resources and to plan inspection visits based on all relevant risk parameters, but is also used by all institutions active in the food safety sphere, and thus allows sharing of plans and inspection results.

In Estonia, decisions on which businesses must be inspected are largely based on the number of complaints and incidents. Nevertheless, Estonia also sources inspections from pre-developed plans, which draw from risk assessment analyses identifying sectors that could potentially cause the most damage to consumers. The information used to develop such plans includes business operations data (that is, types of products, methods, and materials), the scale of business operations and prior inspection records. However, this practice does not apply uniformly to all regulatory domains. Depending on what share of inspections is “reactive” (purely based on complaints or incidents) or “proactive” (making use of a combination of criteria such as intrinsic risk, scope of operations and track-record), or on the weight of the two approaches, it would be possible to say with more certainty whether the system is in line with good practice or not. However, the methodology is published for the industrial emissions domain only.

### *Compliance promotion and transparency measures*

In the food safety domain in Yugozapaden, the national Food Safety Agency provides guidance on relevant laws and is responsible for ensuring that businesses and stakeholders receive direction on how to interpret and implement various regulatory requirements. The primary means of communication is through an online inquiry on the agency’s website. The agency’s responses to comments are posted on the website and are publicly available. The lack of examples, illustrations, and explanations of regulatory objectives results in a small deduction of points for Yugozapaden on this index. Questionnaire contributors also noted that the Food Safety Agency provides on-demand interpretations of specific legal texts. The existing system of legal clarifications and guidance falls under generally accepted good practices.

In the industrial emissions domain, regulators and legislators provide guidance to businesses on the completion of applications for integrated permits, compliance with EU requirements and determination of best available techniques (BAT) for environmental performance. Compliance guidelines for the industrial emissions domain are publicly available on the website of the Ministry of Environment and Water and apply uniformly to all regions. The Ministry of Environment and Water provides supplementary guidance on its website through the frequently asked questions (FAQ) section. Replies to specific questions are published and widely accessible, while concrete examples are also provided.

In Campania, national ministries and regulatory agencies provide guidance to businesses on how to implement regulatory requirements for food safety and industrial emissions on the national level. These guidelines include illustrations, real-life examples, FAQs, and a discussion of the underlying objectives of regulations. Regional authorities provide additional guidance on food safety regulations only.

In Estonia, regulatory authorities in the food safety sector provide guidance to businesses on how to interpret and implement different regulatory requirements, including a discussion of the underlying objectives of each regulation, an FAQ section, and—when requested—illustrations on how to apply the laws using tangible examples. Authorities publish a nationwide document outlining methodologies and

approaches used for inspections. This document includes the criteria on how to select businesses for inspection, the methods of inspection and how to enforce post-inspection decisions. In the case of IED, the document also includes explanations on risk assessment.

### *Making inspection and enforcement decisions*

In Yugoapaden, failed inspections in the food safety domain can result in the following actions: (i) notice for improvement with specific delay (when the lapses are minor); or (ii) notice for improvement with specific delay and temporary suspension of some or all activities. Serious non-compliance infractions can result in fines, orders to withdraw specific goods or services from the market, suspension of license to operate, permanent withdrawal of license to operate, and even criminal prosecution. At the regional level, a failed inspection could result in any of the actions above, including oral and written warnings.

For the industrial emissions domain, guidance documents for inspections are prepared on a case by case basis. As in food safety, a standard methodology for industrial emissions inspections is not yet available. Failed inspections in the industrial emissions sector can result in written warnings, notice for improvement, notice for improvement with specific delay (when the lapses are minor) or notice for improvement with specific delay and temporary suspension of some or all activities. More serious findings can result in fines, suspension of license to operate, and even criminal prosecution. All sanctions are imposed with a notification issued by the Minister of Environment and can be challenged in accordance with the provisions of the Law on Administrative Penalties.

For businesses operating in Campania, there is no unified national regulation outlining methodologies and approaches for conducting inspections. However, such regulation exists at the regional level for food safety. It outlines inspection methods applied by regional agencies (but not by national agencies, which also conduct some food safety inspections). When a business violates a specific regulation, enforcement agencies have a variety of measures available at their disposal. They can issue written warnings, notices of improvement with specific delay, a temporary suspension of activities, orders to withdraw particular goods or services from the market, or impose fines. Moreover, authorities can suspend businesses' operating licenses or even permanently withdraw them. As a last resort, authorities can pursue criminal prosecution. Regional agencies follow similar processes.

In Estonia, once a regulatory agency identifies a violation, it has a series of tools at its disposal including warnings (oral and written), notices of improvement (with or without suspension of activities), orders to withdraw specific goods or services from the market (for food safety only), fines, suspensions of licenses, and the permanent withdrawal of operating licenses. In the domain of industrial emissions, criminal prosecution is also possible.

### *Inspection appeals, feedback on inspections, and performance management*

After the inspection reports are issued, businesses have the right to appeal them. For businesses operating in Yugoapaden, several levels of appeals are available, including independent administrative appeals and judicial channels (court reviews, Ombudsman). The right to appeal a decision applies universally to all regulatory domains at the national level and all regions. Currently, inspection results are only used as indicators of necessary adjustments. However, the mechanisms allowing businesses to provide feedback are very limited. The absence of comprehensive online systems resulted in a reduction of points awarded to Yugoapaden on this index.

In the industrial emissions domain, at the national level, the Environment Agency and the Ministry of Environment provide channels through which businesses can submit feedback (letters, online feedback, visits). According to one national contributor, there are typically more than 50 instances of feedback communication annually. In the industrial emissions domain in Bulgaria, performance reviews of the

Agency Directorates are carried out by the internal evaluation unit of the Ministry of Environment. While these reviews are performed on an annual basis, no external evaluation is conducted in this domain, which resulted in point reduction. This practice applies uniformly to the entire country. In the food safety sector, reviews are carried out by internal evaluation units within the Agency for Food Safety, as well as external assessors such as the Ministry of Agriculture or the Court of Auditors. These reviews are implemented on an annual basis and are publicly available.

Regulatory enforcement agencies in Campania are subject to formal performance reviews. On the national level, such reviews are conducted by both internal and independent evaluation units. In the industrial emissions domain, reviews are performed on an annual basis. In the food safety domain, regional authorities also undergo formal performance reviews, which is not the case in the industrial emissions sector. Regional-level performance reviews are conducted by the Regional Body for Internal Audits and by the relevant ministries. Moreover, the Italian government can issue instructions and guidance to regulatory enforcement agencies in regards to their decisions. For both food safety and industrial emissions, those can pertain to long-term strategy objectives as well as decisions to conduct inspections.

In the food safety domain, there are national and regional channels through which businesses can provide feedback on the way inspections are carried out. These include letters and in-person visits to national level regulators. At the regional level, feedback is funneled through an online system with more than 100 interactions documented per year. Notably, at the regional level, food safety sector authorities report on actions taken that have been prompted by stakeholder feedback. In the industrial emissions regulatory domain, there are no such channels for stakeholder feedback.

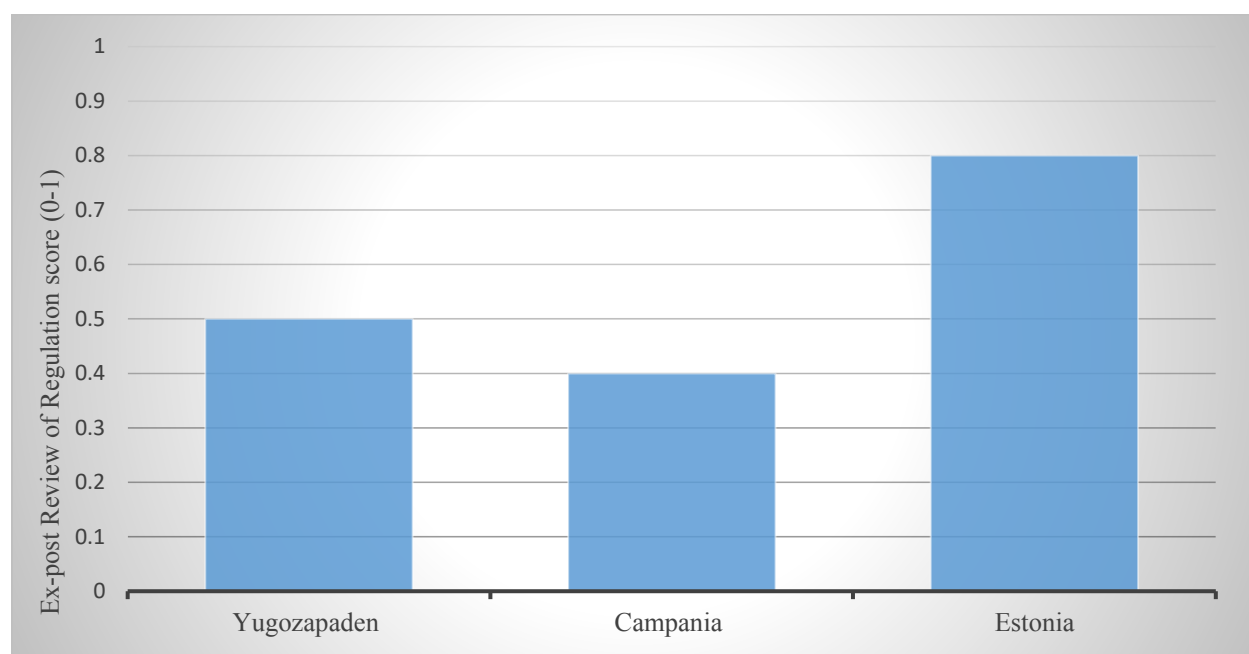
Estonia provides a variety of channels for businesses to submit feedback on the way inspections are conducted. The existing avenues of communication include an online portal, a hotline (for food safety only), analog correspondence, and even an option for in-person visits to the regulators. It is estimated that annually there are more than 100 communications on food safety inspection-related feedback. However, regulators do not report on the outcome of the feedback and on whether or not any concrete actions are taken as a result of this feedback.

Even more tangible than feedback is the ability that companies have to appeal enforcement decisions. In Estonia, available options include independent administrative appeals processes, judicial review, and the Ombudsman (for food safety only). The appeals process takes place exclusively on the national level. Regulatory enforcement agencies are also subject to formal performance reviews by both internal evaluation units and external evaluators (for food safety only). In the food safety domain, the evaluations take place more than once a year, while they occur annually in the industrial emissions domain. Finally, the national government can issue guidance to any regulatory agency on its long-term strategy to appropriately steer its focus.

## Ex-post review of regulation

The ex-post review dimension of regulatory governance looks at practices and periodicity of reviews of existing regulations and how the public can provide feedback on these regulations in the two surveyed domains. Estonia and Yugoapaden score highest, reflecting a more systematic and transparent approach to ex-post reviews and more widespread and systematic use of feedback mechanisms (Figure 6.4).

**Figure 6.4 Estonia performs best on ex-post reviews of regulation**



*Source:* Actionable Regulatory Governance Indicators for EU Regions, the World Bank Group.

#### *Scope and periodicity of ex-post reviews*

Periodic ex-post reviews of existing regulation in the two regulatory domains surveyed take place in all three regions. However, the specific scope, supporting guidance, and transparency measures related to the reviews vary considerably. Responses suggest that sector regulators are not always fully aware of government-wide requirements on when and how frequently reviews must be conducted.

For regulation implemented in Yugoapaden, new mandatory national-level and crosscutting requirements for regular ex-post reviews were issued in 2016. These requirements stipulate that ex-post reviews must be carried out within five years (or less if indicated) after a law comes into force. The measure appears to have codified several existing ex-post review practices. National-level ministries and agencies responsible for food safety and industrial emissions in Bulgaria report that they periodically conduct reviews of existing regulations. The purpose of these ex-post assessments is to compare the objectives set at the adoption stage against the achieved results.<sup>13</sup> Despite the formal requirement to conduct ex-post reviews, there is no written guidance on how to conduct the reviews, and reviews are not systematically made public. Authorities in the Yugoapaden region do not carry out ex-post reviews because they are implemented by national-level authorities responsible for the regulation in question.

National authorities conduct most ex-post reviews for regulation implemented in Campania. These reviews are mandatory and focus on comparing actual versus predicted impacts of regulations, on measuring any unintended consequences, as well as on achievement of the underlying policy objectives. While there are publicly available guidelines on how to conduct ex-post evaluations, the actual ex-post reviews are not made public. These general requirements apply to all regulatory domains, including food-safety and industrial emissions. However, information provided by sector regulators suggest that their awareness of

<sup>13</sup> An example of a relatively recent ex-post review is the review of Chapter VII, section II of the Environmental Protection Act (EPA). It was amended in 2012 to transpose Directive 2010/75/EC on industrial emissions.



government-wide requirements to conduct ex-post reviews may be limited. For example, industrial emissions regulators report that they do not conduct systematic ex-post reviews.

In Estonia, ex-post reviews are conducted for both food safety and industrial emissions regulations. In the area of food safety, decisions to conduct reviews are taken on an ad-hoc basis, in part driven by feedback from the sector. In the case of industrial emissions, reviews are mostly prompted by sunset provisions and can also occur as part of general regulatory overhauls, which are commonly triggered by changes in EU regulation. While specific guidelines are available to regulators and the public on how to provide ex-post reviews, the results of these reviews are not publicized.<sup>14</sup>

### *Regulatory feedback mechanisms*

For businesses and citizens in Yugoapaden, there are few mechanisms through which the public can provide feedback and make recommendations to modify existing regulations. In the food safety domain, stakeholders can provide input only through petitions or the involvement of an Ombudsman. In the industrial emissions domain, feedback can be provided via the online portal of the Ministry of Environment and Water, written correspondence, or petitions through an Ombudsman. These provisions are established at the national level and there are no region-specific feedback provision mechanisms.

In Campania, stakeholders can provide feedback and make recommendations to change existing national and regional regulations for the food safety and industrial emissions domains. Recommendations are received through an online system, the judicial system, and petitions. In the case of the food safety domain, recommendations are processed through the public relations offices (URP) of each institution. On the national level, consumer associations can also interact with institutions through the *Consulta dei Consumatori* (the consumer advocate board). On the local level, the local health authorities (ASLs) collect feedback from the general public.

In Estonia, the public can give feedback on existing food safety and industrial emissions regulations through several channels. They include an online portal, an Ombudsman, the judicial system, petitions, and regular stakeholder meetings held by regulators. While ministries and the regulatory agencies do not conduct public outreach campaigns to inform the public about these available feedback channels, the survey respondents indicated that the channels are established by legislative acts and are widely known. These feedback processes apply to all regulatory domains.

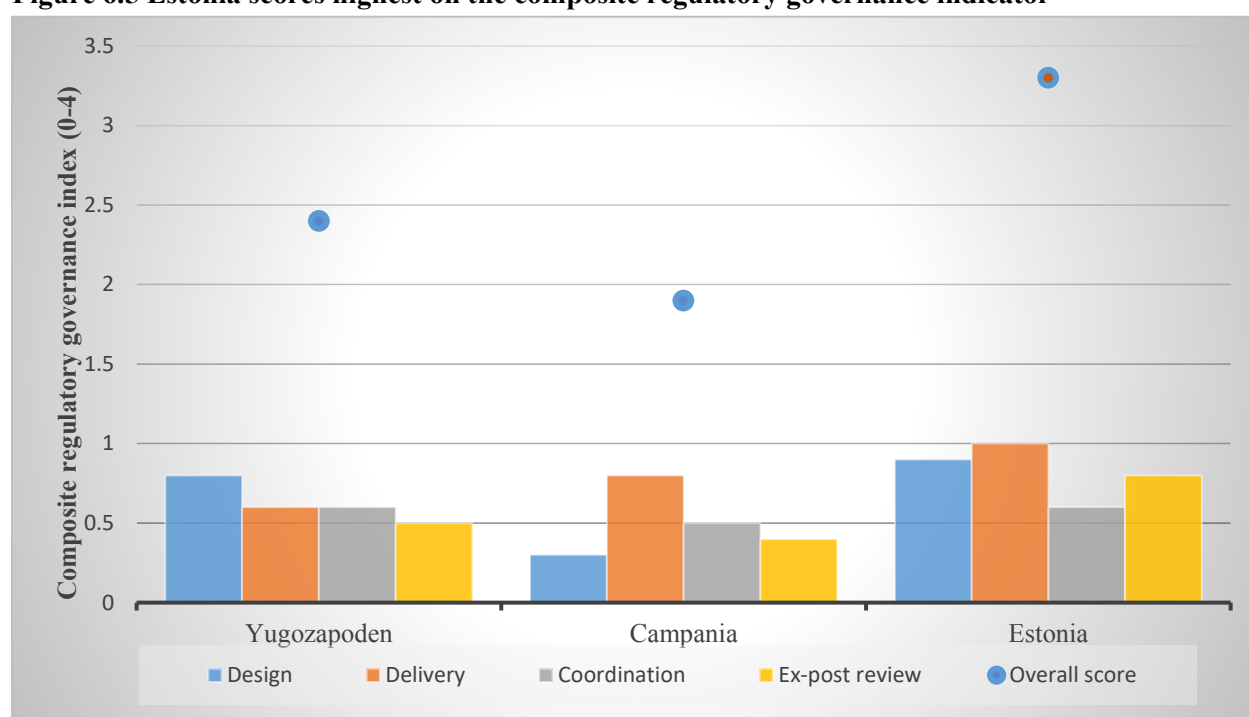
### *Overall regulatory governance*

The idea behind constructing a composite score is that it could serve as an overall indication of a region's regulatory governance practices and it could be comparable to other regions and countries. Based on the previously outlined coding and scoring approaches, out of the three sampled regions, Estonia receives the highest composite score of 3.3 out of maximum possible 4 points, with Yugoapaden scoring 2.4 and Campania scoring 1.9 (Figure 6.5).

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<sup>14</sup> Examples of ex-post reviews include the recent revisions to the Food Act that changed the role of the novelty foods committee. Another example is the 2014 amendment to the Ambient Air Protection Act which reversed or eased some requirements. For example, the requirement for an ambient air permit for filling stations when quantities are up to 2000 m<sup>3</sup> per year was changed to a new limit of 10000 m<sup>3</sup> per year.

**Figure 6.5 Estonia scores highest on the composite regulatory governance indicator**



*Note:* The overall score for regulatory governance is not equal to the sum of the four sub-dimensions, since each of the nominal scores on the sub-dimensions are weighted equally (25%) into the overall score.

*Source:* Actionable Regulatory Governance Indicators for EU Regions, the World Bank Group.

Scoring results on the four main indexes show a meaningful variation across countries. Italy performs worst on the design score, with only 0.3 points out of 1. Bulgaria's weakest score is for coordination and oversight, while Estonia scores lowest on coordination and ex-post review.

Expanding the survey to a broader set of regions would allow the Bank team or DG REGIO to perform a robust regression analysis, examining potential correlations with internal and external social and economic factors that potentially could influence countries' scores.

## Other composite measures

The project constructed several additional composite measures, which could potentially provide insights into regulatory governance variations across regions. The three composite measures explored were: (i) overlap of regulatory authority (how many different levels of government are assigned to conduct the same function?); (ii) sectoral variation (are regulatory governance practices in one domain different from those in other domains?); and (iii) regional variation (are regulatory governance practices in one region of the country different from other regions in the country?). The results from the three pilots are summarized below.

### Overlap of regulatory authority

The proxy index for overlap of regulatory functions was constructed as a simple count of the number of times in which six regulatory functions explored in the survey were reported to be assigned to more than one level of government. The minimum score on this index is 0, reflecting that each of the six regulatory functions is reported to be covered by just one level of government (EU, national, regional or local). The maximum score is 18, reflecting that all of the six regulatory functions investigated are reported to be

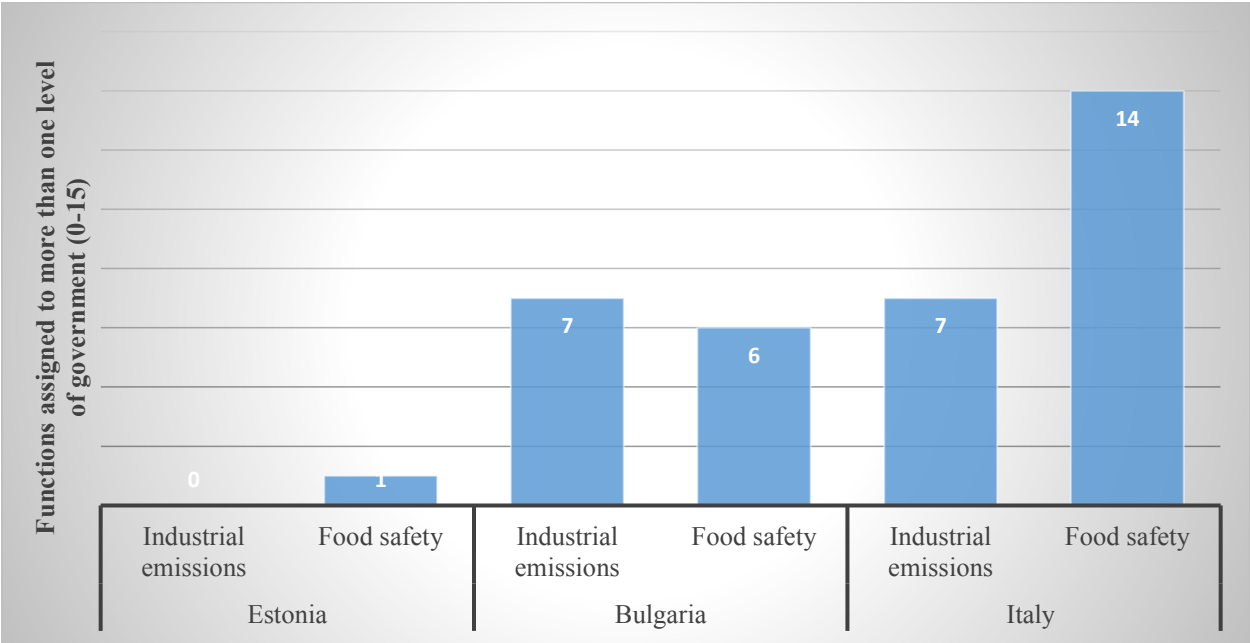


covered by all four levels of government. Earlier sections present the significant caveats and explanations associated with different scores.

Figure 6.6 summarizes the results of the survey regarding regulatory overlap. The order of the three countries makes sense intuitively and may in part reflect the mono-regional and small-economy status of Estonia, the relatively centralized model of Bulgaria, and the significant autonomy delegated to regions in Italy. Italy has a considerably higher number of overlapping jurisdictions for food safety in comparison with Bulgaria and Estonia.

**Figure 6.6 Regulatory overlaps tend to be country *and* sector-specific**

Aggregate count of six regulatory functions assigned to more than one of four levels of government



Source: Actionable Regulatory Governance Indicators for EU Regions, the World Bank Group.

When applied to a larger number of regulatory domains and regions, findings such as these could suggest that countries with a high degree of reported overlaps of regulatory authority should focus on coordination and transparency measures to mitigate inefficiencies related to the regulatory domain in question. In the case of food safety regulation in Italy, for example, information collected from the survey suggest that such coordination initiatives are already underway.

### Sectoral variation

The proxy index for variations in regulatory governance requirements between different domains was constructed as a simple count of the number of times specific regulatory governance practices—such as inspection, coordination, or consultation—were reported to be *specific* for the domain in question (food safety or industrial emissions), as opposed to applicable to all regulatory domains. Also, as mentioned in the methodology section, several caveats and caution must be observed if and when using this index.

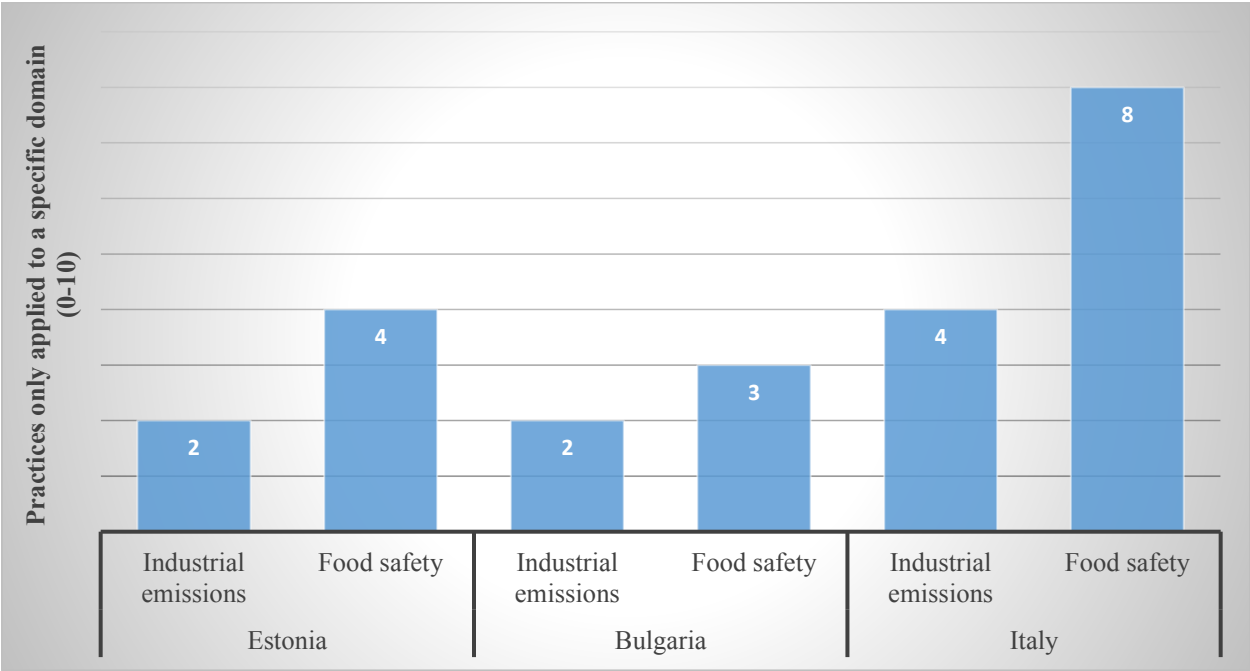
Figure 6.7 summarizes the results of the survey regarding sectoral variation. Italy is characterized by a relatively high level of sectoral variation, Bulgaria at an intermediate level, and Estonia with the lowest sectoral variation. These findings suggest that, regarding homogeneity across regulatory domains, Estonia exhibits a more standardized approach to cross-sector governance, as opposed to Italy and Bulgaria. The

latter two countries tend to apply more differentiated regulatory governance standards across regulatory domains. In the case of Italy, this is largely due to its decentralized nature of regulation.

Unsurprisingly, food safety is reported to have the most “domain-specific” regulatory requirements. A detailed examination of the questionnaire responses suggests that these variations are particularly prevalent in the area of “regulatory delivery” (that is, inspection and enforcement).

**Figure 6.7 Highest sectoral variation is observed in the food safety domain in Campania region**

Aggregate count of regulatory governance practices only applied to a specific domain: food safety or industrial emissions



Source: Actionable Regulatory Governance Indicators for EU Regions, the World Bank Group.

The findings raise two issues. First, the index identifies homogeneity in regulatory governance practices across the different regulatory domains, possibly suggesting a higher degree of regulatory predictability for businesses and lower entry barriers for firms to participate in that domain. Second, the index could point to regulatory domains where regional (or national) authorities have chosen to develop specific regulatory governance requirements, suggesting a relatively high need to ensure good communication and transparency, as well as coordination with other regulatory domains.

### Regional variation

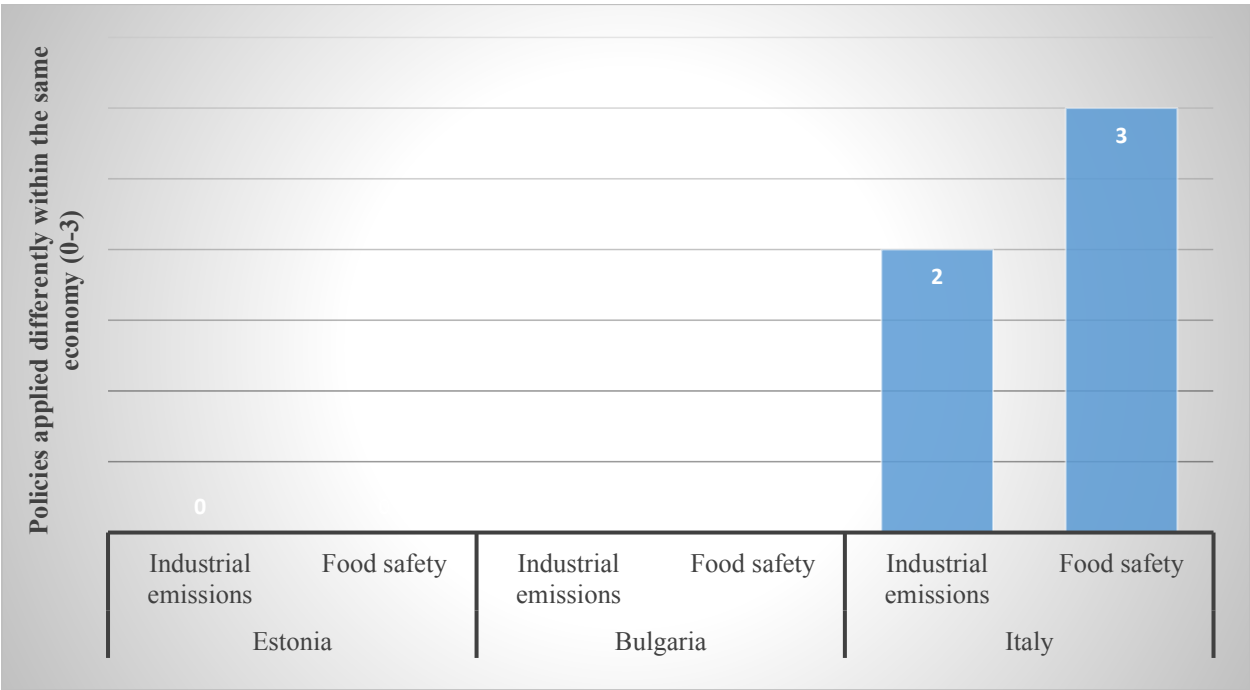
Finally, the project developed a proxy index for variations in regulatory governance practices among regions within a given country. Each national-level questionnaire includes questions on whether a particular practice applies to all regions or whether there is regional variation. The index was constructed as a simple count of the number of times specific regulatory governance practices were reported to be applied differently across regions within the country, as opposed to uniformly to all regions of the country.

Figure 6.8 summarizes results of the survey regarding regional variability. Italy reports most significant regional variability with a total of five regulatory governance practices reported to be applied differently across regions for the two domains. Bulgaria demonstrates a high degree of uniformity in regulatory practices in the two domains; respondents from both food safety and environmental regulations related to

industrial emissions domains reported no variations in any of the surveyed regulatory governance practices across regions in the country. As a single region, Estonia has no reported regional variation.

**Figure 6.8 Italy shows the highest degree of regional variability**

Aggregate count of regulatory governance practices applied differently across regions within the economy



Source: Actionable Regulatory Governance Indicators for EU Regions, the World Bank Group.

As for the other two experimental indexes, several caveats apply to the interpretations of scores on this index. Inherently, a larger, federal country can be expected to have more such variation. To the extent that this constitutes a challenge to economic operators in terms of reduced regulatory predictability and certainty, mitigating measures would include increased transparency and guidance, and coordination mechanisms.

## VII. Conclusions and Next Steps

The pilot surveys conducted in three EU regions suggest that the underlying analytical framework and data collection strategy for the regulatory governance indicators are robust. As importantly, the results from the pilots suggested that EU regions' regulatory governance practices have implications for their capacity to establish an efficient regulatory framework, which can facilitate the leverage and impact of EU Cohesion Funds.

The potential of the expanded and systematic use of regulatory governance indicators is significant. If deployed to a larger set of EU regions, the indicators could:

- i. Provide a baseline for measuring the performance of EU regions and comparisons across regions within a single EU Member State;
- ii. Identify good regional regulatory governance practices that can be replicated or adapted from one region to another; and
- iii. Link allocation of Cohesion Policy funds to regulatory governance reforms, thereby providing strengthened incentives to improve regulatory governance practices.

How can the developed methodology be applied more systematically and to a broader set of EU regions? A gradual expansion of the coverage of the indicators could be organized along the following main parameters:

- i. A first round (2018–2019) could cover 8–10 regions spanning 3–4 countries. This would allow for both inter-regional and in-country benchmarking (and further refinement of the survey tool).
- ii. Subsequent surveys (starting in 2021) could cover 15–20 regions spanning 6–8 countries on a rotating and bi-annual basis.
- iii. Surveys should remain focused on a limited number of sectors—while also covering the observed regions' cross-cutting regulatory governance practices—to provide a more feasible analytical scope, allowing for relatively detailed recommendations and insights.

The Actionable Regulatory Governance Indicators for EU Regions have the potential to stimulate and guide important reforms which can improve the leverage and impact of the EU's Cohesion Funds. To support these reforms, building on insights generated from the associated surveys, the European Commission could consider a number of capacity-building measures. These include:

- i. Technical assistance programs providing support to the design and implementation of specific regulatory governance reforms;
- ii. A compilation of good regulatory governance best practices in EU regions; and
- iii. Regulatory governance learning modules for regulatory authorities in EU regions;

The World Bank would be pleased to cooperate with the European Commission and DG REGIO on the continued rollout and gradual expansion of the Actionable Regulatory Governance Indicators for EU Regions.

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## IX. Annex 1: Scoring Methodology

### Parent questions and sub-questions

The questionnaires were divided into several thematic sections, and each section included a primary question with several sub-categories or options. Most of the sub-questions included multiple options from which respondents had to select the correct responses. Both the primary and sub-questions were assigned weights reflecting good practices as ascertained by the World Bank project team.

An example is provided below. The primary question “Can the government issue instructions or guidance to the regulatory enforcement agency regarding its decisions?” can have a maximum score of 1. Each sub-component of the main question is assigned a specific score. The light blue section in the illustration indicates the scores assigned to these sub-questions. In the illustrated example,  $0.15 \times 5 + 0.25$  equals the total possible score for the primary question of 1. If the answer to the primary question is “no,” then for this question, including all the sub-questions, 0 points are scored. The score assignment was not indicated to respondents to ensure that the scoring system did not influence their answers.

**Figure A1.1 Example of a parent question with non-mutually exclusive sub-questions**

≤ 1	<b>4.3.2. Can the government (national, regional or local) issue instructions or guidance to the regulatory enforcement agency regarding its decisions?</b> – Click to Select -
	4.3.2.1. For which decisions can the government (at any level) issue instructions/guidance?
0.15	<input type="checkbox"/> Long-term strategy
0.15	<input type="checkbox"/> Operational planning
0.15	<input type="checkbox"/> Decisions to conduct inspections
0.15	<input type="checkbox"/> Individual enforcement decisions
0.15	<input type="checkbox"/> Appeals
	<input type="checkbox"/> Other (please specify): [      ]
0.25	4.3.2.2. If the government issues instructions/guidance on individual cases and/or appeals, is there a legal requirement to make these instructions public? – Click to Select -
	Please provide any additional comments: [      ]

Some of the primary questions—the one shown in Figure A1.1, for example—include non-mutually exclusive cumulative sub-questions. In such cases, multiple responses are possible. Most primary questions in the questionnaires, however, require respondents to choose from a set of mutually-exclusive options. As depicted in Figure A1.2, for question 3.2.2.1 the respondent can select only one of the provided options and each of these options has a pre-assigned score. Since there can be only one selected response, the score for sub-section 3.2.2.1 cannot exceed 0.6, as indicated in the outer left light blue column; the scoring for this primary question is  $0.6 + 0.2 + 0.2$  equals 1. Thus, this primary question “Do ministries/regulatory agencies in your country provide responses to the feedback received through consultations?” consists of several sub-sections, with some of the options being mutually exclusive.



**Figure A1.2 Example of a parent question with mutually exclusive sub-questions**

≤ 1	<b>3.2.2. Do ministries/regulatory agencies in your country provide <u>responses to the feedback received through consultations</u>? – Click to Select - (If no, please go to section 3)</b>
≤ 0.6	3.2.2.1. How are the responses provided?
	<input type="checkbox"/> As one consolidated response published online
	<input type="checkbox"/> As one consolidated response distributed to all consultation participants
	<input type="checkbox"/> Separate responses for each comment published online
0.6	<input type="checkbox"/> Separate responses for each comment distributed directly to the author of the comment
	<input type="checkbox"/> Other, please specify: [            ]
0.2	3.2.2.2. Does the above practice for responding to feedback apply to all regulatory domains?
	<input type="checkbox"/> It applies to all regulatory domains
	<input type="checkbox"/> There are separate practices in the area of food safety regulation.
0.2	3.2.2.3. Does the above practice for providing responses apply to all regions in your country, or are there regional variations?
	<input type="checkbox"/> It applies uniformly to all regions of the country
	<input type="checkbox"/> Regions apply different practices
	Please provide any additional comments: [            ]

**Main indicators and weights**

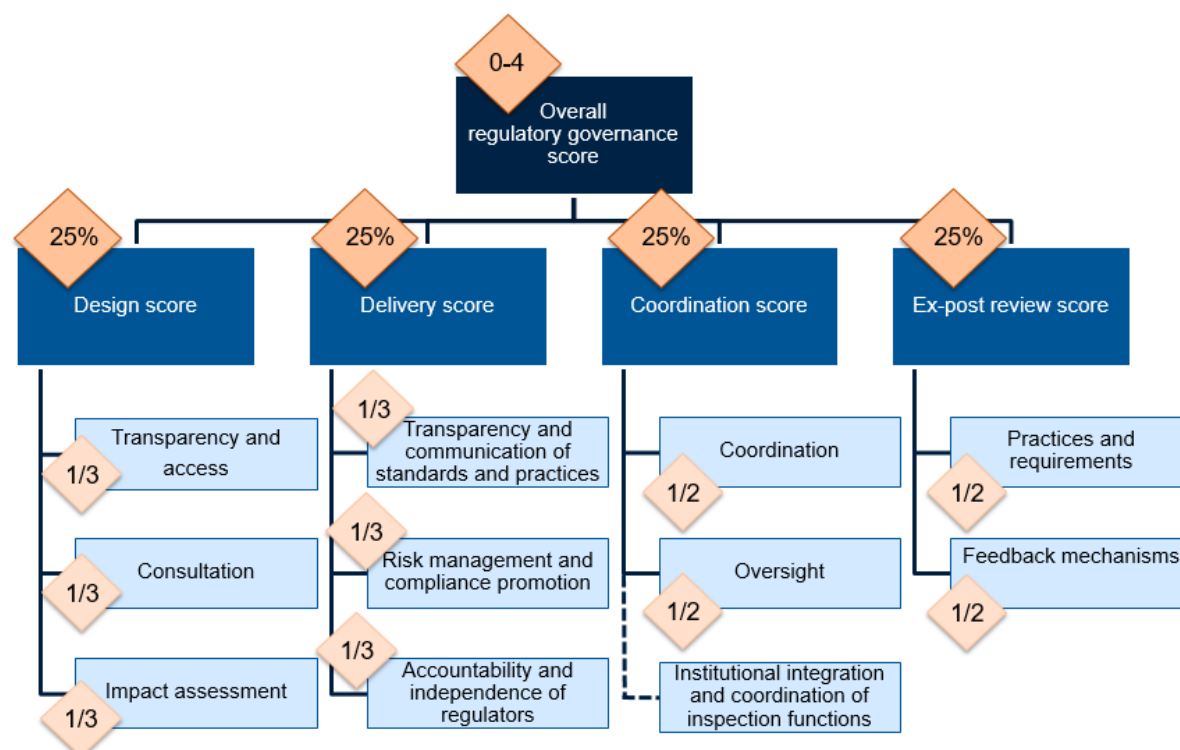
Based on the underlying data, the team calculates the regulatory governance composite index. The composite index has a minimum score of 0 and a maximum score of 4 as it is composed of four main indicators, each equally weighted and having a maximum possible score of 1 (Figure A1.3). Equal weights have been assigned given the similar regulatory importance of all four categories: design, coordination, delivery and ex-post review. Each of the four core indicators has a minimum score of 0 and a maximum score of 1, with an assigned weight of 0.25.

**Figure A1.3 Main indicators and weights**



Subsequently, each of the four core indicators is divided into sub-indicators (Figure A1.4) and each core indicator represents a simple average of its sub-components. A country’s score on the design indicator, for example, is comprised of thee equally-weighted sub-indicators: (i) transparency and access of rulemaking processes; (ii) the level of consultations and stakeholder involvement in the formation of regulations; and (iii) the practice of conducting regulatory impact assessments. To compute the design score, the scores of these three sub-indicators are simply averaged.

**Figure A1.4 Composition of the main indexes**



Similarly, the sub-indicators comprising the delivery indicator are (i) transparency and communication of standards and practices, (ii) risk management and compliance promotion, and (iii) accountability and independence of regulatory enforcement agencies. Each of these sub-indicators also carries an equal weight of one-third. The three sub-indicators comprising the coordination indicator are (i) coordination, (ii) oversight, and (iii) institutional integration and coordination of inspection functions. Lastly, the ex-post review indicator is comprised of another two sub-indicators—(i) practices and requirements and (ii) feedback mechanisms.

It is important to note that only comparable questions from the food safety and environmental regulations questionnaires are used to develop the composite score, encompassing the two regulatory domains. If questions used for calculating the overall score were left blank by respondents, the team conducted additional follow-up in order to have a complete dataset and avoid dropping questions. Furthermore, all the “Other” categories were disregarded for the purposes of scoring because of the high level of variability in responses, which made the data non-comparable.

The team chose to follow relatively simple quantitative methods in assessing regulatory practices as these techniques prove to be fully transparent, replicable, actionable, and easy to understand. These indicators allow for straightforward cross-region comparisons as well as comparisons with global good practices. Finally, this scoring method allows the computation of an objective and comparable overall outcome score that can be broken down into individual sub-indicators and components that are traceable to specific practices. In turn, this technique allows for the portrayal of a clear path to improved regulatory practices across diverse economies and regions.

### Other composite measures

In addition to measures and scores for each of the four pillars of regulatory governance and the overall regulatory governance score, the project experimented with creating additional indexes drawing upon a combination of the collected data points. Considerations of these additional indexes started after the data was collected and were not part of the original set of indicators. However, a closer examination of the regions' scoring profiles and conversations among the project team led to the idea to create three additional indexes. Although the indexes likely have limited explanatory value in the context of the three pilot regions, they may be of more relevance when larger cross-country and inter-regional data are developed.

The three indexes are the overlap of regulatory authority index, the sectoral variation index, and the regional variability index.

### Overlap of regulatory authority index

This index captures perceptions of overlaps of regulatory authority in the regulatory domains covered by the survey. The index is constructed on the basis of the number of overlapping jurisdictions for one particular authority. For example, if both national, regional and local governments are authorized to issue binding guidance to regulated entities, this would be associated with a higher degree of overlap of regulatory authority than if only two or one level of government has this authority. In its simplest form, the index is the sum of the number of levels of government with a given authority. Each ticked box in Figure A1.5 (except those in the European Union column), is assigned a score of 1, yielding the maximum of 18 points (the range of scores is from 0-18). The structure of the index implicitly assumes that overlaps are associated with regulatory inefficiencies. However, given specific country scenarios, it is possible that overlaps are mitigated by coordination and transparency measures. Such cases will be given special attention when coding the data. It is also likely that this index would tend to result in worse scores for federal/highly decentralized countries because some level of overlap in responsibilities is often inherent in their structures. Careful attention should be given to this issue and, if indeed (if the instrument produces a consistent bias), it would be addressed in a successive iteration.

**Figure A1.5 Snapshot of questions used to generate the overlap of regulatory authority index**

2.1. How is authority divided between the different levels of government in your country when issuing, guiding and enforcing food safety regulation? (Select all that apply)	European Union	National Government	Regional Government	Local Government
Authority to issue primary/framework legislation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to issue secondary legislation/bylaws	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to issue technical standards and procedures in addition to what is prescribed in primary and secondary legislation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to issue binding guidance to regulated entities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to issue non-binding guidance to regulated entities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to inspect and enforce regulatory compliance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Sectoral variation index

This index captures variations in regulatory governance requirements and practices among the surveyed regulatory domains. The underlying assumption behind the index is that a high degree of homogeneity in regulatory governance requirements and practices is preferable to different standards across regulatory domains. For example, civil servants, businesses, and citizens that provide services or operate across several regulatory domains may be constrained by different practices for conducting consultations, impact assessments, or coordinating regulatory proposals. The index draws upon reported variations in practices among the surveyed domains (food safety and industrial emissions) and other regulatory domains (Figure A1.6).

**Figure A1.6 Example of questions capturing variations in practices between regulatory domains**

<p>3.2.1.3. Does the above consultation practice apply to all regulatory domains?</p> <p><input type="checkbox"/> It applies to all regulatory domains</p> <p><input type="checkbox"/> There are separate practices in the area of food safety regulation</p>
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The index is constructed as the sum of responses suggesting that practices in a particular dimension of regulatory governance is separate from other regulatory domains. Given the number of data points covering these variations, this variable creates a spread of scores from 0-10.

### Regional variability index

This index measures differences in regulatory governance practices among regions in a given country. The index is constructed as the sum of the times contributors answered that there are different practices for the particular regulatory governance tool in question (Figure A1.7). There is not *a priori* a normative standard for how to interpret high or low variations in regulatory governance practices within a country. High variation may reflect intended and well-administered regional autonomy. However, it may also reflect a

degree of inconsistency and incoherence across regions within a country, which may be reducing regulatory certainty and predictability for citizens and businesses. Scores must be carefully considered in the context of other data observations.

**Figure A1.7 Example of questions capturing variations in practices between regions within a country**

<p>3.2.2.3. Does the above practice for providing responses apply to all regions in your country, or are there regional variations?</p> <p><input type="checkbox"/> It applies uniformly to all regions of the country</p> <p><input type="checkbox"/> Regions apply different practices</p> <p>Please provide any additional comments: [ <input type="text"/> ]</p>
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## X. Annex 2: Regulatory Framework for Food Safety

### Yugozapaden (Bulgaria)

In the regulatory domain of food safety, both the European Union and the national government serve as the primary actors overseeing and implementing the general regulatory framework. Several key EU regulations bind EU Member States and oblige them to implement local provisions. These include ensuring safe and nutritious food and animal feed, high standards of animal health and welfare, and plant protection as well as clear information on the origin, content/labeling, and use of food. The European Union (specifically, the European Parliament and the Council of the European Union) is the main source of primary legislation in the country. The government of Bulgaria is also responsible for primary legislation, but more importantly, it is responsible for secondary laws and for providing guidance on their implementation, including technical guidance, interpretation, and instructions (Figure A2.1).

**Figure A2.1 Food safety regulatory framework in Bulgaria**



The government of Bulgaria, particularly the Ministry of Agriculture and Food and the Ministry of Health, is also tasked with adopting national regulations and ensuring their implementation in accordance with EU regulatory acts, including ordinances and guidance notes. Food safety legislation is issued at the national level and applies uniformly to all regions. A prominent regulatory authority operating under the purview of the Ministry of Agriculture and Food is the Bulgarian Food Safety Agency, which is a unified control body created in 2011 to guarantee food safety and plant and animal protection. The agency operates in active collaboration with the European Food Safety Authority and provides interpretations of EU laws, especially when they are adapted to national food safety legislation (the interpretation of Regulation 854/2004 on food

hygiene, for example). The agency works in coordination with its 28 regional branches across Bulgaria to discuss, negotiate, and adopt standards aimed at increasing the quality and safety of various food types.

Furthermore, these 28 regional branches collaborate with the Regional Health Inspectorates of the Ministry of Health. Ex-post inspections and enforcement processes are implemented on the regional level through the Regional Directorates, as well as the Regional Health Inspectorates. Bulgaria's laws on food safety are drafted by the Ministry of Health and the Ministry of Agriculture and Foods, integrating EU legislation. They comprise laws and ordinances, as well as guidance on enforcement and application.

## Campania (Italy)

Compared to the other two pilot countries (Estonia and Bulgaria), Italy has a relatively complex regulatory environment. To ensure proper issuance, integration and enforcement of regulations, the supranational, national and subnational/regional levels of government interact among themselves through a variety of different communication channels. The EU regulatory bodies, however, hold responsibility for primary and framework legislation, while the Italian government shares the EU prerogative to issue secondary legislation, guidance, and technical standards. The national government also coordinates certain legislation with regional and local authorities.

Italy's food safety sector is overseen by a large number of regulatory institutions and agencies. The primary national actors are the Ministry of Health and the Ministry of Agriculture. The Ministry of Health is mainly tasked with ensuring the safety of goods and products sold and consumed in the country. Some of the well-defined areas of the Ministry of Health's focus include safety of food from farm to fork, community alert systems, border checks, food exports, and food hygiene as well as microbiological and chemical safety. In turn, the Ministry of Agriculture and its agencies are responsible for ensuring the safety of agricultural products through safeguarding and elimination of fraud.

On the national level, the *Nuclei Antisofisticazione e Sanità* (NAS), under the *Carabinieri* military police, is the focal agency that conducts quality controls. Within its multiple tasks are the monitoring and traceability of various food substances along with the execution of unplanned inspections of restaurants and food-producing/processing facilities. NAS operates in close collaboration with the Ministry of Health, judicial authorities, regional health authorities, and municipal health authorities (*Azienda Sanitaria Locale*, ASLs).

The Italian Institute of Health (*Istituto Superiore di Sanità*, ISS) operates under the supervision of the Ministry of Health and conducts scientific research as well as quality controls of foods. It also performs the functions of an advisory body by providing assistance with food controls in the regions. The Veterinary Offices for Community Procedures (UVAC), which also operate under the Ministry of Health, are responsible for inspections and checks of goods originating from outside of the European Union and ensuring their compliance with EU standards and regulations.

On the regional/local level, the ASL is the primary food safety regulatory body; each region has an independent ASL (or similar) agency.<sup>15</sup> These agencies fall under the jurisdiction of the regional health authorities and execute controls and inspections of a variety of food-related producers. The regional health authorities, under the purview of the Ministry of Health, are local bodies that are responsible for risk management and inspection planning. NAS on the national level and ASL on the regional level form the

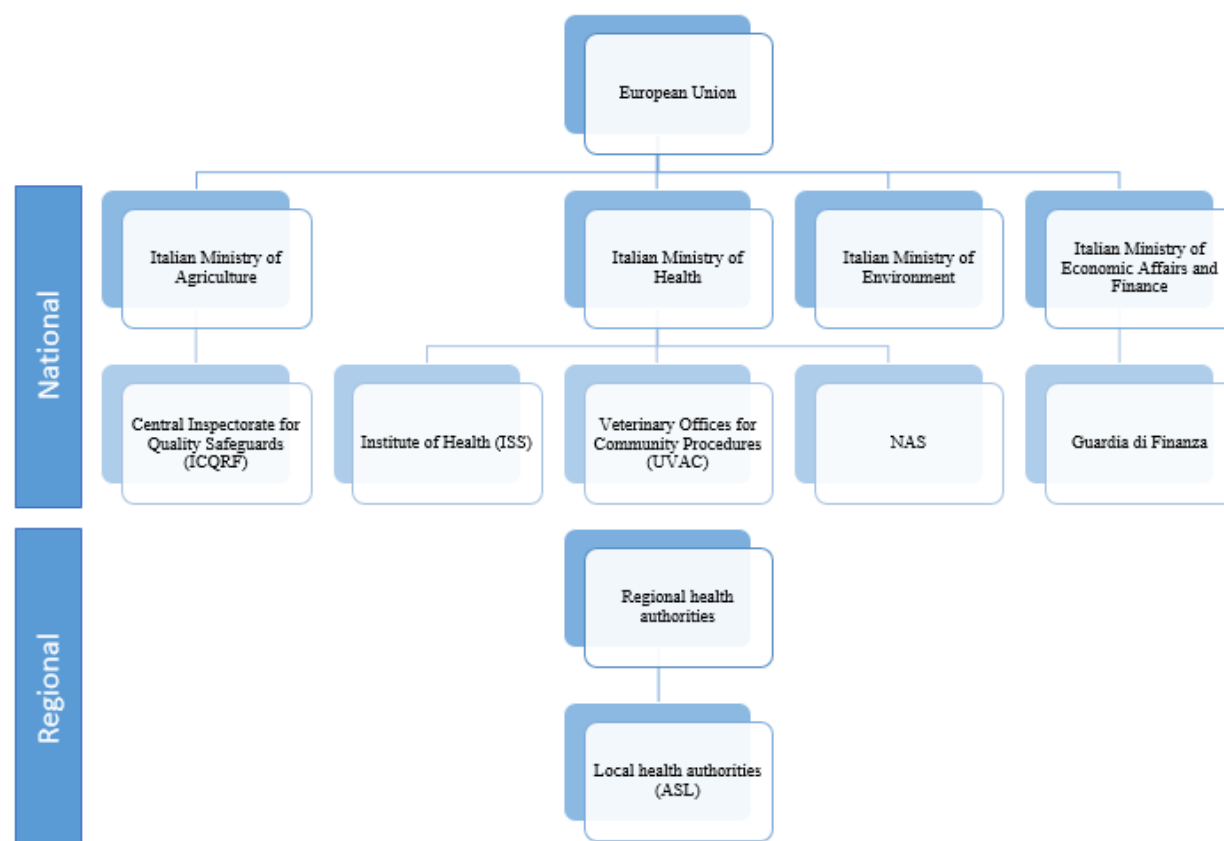
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<sup>15</sup> In Abruzzo, Campania, Lazio, Liguria, Piedmont and Puglia they are referred to as ASL. For the rest of the regions the names are as follows: Valle d'Aosta: AUSL VDA; Lombardy: AT; Trentino: APSS; South Tyrol: ASDAA; Veneto: AULSS; Friuli-Venezia Giulia: ASS; Emilia-Romagna, Tuscany and Umbria: AUSL; Marche: ASUR; Molise: ASREM; Basilicata, Calabria and Sicily: ASPs; and Sardinia: ATS.



backbone of food safety enforcement and inspection mechanisms. There is a considerable degree of overlap between NAS and ASL responsibilities (Figure A2.2).

**Figure A2.2 Governance structure of Italy’s food safety sector**



While the Ministry of Health is the main regulatory body responsible for food safety controls, the Ministry of Agriculture, Food and Forestry Policies also has a specialized inspection body—the *Dipartimento dell'Ispettorato centrale della tutela della qualità e repressione frodi dei prodotti agroalimentari* or ICQRF (the central inspectorate for the safeguarding of quality and the repressing of fraud in agricultural and foodstuff products). ICQRF is an agribusiness control agency which is divided into ten “territorial offices” and 19 “area offices.” Some of the responsibilities of ICQRF overlap with those of ISS and UVAC.

The Ministry of Environment ensures compliance with environmental standards. NAS along with the Guardia di Finanza (Finance Police) of the Ministry of Economic Affairs and Finance conduct fraud control operations. Fraud prevention and control is practiced across all levels of the Italian government with the Ministry of Finance and the *Carabinieri* military police being the two main agencies responsible for these controls.

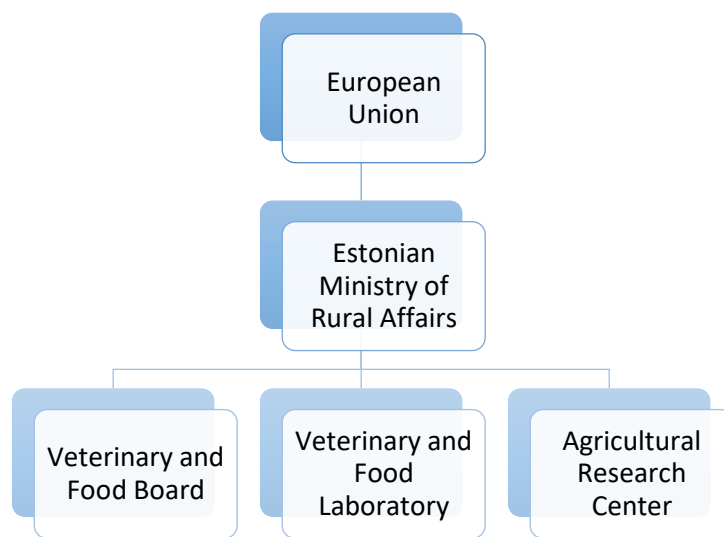
## Estonia

Because Estonia is a relatively small economy with only one administrative region, most of the legislative power is concentrated at the national level. There are no subnational or regional levels of regulatory governance in the food safety domain. Nevertheless, as an EU Member State, Estonia is still bound by supranational EU regulatory authorities.

While the European Union, along with the national government, is responsible for the issuance of primary/framework legislation, all secondary legislation and bylaws have to be adopted and promulgated at the national level. Furthermore, technical standards and procedures, as well as guidance to regulated entities (binding and non-binding), are delegated to the national governments. The power to inspect and enforce regulatory compliance lies with the national authorities.

Regarding Estonia's food safety regulatory framework, the Ministry of Rural Affairs serves as the first national point of contact. It has the authority to integrate EU regulations into the national legal framework as well as to develop national-level legislation to ensure compliance with pre-determined standards, including food hygiene, proper labeling of products, and prevention of food contamination. The Ministry of Rural Affairs also has the authority to monitor and regulate food contact materials, novel foods, and genetically modified organisms. It is responsible for the proper implementation of the international food standards program, Codex Alimentarius, and for coordination with the European Food Safety Authority (EFSA) (Figure A2.3).

**Figure A2.3 Food safety regulatory hierarchy in Estonia**



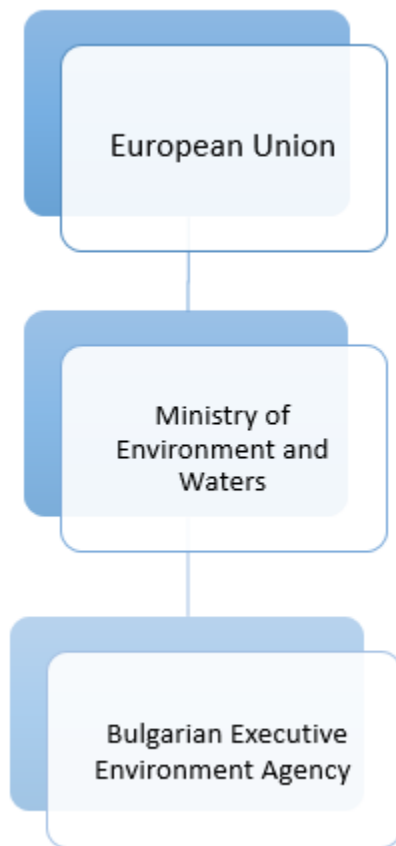
The Veterinary and Food Board is another key regulatory actor that oversees food safety standards in Estonia. It is charged with organizing and monitoring food processing chains, while the Veterinary and Food Laboratory and the Agricultural Research Center are responsible for conducting studies on food safety and quality control and for analyzing their effects on the market. The latter two agencies are the main enforcement bodies in the area of food safety. More specifically, the [Veterinary and Food Laboratory \(VFL\)](#) specializes in the diagnosis of diseases found in “cattle, pigs, sheep, poultry, horse, fish and honeybees as well as the analyses of alcohol and contaminants (heavy metals),” and it carries out the functions of the official control laboratory in compliance with the [Food Act](#). The responsibility to ensure safety of foods contact materials falls with the Central Laboratory of the Health Board.

## XI. Annex 3: Regulatory Framework for Environmental Regulations for Industrial Emission

### Yugozapaden (Bulgaria)

The government of Bulgaria, specifically the Ministry of Environment, is in charge of adopting legislation that incorporates and implements the EU framework into national laws. The government also adopts secondary legislation—ordinances, guidance notes and binding and non-binding guidance to the regulated entities. Emissions from industrial installations have therefore been subject to EU-wide legislation. Bulgaria has made significant improvements in its environmental performance since its EU accession in 2007. While Bulgarian legislation accurately reflects the environmental requirements established at the EU level, implementation remains a challenge. The Ministry of Environment and Water and the Ministry of Energy play a central role in the legislative process. The Executive Environment Agency (ExEA) is an administration within the Ministry of Environment and Water that carries out management, coordination and information functions regarding environmental protection. The ExEA is the national coordination link to the European Environmental Agency and a member of the European Network of the Heads of Environment Protection Agencies (EPA Network), a platform for sharing knowledge and experience. The EPA Network also oversees the functioning of the National System for Environmental Monitoring. The Executive Environment Agency is a National Reference Centre within the European Environment Agency (EEA) (Figure A3.1).

**Figure A3.1 Industrial emissions regulatory framework in Bulgaria**



## Campania (Italy)

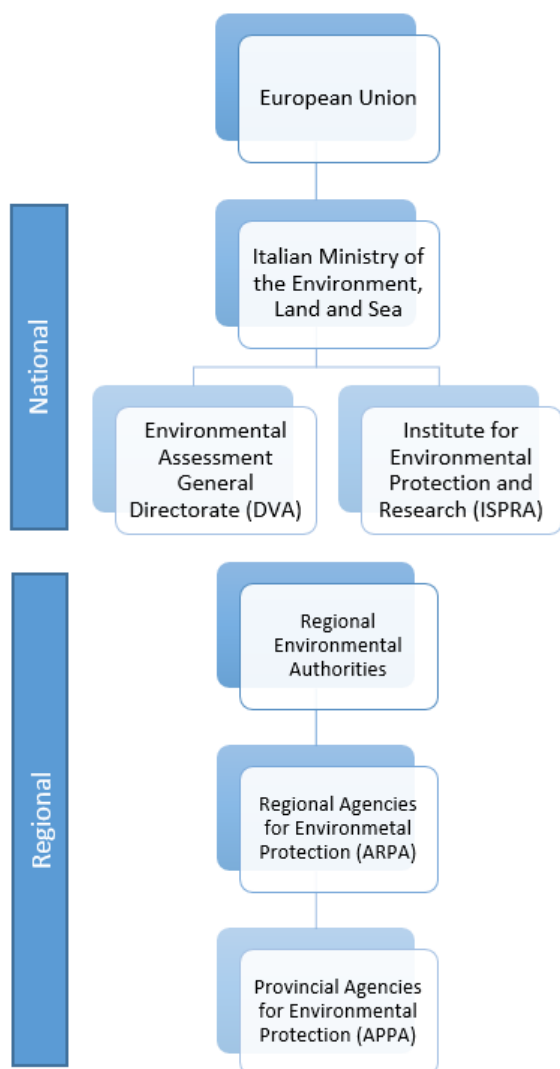
In the regulatory domain of environmental regulations for industrial emissions, the main oversight regulatory agency is the Ministry of the Environment, Land and Sea. On the national level, there are two main regulatory bodies that operate under the Ministry of the Environment: (i) the Environmental Assessment General Directorate (DVA) of the Ministry of the Environment and (ii) the Institute for Environmental Protection and Research (ISPRA).

The DVA has four divisions: (i) budget, internal controls and support; (ii) environmental assessment systems; (iii) relevant risks and integrated environmental authorizations; and (iv) risk assessment and reduction from chemicals and genetically modified organisms. The third division coordinates with the ISPRA to issue national Integrated Environmental Authorizations (AIA) for industrial facilities and to manage such permits. It also collaborates with ISPRA on risk assessment. Conversely, ISPRA is the main control and inspection unit for industrial emissions on the national level. Among other things, it specializes in controls related to AIA permits (Figure A3.2).

On the regional level, the Regional Environmental Authority oversees all the relevant industrial emissions regulations, coordinates and plans inspections and issues licenses (including regional AIA permissions) for industrial facilities with a risk level below the national threshold. In the case of Italy, the regional Environmental Authority in conjunction with DVA are the main decision-making bodies regarding local industrial emissions regulations. These agencies are endowed with equal powers and collaborate through coordination boards (*tavolo di coordinamento*).

Furthermore, Regional Agencies for Environmental Protection (ARPA) operate under the regional environmental authorities and are primarily responsible for controls and inspections, as well as monitoring of AIA permits. Most inspections are performed at the request of the regional environmental authorities. Also, under the purview of regional ARPAs are Provincial Agencies for Environmental Protection (APPA, technically ARPA provincial offices). These offices perform inspections and controls and monitor AIA permits. ARPA and APPA on the regional level, along with ISPRA on the national level, are the main regulatory bodies in charge of conducting and monitoring industrial emissions inspections. These are now part of the recently instituted National System for the Protection of the Environment (as per Law of June 28, 2016).

**Figure A3.2 Governance structure of Italy's industrial emissions regulatory framework**



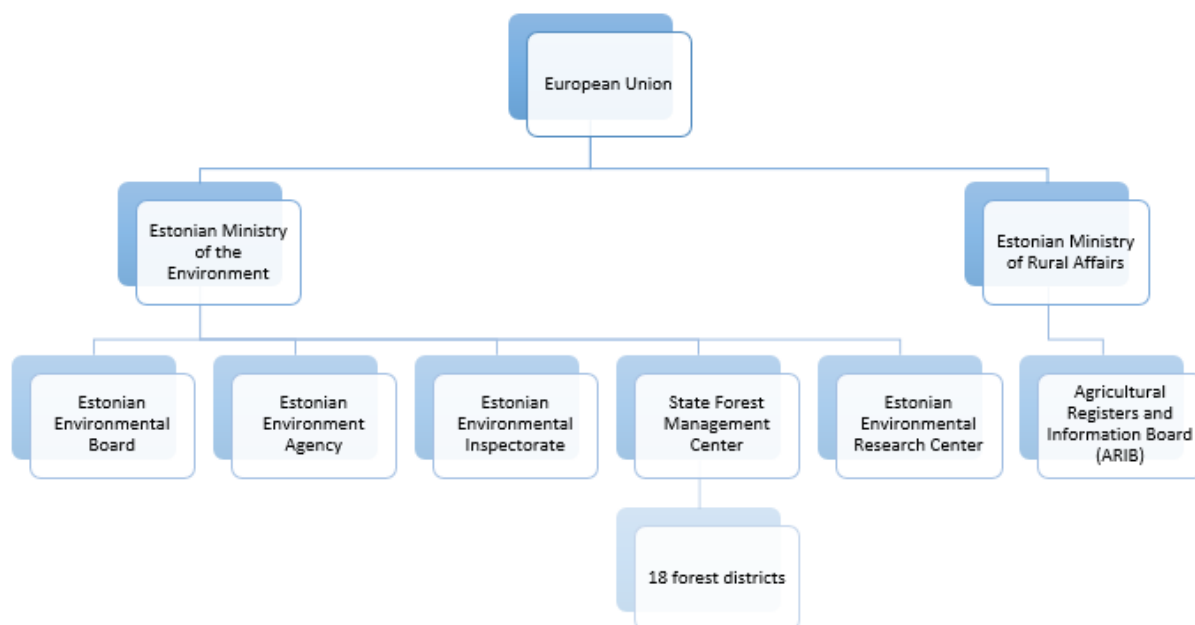
## Estonia

In the area of environmental regulation of industrial emissions, there are no subnational or regional levels of regulatory governance. The Ministry of the Environment plays the main regulatory role in this field. It possesses the authority to integrate EU regulations into the national legal framework as well as to develop national-level legislation to ensure compliance with pre-determined standards. The Ministry of the Environment works on a variety of issues, including climate, mineral resources, and air/marine environment protection.

The Estonian Environmental Board is the Ministry of the Environment's primary agency overseeing environmental issues. It is tasked with implementing policies and with contributing to the development of legal acts related to the environment. Furthermore, it provides guidance on environmental issues, issues permits and licenses, conducts environmental impact assessment studies, and monitors the use of natural resources. The Estonian Environment Information Center (EEIC), the liaison of the European Environment Agency (EEA) in Estonia, falls under the Ministry of the Environment and it [“collects, processes, analyses and distributes information about nature in Estonia, the state of the environment and the factors that impact](#)

them.” The Estonian Environmental Inspectorate is an administrative unit under the Ministry of the Environment, which supervises all areas of environmental protection. It coordinates and executes supervisory activities that pertain to the usage of natural resources (Figure A3.3).

**Figure A3.3 Industrial emissions regulatory hierarchy in Estonia**



The Estonian State Forest Management Center is the agency responsible for the country’s forestry, which covers about half of Estonia’s territory. There are 18 forest districts in Estonia. The Estonian Agricultural Registers and Information Board (ARIB) falls under the Ministry of Rural Affairs and was established to implement the Special Assistance Program for Agricultural and Rural Development (SAPARD) in Estonia, which is responsible for agricultural aid. The Estonian Environmental Research Centre (EKUK) offers chemical and physical lab analysis and geotechnical investigations. Amongst other things, it functions as a reference laboratory on surface water, groundwater, sea, waste water, and sewage sludge.

## XII. Annex 4: Overview of Existing Regulatory Governance Databases and Indicators

Source	Methodology	Coverage	Subnational coverage	Content	Examples of RG related indicators
<b>Business Environment and Enterprise Performance Survey</b>	Firm-level survey of a representative sample of an economy's private sector	Eastern Europe and Central Asian economies	No	A broad range of business environment topics including access to finance, corruption, infrastructure, crime, competition, and performance measures.	<ul style="list-style-type: none"> <li>Days to obtain an operating license</li> <li>How problematic are labor regulations for the growth of your business?</li> </ul>
<b>The Bertelsmann Stiftung's Transformation Index</b>	Country expert assessments	129 economies	No	Analyzes whether and how developing countries and countries in transition are steering social change toward democracy and a market economy.	<ul style="list-style-type: none"> <li>Anti-monopoly policy</li> <li>Banking system</li> <li>Regional coordination</li> <li>Policy coordination</li> </ul>
<b>Citizen Engagement in Rulemaking</b>	Surveys	185 economies	No	The experience of citizens and firms in learning about new business regulations and engaging with the government on their content and how governments assess the possible impact of new regulations—including economic, social, and environmental perspectives.	<ul style="list-style-type: none"> <li>Publication of proposed text</li> <li>Conduct consultation</li> <li>Conduct impact assessment</li> <li>Specialized body for impact assessment</li> </ul>
<b>Transparency International Corruption Perception Index</b>	A composite index based on a combination of surveys and assessments of corruption levels.	175 economies	No	Aggregates data from a number of different sources that provide the perceptions of business people and country experts of the level of corruption in the public sector.	<ul style="list-style-type: none"> <li>Perceived level of corruption in the public sector</li> </ul>
<b>World Bank Doing Business Indicators</b>	Varies across sector (expert surveys/objective assessments of frameworks)	190 economies	Yes (for a few selected countries and cities)	Regulatory cost of carrying out business activities	<ul style="list-style-type: none"> <li>Starting a business</li> <li>Paying taxes</li> <li>Enforcing contracts</li> <li>Labor market regulation</li> </ul>
<b>The European Quality of Government Index</b>	Combination of national level assessment (WGI) and of perceptions and experiences (surveys)	EU 28 Member States plus Serbia and Turkey	Yes (at the NUTS 1 or NUTS 2 level, depending on the country)	Perceptions and experiences with public sector corruption, and the extent to which citizens believe various public sector services are impartially allocated and of good quality.	<ul style="list-style-type: none"> <li>Equal treatment of all citizens by the police force</li> <li>Citizen use of bribery to obtain public services</li> </ul>



Source	Methodology	Coverage	Subnational coverage	Content	Examples of RG related indicators
<b>Global Integrity Index</b>	Expert assessments	~33 countries assessed each year	No	The indicators measure both design and performance of public accountability frameworks. Scorecards take into account both existing legal measures on the books and de facto realities of practical implementation in each country.	<ul style="list-style-type: none"> <li>In practice, are tax laws enforced uniformly and without discrimination?</li> <li>In practice, citizens can obtain any necessary business license within a reasonable time period.</li> <li>In law, basic business regulatory requirements for meeting public safety standards are transparent and publicly available</li> </ul>
<b>Heritage Foundation Index of Economic Freedom</b>	Composite index relying on data from other indices and official government publications of each economy	186 economies	No	Overall indicator of the efficiency of government regulation of business. The quantitative score is derived from an array of measurements of the difficulty of starting, operating, and closing a business.	<ul style="list-style-type: none"> <li>Business freedom</li> </ul>
<b>OECD Indicators of Regulatory Policy and Governance</b>	Regulatory Indicators survey, responses provided by delegates to the OECD Regulatory Policy Committee (RPC) and central government officials	All 34 OECD member countries and the European Commission	No	Covers three principles of the 2012 Recommendation: stakeholder engagement, regulatory impact assessment (RIA) and ex post evaluation.	<ul style="list-style-type: none"> <li>Regulatory impact analysis for developing regulations</li> <li>Stakeholder engagement in developing laws and regulations</li> <li>Ex-post evaluation for development of primary laws</li> </ul>
<b>OECD Product Market Regulation Indicators</b>	Survey data complemented by data from publicly available sources	34 OECD and 22 non-OECD economies	No	Indicators that measure the degree to which policies promote or inhibit competition in areas of the product market where competition is viable.	<ul style="list-style-type: none"> <li>State control</li> <li>Barriers to entrepreneurship</li> <li>Barriers to trade and investment</li> </ul>
<b>OECD Indicators on Regulatory Management in Network Sectors</b>	Surveys	35 OECD and 22 non-OECD economies	No	Measure regulatory management practices (governance of the bodies that design, implement and enforce these regulations) in six network sectors: electricity, gas, telecom, railroad transport infrastructure, airports and ports.	<ul style="list-style-type: none"> <li>Governance of regulatory bodies</li> </ul>

Source	Methodology	Coverage	Subnational Coverage	Content	Examples of RG related indicators
<b>World Economic Forum Global Competitiveness Report</b>	Combination of objective data and survey of business executives	144 economies	No	Assesses the competitiveness landscape, providing insight into the drivers of productivity and prosperity.	<ul style="list-style-type: none"> <li>• Efficiency of legal framework in challenging regulations</li> <li>• Favoritism in decisions of government officials</li> <li>• Burden of government regulation</li> </ul>
<b>World Bank Worldwide Governance Indicators</b>	Composite index based on over 30 individual data sources	215 economies	No	Regulatory quality captures perceptions of the ability of the government to formulate and implement sound policies and regulations that permit and promote private sector development.	<ul style="list-style-type: none"> <li>• Regulatory quality</li> </ul>
<b>World Justice Project</b>	Relies on over 100,000 household and 2,400 expert surveys	102 economies	No	Measures how the rule of law is experienced in practical, everyday situations by ordinary people around the world.	<ul style="list-style-type: none"> <li>• Government regulations are effectively enforced</li> <li>• Government regulations are applied and enforced without improper influence</li> <li>• Administrative proceedings are conducted without unreasonable delay</li> </ul>

### XIII. Annex 5: Public and Private Sector Answers to Key Questions

Discrepancies

Missing or contradictory data

Key questions	Bulgaria FS		Bulgaria IED		Estonia FS		Estonia IED		Italy FS		Italy IED	
	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private
3.1.1. publicly available online database of current laws and regulations	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	n/a	Yes	n/a
3.1.2. plan of regulations	Yes	Yes	No	No	No	Yes	Yes	No	No	n/a	No	n/a
3.2.1. consult with the general public and/or targeted stakeholders on proposed regulation	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	n/a	Yes	n/a
3.2.2. provide responses to the feedback received through consultations?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	n/a	n/a	No	n/a
3.3.1. conduct impact assessments of proposed regulations	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	n/a	Yes	n/a
4.1.1. guidance to industries/businesses on how to interpret and implement	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	n/a	Yes	Yes
4.1.2 (FS) system for rating food businesses based on the outcomes of inspection visits	No	No	n/a	n/a	No	No	n/a	n/a	Yes	n/a	n/a	n/a
4.1.2/3 publish a document explaining the methodologies and approaches used for inspections	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	n/a	No	No
4.1.3/4 provide channels through which industries can submit feedback on the way inspections take place	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	n/a	No	No
4.1.4/5 provide any mechanisms to industries through which they can appeal enforcement decisions	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	n/a	Yes	n/a
4.4.1. more than one regulatory enforcement agency responsible for inspections	No	Yes	No	No	Yes	No	No	No	Yes	n/a	Yes	Yes
6.1.1. ministries/regulatory agencies conduct reviews of existing regulations	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	n/a	No	No
6.1.2. major reviews of existing regulations in the past 5 years	n/a	No	Yes	Yes	Yes	n/a	No	No	Yes	n/a	No	n/a
6.2.1. mechanisms through which the public can make recommendations to modify or provide feedback on existing regulations	n/a	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	n/a	Yes	Yes

## XIV. Annex 6: National and Regional Level Answers to Key Questions

*Missing or contradictory data*

Key questions public sector national/regional								
Key questions	Bulgaria FS		Bulgaria IED		Italy FS		Italy IED	
	National	Regional	National	Regional	National	Regional	National	Regional
2.2. responsibilities established in a law	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3.1.1. publicly available online database of current laws and regulations	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
3.1.2. plan of regulations	Yes	No	No	Yes	No	No	No	No
3.2.1. consult with the general public and/or targeted stakeholders on proposed regulation	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
3.2.2. provide responses to the feedback received through consultations?	Yes	No	Yes	Yes	n/a	No	No	No
3.3.1. conduct impact assessments of proposed regulations	Yes	No	Yes	No	Yes	Yes	Yes	Yes
3.3.2. regional or national guidelines for how ministries and regulatory agencies implement EU legislation	Yes	Yes	No	No	Yes	Yes	No	No
4.1.1. guidance to industries/businesses on how to interpret and implement	Yes	No	Yes	No	Yes	Yes	Yes	No
4.1.2 FS system for rating food businesses based on the outcomes of inspection visits	No	No	n/a	n/a	Yes	Yes	n/a	n/a
4.1.2/3 publish a document explaining the methodologies and approaches used for inspections	Yes	No	Yes	No	Yes/No	Yes	No	No
4.1.3/4 provide channels through which industries can submit feedback on the way inspections take place	No	No	Yes	n/a	Yes	Yes	No	No
4.1.4/5 provide any mechanisms to industries through which they can appeal enforcement decisions	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
4.2.4. agencies subject to formal performance reviews	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
4.3.2. government can issue instructions or guidance to the regulatory enforcement agency regarding its decisions	Yes	Yes	n/a	Yes	Yes	Yes	Yes	Yes
4.4.1. more than one regulatory enforcement agency responsible for inspections	No	No	No	No	Yes	Yes	Yes	Yes
4.4.2. formal structure or agency with the responsibility of coordinating inspections	n/a	n/a	Yes	Yes	Yes	No	Yes	n/a
5.1.1. formal regulatory co-ordination mechanisms between the national and sub-national	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes

5.2.1. unit responsible for regulatory oversight or quality assurance across the country	n/a	Yes	Yes	No	Yes	Yes	No	n/a
6.1.1. ministries/regulatory agencies conduct reviews of existing regulations	Yes	Yes	Yes	No	Yes	Yes	No	Yes
6.1.2. major reviews of existing regulations in the past 5 years	n/a	Yes	Yes	No	Yes	n/a	No	n/a
6.2.1. mechanisms through which the public can make recommendations to modify or provide feedback on existing regulations	n/a	No	Yes	No	Yes	Yes	Yes	Yes

## XV. Annex 7: List of Identified Contributors from the Public Sector (after Data Collection)

### Generic contact

Ministry or Agency	Administration	Department	Primary Contact
<b>Bulgaria</b>			
Sustainable Energy Development Agency	IED (national)	Secretary General	Nikola Tsankov
Agriculture and Foods Committee at the National Assembly	IED (national)	Regional Directorate	Sashko Kamenov, Administrator
		Chair	Roumen Dimitrov Hristov
Energy and Water Regulatory Commission	IED (national)	Inquiries on price regulation and licenses	Administrator
Ministry of Energy	IED (national)	Secretary General	Tatyana Sekulova
		Energy Strategies and Policies for Sustainable Energy Development	Nikolay Nalbantov
		Corporative Management in Energy	Lilyana Dragieva
		Inspectorate	Todor Batsanov
Environmental Executive Agency	IED (national)	Executive Director	Vanya Grigorova
Ministry of Environment and Water	IED (national)	International Cooperation Department	Ms. Emiliya Kraeva, head of department
	IED (national & regional)	Preventive Activities Directorate	Parvoleta Luleva, head of department
Department of Agriculture – Blagoevgrad Regional Office	IED (regional)	Blagoevgrad	Vania Petsanova
Department of Agriculture – Kyustendil Regional Office	IED (regional)	Kyustendil	Administrator
Department of Agriculture – Pernik Regional Office	IED (regional)	Pernik	Administrator
Department of Agriculture – Sofia City Regional Office	IED (regional)	Sofia City	Administrator
Department of Agriculture – Sofia Region Regional Office	IED (regional)	Sofia Region	Administrator
Regional Inspectorate of Environment and Water - Blagoevgrad	IED (regional)	Blagoevgrad	Administrator

Regional Inspectorate of Environment and Water - Pernik	IED (regional)	Pernik	Administrator
Regional Inspectorate of Environment and Water - Sofia	IED (regional)	Sofia	Administrator
Regional Inspectorate of Environment Protection and Water	IED (regional)	Pernik-Control of the environment	Administrator
Bulgarian Focal Centre at the European Food Safety Authority	Food Safety (national)	Management	Dr Tencho Tenev, MPHSc
Bulgarian Food Safety Agency	Food Safety (national)	CEO	Dr. Damyan Iliev
Ministry of Agriculture and Food	Food Safety (national)	Public Relations and Protocol Directorate	Evelina Stoyanova, director
Ministry of Health	Food Safety (national)	Management team	Petăr Moskov, minister
District Directorates of Food Safety	Food Safety (regional)	Blagoevgrad	Administrator
Regional Directorate for Food Safety Blagoevgrad	Food Safety (regional)	Blagoevgrad	Administrator
Regional Directorate for Food Safety Kyustendil	Food Safety (regional)	Kyustendil	Administrator
Regional Directorate for Food Safety Pernik	Food Safety (regional)	Pernik	Administrator
Regional Directorate for Food Safety Sofia City	Food Safety (regional)	Sofia City	Administrator
Regional Directorate for Food Safety Sofia Region	Food Safety (regional)	Sofia Region	Administrator
Regional Health Inspectorate Blagoevgrad	Food Safety (regional)	Blagoevgrad	Administrator
Regional Health Inspectorate Kyustendil	Food Safety (regional)	Kyustendil	Administrator
Regional Health Inspectorate Pernik	Food Safety (regional)	Pernik	Antoaneta Grigorva, administrator
Regional Health Inspectorate Sofia / Pernik	Food Safety (regional)	Sofia	Dancho Penchev, administrator, RZI SOFIA GRAD
National Association of Municipalities in the Republic of Bulgaria	Food Safety & IED (regional)	n/a	Administrator



Basin Directorate "West region"	Food Safety & IED (regional)	West region	Administrator
<b>Estonia</b>			
Ministry of the Environment	IED	Environmental Management Department	Kaupo Heinma, Head of Department
		Climate and Radiation Department	Evelyn Mürsepp
		Fisheries Department	Kaire Märtin
		Forest Department	Riina Martverk
		Water Department	Karin Kroon
		Waste Department	Peeter Eek
		Ambient Air Department	Heidi Koger
		Nature Conservation Department	Taimo Aasma
The Environmental Board	IED	Head Office	n/a
	IED	Harju-Järva-Rapla Region	Harju County
		Hiiu-Lääne-Saare Region	Hiiu County
		Jõgeva-Tartu Region	Jõgeva County
		Põlva-Valga-Võru Region	Põlva County
		Pärnu-Viljandi Region	Pärnu County
		Viru Region	Ida-Viru County
		Radiation Safety Department	General Management
Environmental Inspectorate	IED	Nature conservation department Environmental protection department Fisheries protection department	General Management
Estonian State Forest Management Center	IED	Nature Protection Department	Kristjan Tõnisson, Head of Department
Estonian Agricultural Registers and Information Board	IED	General Management	Jaan Kallas, Director General
		Direct Payments and Rural Development Dept.	Andrus Rahnu, Head of Department
The Estonian Environment Agency	IED	Environmental analysis department	Anne Aan, Leading Specialist
		Management	Taimar Ala, Director General
		General Department	Kersti Kuk, Lawyer
		General Department	Peep Jürmann, Head of Department
		Generic	n/a
The Veterinary and Food Board	Food Safety	General Management	General Management

		Food Department	Heneli Lamp, Head of Department
Veterinary and Food Laboratory	Food Safety	General Management	General Management
		Director	Olev Peetsu
Ministry of Rural Affairs	Food Safety	General Management	Urmas Kruuse, Minister
		Food Safety Department	Martin Minjajev, Head of Department
The Agricultural Research Centre	Food Safety	Administration	Kalle Talviste, Director
Estonian Environmental Research Centre	Food Safety & IED	Tallinn	n/a
		Tartu	n/a
		Virumaa	n/a
		Pärnu	n/a
Health Board	Food Safety & IED	Legal Adviser	Anastasia Levin
		Legal Adviser	Tõnu Kaur
Ministry of Justice	Food Safety & IED	Deputy Secretary General	Kai Härmand
		Legislative Quality Division	Karmen Vilms, Director
Ministry of Finance	Food Safety & IED	Deputy Secretary General for Financial Policy and External Relations	Märten Ross
<b>Italy</b>			
Ministry of the Environment and Land and Sea Protection	IED (national)	General Management	Nicoletta Trotta
		Public Relation Office	n/a
		Legislative office	Cecchetti Marcello
		Directorate-General for assessments and environmental permits (DVA)	Renato Grimaldi
		Directorate-General for waste and pollution (RIN)	Grillo Mariano
		General Directorate for the Protection of Nature and the sea (PNM)	Giarratano Maria Carmela
		Climate and environmental certification	Tombolini Cristina
		Directorate-General for Sustainable Development, for environmental damage and for relations with the European Union and international bodies (SVI)	Francesco La Camera
Superior Institute for Environmental Protection and Research – ISPRA	IED (national)	General Management	n/a
	IED (regional)	General Management	Dott. Pietro Vasaturo

Regional Environmental Protection Agency in Campania – ARPAC		Legal Office	n/a
		Provincial Department of Avellino	Dott. Antonio De Sio
		Provincial Department of Benevento	dottoressa Barricella
		Provincial Department of Caserta	dott. Serafino Barbati
		Provincial Department of Naples	dott. Nicola Adamo
		Provincial Department of Salerno	dott. Antonio De Sio
Ministry of Health	Food Safety (national)	General Secretariat	n/a
		Directorate-General for hygiene, food safety and nutrition	General
			Francesca Di Giacomo (Office 1 - General Affairs)
			Pietro Noè (Office 2 - Food hygiene and export)
			Elvira Cecere (Office 7 - Safety and regulation of plant protection products)
			Alessandra di Sandro (Office 8 - Alert system, food emergencies and controls scheduling)
		Directorate-General for Communication and European and international relations	Maria Grazia Pompa (Office 5 - Relations with the European Union, the Council of Europe, OECD, WHO, and other UN agencies and international organizations)
Ministry of Agricultural, Food and Forestry Policies	Food Safety (national)	Minister	Maurizio Martina
	Food Safety (national)	Ufficio Legislativo	Antonini Ilaria
	Food Safety (regional)	ICQRF Italia meridionale	Raimondo Antonio
Campania Region	Food Safety & IED (regional)	General Management	Sergio Negro
	Food Safety (regional)	General Directorate for Health Protection and Coordination of the Regional Health System	Antonio Postiglione
	IED (regional)	General Directorate of Environment and Ecosystem	Michele Palmieri, Manager
			Dott. Antimo Maiello
			Adelaide Pollinaro, Technical and operational support functions to the Directorate General
			Raimondo Santacroce
			Dott. Gianfranco Di Caprio

	Food Safety & IED (regional)	General Directorate for Economic Development and Production Activities	Roberta Esposito
Higher Institute of Health Care	Food Safety (national)	General Management	Mirella Taranto, Head of Office
		Focal Point EFSA	n/a
Local Health Units of Naples – ASL Napoli	Food Safety (regional)	General Management	n/a
		Department of Prevention - Food hygiene and nutrition	Dr. Luigi Castellone, Director
Campania Region	Food Safety & IED (regional)	General Management	Sergio Negro
	Food Safety (regional)	General Directorate for Health Protection and Coordination of the Regional Health System	Antonio Postiglione
	IED (regional)	General Directorate of Environment and Ecosystem	Michele Palmieri, Manager
			Dott. Antimo Maiello
			Adelaide Pollinaro, Technical and operational support functions to the Directorate General
			Raimondo Santacroce
			Dott. Gianfranco Di Caprio
	Food Safety & IED (regional)	General Directorate for Economic Development and Production Activities	Roberta Esposito
	Food Safety & IED (regional)	Programmazione Unitaria	Dott. Pier Giorgio de Geronimo
	Food Safety & IED (regional)	Direz, Gen, Tutela Della Salute e Coord. SSR	Dott. Paolo Sarnelli
	Food Safety & IED (regional)	ARPAC Campania	Dott.ssa Marinella Vito

## XVI. Annex 8: List of Identified Potential Contributors from the Private Sector

### Generic contact

Company or Association	Department	Primary Contact	Profession
<b>Bulgaria</b>			
Association of Forest Companies in Bulgaria	Steering Committee	Ivan Penkov	President
Association of Modern Commerce		Yordan Mateev	President
Association of Recycling Industry	Board	n/a	Chairman
Bg Farmers' Association		Stefan Stefanov	President
Bulgarian Association Natural Gas	Management	Sasho Donchev	Chairman
Bulgarian Association of Dairy Processors	Board	Dimitar Zorov	Chairman
Bulgarian Chamber of Chemical Industry	Board	Silviya Nestorova	Chairman
Bulgarian Chamber of Commerce and Industry	Management	Tsvetan Simeonov	President
Bulgarian Industrial Association	Board	Sasho Donchev	Chairman
Free Energy Market Association		Krasmira Pishtuhina	Executive Director
International Chamber of Commerce (ICC) Bulgaria	Management	Ognian Donev	Chairman
KRIB Confederation of Employers and Industrialists in Bulgaria	Management	Kiril Domuschiev	Chairman
The Bulgarian Association of Regional Development Agencies	Management	Tanya Tzvetkova	Chairman
The Resource Center Foundation	Management	Valeri Rousanov	Chairman
<b>Estonia</b>			
Association of Estonian Food Industry	Board	Sirje Potisepp	Managing Director
Central Union of Estonian Farmers	Board	Vahur Tõnissoo	Chairman
Estonian Association of Fishery	Board	Thomas Kõuhkna	Chairman
Estonian Chamber of Agriculture and Commerce	Services Department	Piret Potisepp	Lawyer
Estonian Chamber of Commerce and Industry	Board	Roomet Sõrmus	Chairman
Estonian Dairy Association	Board	Jaanus Murakas	Chairman
Estonian Farmers' Federation	Board	Kalle Hamburg	Chairman
Estonian Oil Association	Board	Toomas Saks	Chairman

Estonian Plastics Industries Federation	Board	Pilleriin Laanemets	Managing Director
The Federation of Estonian Chemical Industries	Board	Hallar Meybaum	Managing Director
<b>Italy</b>			
Confindustria (National Business Association)	Director Legal and Regulatory Affairs	Marcella Panucci	Lawyer
Confindustria (National Business Association) Ascoli Piceno	Council	Simone Mariani	President
Confindustria (National Business Association) Alessandria	Council	Alberto Cazzani	President
Confindustria (National Business Association) Fermano	Council	Giampietro Melchiorri	President
Confindustria (National Business Association) Pavia	Council	Fabrizio Riva	Director
Confindustria (National Business Association) Piacenza	Council	Ing. Alberto Rota	President
Confindustria (National Business Association) Umbria	Council	Ernesto Cesaretti	President
Industrial Association of Brescia	Council	Marco Nicolai	Director
Industrial Association of Novara	Council	Aureliano Curini	Director
Industrial Union of the Province of Asti	Council	Paola Malabaila	President
Industrial Union of the Province of Pordenone	Council	Paul Candotti	General Manager
International Chamber of Commerce	Council	Andrea Tomat	President

## XVII. Annex 9: Introductory Letter from DG REGIO and World Bank Group sent to all Contributors



DATE, 2016

### EU Actionable Regulatory Governance Indicator Questionnaire

Dear NAME,

We would like to introduce you to the **EU Actionable Regulatory Governance Indicator** initiative, which is funded by the European Commission and implemented by the World Bank Group.

The initiative is developing and testing a new set of indicators to measure the capacity to prepare, assess, consult, disseminate and enforce high-quality regulation at the national and regional level within the EU. It is a unique effort to gather data focused not only on national, but also subnational regulatory management capacities. The aim is that these new indicators will provide policy-makers with an actionable assessment framework for regulatory reform that take regional variations into account. Scores on the indicators are generated primarily on the basis of questionnaires filled out by relevant experts and stakeholders.

COUNTRY has been selected to take part in this study. As a regulatory expert, your contribution to this pilot program is critical to making sure that the data we collect for COUNTRY is accurate and comprehensive. We ask you to designate an appropriate staff member to complete the attached questionnaire and submit your answers as instructed on the second page of the questionnaire.

The team members remain at your disposal to answer any questions you might have.

Thank you very much in advance for your cooperation in this effort.

A handwritten signature in black ink, appearing to read "Peter Ladegaard".

**Peter Ladegaard**  
Global Lead – Regulatory Policy and  
Management  
Governance Practice – World Bank  
Tel: +1 202 458 5625  
Email: Pladegaard@worldbank.org

A handwritten signature in black ink, appearing to read "Lewis Dijkstra".

**Lewis Dijkstra**  
Deputy head of the Economic Analysis Unit  
DG for Regional and Urban Policy  
European Commission  
Tel: + 32 2 269 23  
Email: Lewis.Dijkstra@ec.europa.eu





## Annex 9a: Examples of email request to respondents

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**From:** Rule Making  
**Sent:** Monday, November 14, 2016 10:45 AM  
**To:** 'n.adamo@arpacampania.it'  
**Subject:** Request for participation - EU Actionable Regulatory Governance project  
**Attachments:** EU and World Bank introduction letter - Nicola Adamo.pdf; Glossary\_IT.docx; IED\_Regional level\_IT.docx

Gentilissimo Sig. Nicola Adamo,

Le scriviamo per invitarla a partecipare ad un progetto sulla Governance Normativa Fruibile per le Regioni UE lanciato dalla **Commissione Europea** in collaborazione con il **Gruppo Banca Mondiale**

La preghiamo di trovare in allegato la lettera di invito da parte del Direttore Aggiunto dell'Unità di Analisi Economica, DG Politica Regionale e Urbana, Commissione Europea e da parte del Direttore dell'Unità *Regulatory Policy and Management* del Gruppo Banca Mondiale.

Rimaniamo in attesa di cortese riscontro e speriamo di poter contare sul suo contributo nel contesto di tale progetto.

---

Dear Mr. Nicola Adamo,

We solicit your participation in the EU Actionable Regulatory Governance project, which is implemented at the request of the **European Commission** in collaboration with **the World Bank Group**.

Attached please find the letter of invitation from the Deputy Head of the Economic Analysis Unit, DG for Regional and Urban Policy, European Commission and the Global Lead, Regulatory Policy and Management of the World Bank Group.

We are looking forward to receiving your contribution to the project,

The EU Actionable Regulatory Governance team

E [rulemaking@worldbank.org](mailto:rulemaking@worldbank.org)

W <http://www.worldbank.org/>

2121 Pennsylvania Ave NW · Washington DC 20433 · USA



**WORLD BANK GROUP**



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**From:** Rule Making  
**Sent:** Tuesday, November 08, 2016 10:29 AM  
**To:** 'sekretar@abv.bg'  
**Subject:** Request for participation - EU Actionable Regulatory Governance project - Yugozapaden  
**Attachments:** IED\_Regional level\_BG.docx; Glossary\_BG.docx; EU and World Bank introduction letter - Vania Petsanova.pdf

Уважаеми Г-жа Vania Petsanova,

Имаме удоволствието да Ви поканим да участвате в проект на тема „Ефективни регулаторни практики в Европейския съюз“. Проектът се осъществява от **Европейската комисия** в сътрудничество с **групата на Световната банка**.

В приложение, прилагаме официална покана от заместник-директора на отдел „Икономически анализи“, ГД „Регионална и урбанистична политика“, Европейска комисия и главния ръководител на отдел „Регулаторна политика и управление“, Група на Световната банка.

Очакваме да получим Вашите отговори и благодарим предварително за участието Ви.

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Dear Ms. Vania Petsanova,

We solicit your participation in the EU Actionable Regulatory Governance project, which is implemented at the request of the European Commission in collaboration with the World Bank Group.

Attached please find the letter of invitation from the Deputy Head of the Economic Analysis Unit, DG for Regional and Urban Policy, European Commission and the Global Lead, Regulatory Policy and Management of the World Bank Group.

We are looking forward to receiving your contribution to the project,

The EU Actionable Regulatory Governance team  
E [rulemaking@worldbank.org](mailto:rulemaking@worldbank.org)  
W <http://www.worldbank.org/>  
2121 Pennsylvania Ave NW · Washington DC 20433 · USA



## Annex 9b: Examples of follow-up email sent to respondents after data collection

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**From:** Rule Making  
**Sent:** Monday, January 23, 2017 5:58 PM  
**To:** 'Yoncho Pelovski'  
**Subject:** RE: Request for participation - EU Actionable Regulatory Governance project

Dear prof. Yoncho Pelovski,

Thank you again very much for completing the questionnaire of the **EU Actionable Regulatory Governance** project. The information you have provided has been extremely beneficial to the study.

As you already know, this project is funded by the **European Commission** and implemented by the **World Bank Group**. The initiative is testing a new set of indicators to measure the capacity to prepare, assess, consult, disseminate and enforce high-quality regulation at the national and regional level within the EU.

Given that this is a pilot, we would like to solicit your feedback on the questionnaire you completed in order to assess its comprehensibility and address any issues you may have noticed. We would therefore appreciate if you could please briefly comment on the following questions:

- Was the questionnaire easy to understand?
- Were all the sections relevant to your work?
- Did the questionnaire capture well all the relevant aspects of the regulatory processes?
- How long did it take you to fill out the questionnaire?
- How could the data collection process be improved to make it easier for you to respond?
- Do you have any additional comments/suggestions?

Also we would like to know if you thought that this method of data collection was appropriate or if you would be more comfortable meeting in person to discuss these issues.

Please send your feedback to us at your earliest convenience.

With kind regards,  
Joseph

**Joseph Lemoine**  
E [rulemaking@worldbank.org](mailto:rulemaking@worldbank.org)  
W <http://www.worldbank.org/>  
2121 Pennsylvania Ave NW · Washington DC 20433 · USA



**WORLD BANK GROUP**



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**From:** Rule Making  
**Sent:** Monday, January 23, 2017 6:09 PM  
**To:** 'c.campagnoli@sanita.it'  
**Subject:** Ringraziamento e richiesta di feedback

Gentile signora Campagnoli,

La ringraziamo molto per la compilazione del questionario del progetto UE Governance normative fruibili. Le informazioni che Lei ha fornito sono stati estremamente utili per lo studio.

Come già sa, questo progetto è finanziato dalla Commissione Europea e realizzato dal Gruppo della Banca Mondiale. L'iniziativa sta testando una nuova serie di indicatori per misurare la capacità di preparare, valutare, consultare, diffondere e applicare le normative di alta qualità a livello nazionale e regionale all'interno dell'Unione europea.

Dato che il presente è un pilota, vorremmo sollecitare i Suoi commenti sul completato questionario al fine di valutare la sua comprensibilità e risolvere eventuali problemi che Lei potrebbe aver notato. Saremmo quindi grati per i Suoi brevi commenti alle seguenti domande:

- Il questionario era di facile comprensione?
- Tutte le sezioni sono pertinenti al Suo lavoro?
- Il questionario copriva bene tutti gli aspetti rilevanti dei processi normativi?
- Quanto tempo Le ci è voluto per compilare il questionario?
- Come potrebbe essere migliorato il processo di raccolta dati per renderle più facile rispondere?
- Ha ulteriori commenti / suggerimenti?

Inoltre vorremmo sapere se Lei pensa che questo metodo di raccolta dei dati era appropriato o se sarebbe più comodo di avere un incontro di persona per discutere tali questioni.

Si prega di inviare il Suo feedback al più presto.

Cordiali saluti,

**The EU Actionable Regulatory Governance team**

E [rulemaking@worldbank.org](mailto:rulemaking@worldbank.org)

W <http://www.worldbank.org/>

2121 Pennsylvania Ave NW · Washington DC 20433 · USA



**WORLD BANK GROUP**



## Annex 9c: Example of answers received from respondents after following-up

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**From:** KKI Valve <valve@kki.ee>  
**Sent:** Friday, February 03, 2017 3:20 AM  
**To:** Rule Making  
**Cc:** Sirlika Kampus  
**Subject:** EU Actionable Regulatory Governance project (03.02.2017 nr 10-2/16/4918-5)

Dear Sir,

I send my feedback to the completed questionnaire of the EU Actionable Regulatory Governance Project.

My comments on the questions are the following:

- 1) Was the questionnaire easy to understand? Yes, the questionnaire was understandable. It included the background why this questionnaire is developed and also gave the instructions how to request for questions.
- 2) Were all the sections relevant to your work? No, from all the sections there were relevant only the section from 2 to 4, concerning my work (inspection and enforcement activities), that also partly. I had to ask a help from the regulator's side.
- 3) Did the questionnaire capture well all the relevant aspects of the regulatory processes? It's the question to the regulator. In my opinion it captured all the relevant aspects.
- 4) How long did it take you to fill out the questionnaire? To fill the questionnaire it took approximately from 2 to 3 hours.
- 5) How could the data collection process be improved to make it easier for you to respond? It could be easier when the data collection process is web-based and translated into the EU national languages.
- 6) Do you have any additional comments/suggestions? No, e.g answer to question 5.

Yours faithfully,

Reeli Sildnik  
Chief Inspector  
Environmental Protection Department  
Environmental Inspectorate

## XVIII. Annex 10: Questionnaires

This annex includes full versions of the questionnaires developed by the project. Based on a set of core questions asked to all contributors, slight variations were made in questionnaires targeting public officials at the national and regional level. A short version of the questionnaire was developed to solicit views from business associations. A separate glossary with definitions of key terms related to regulatory governance was developed and circulated with the questionnaires.

## Actionable Regulatory Governance Indicators for EU Regions – National, Food Safety

### QUESTIONNAIRE September, 2016

Assessment of regulatory management capacities to produce and enforce  
high-quality regulation

National level regulators  
Food Safety Regulation



**Background:**

This questionnaire is developed under the **EU Actionable Regulatory Governance Indicator** initiative, which is funded by the European Commission and implemented by the World Bank Group.

The initiative is developing and testing a new set of indicators to measure the capacity at the national and regional level within the EU to prepare, assess, consult, disseminate and enforce high-quality regulation. It is a unique effort to gather data focused on not only national, but also subnational regulatory management capacities. The aim is that these new indicators will provide policy-makers with an actionable assessment framework for regulatory reform that take regional variations into account.

[Insert name of country] has been selected to take part in the first pilot of this questionnaire. As a regulatory expert in [name of country], your contribution to this pilot program is critical to making sure that the data we collect for your country is accurate and comprehensive. Our staff would be happy to answer any questions you may have about this project or the questionnaire.

The information collected through this questionnaire will be kept confidential and the identity of the respondents will not be disclosed.

**How to answer the questionnaire:**

- Please save this document as a MS Word file and fill it out on the computer.
- Please tick the appropriate boxes or provide the information requested for each question.
- Some questions ask for the precise legal text or examples of documents. Please attach these separately when you return the questionnaire.
- Respondents may wish to refer to the definitions of terms used in the attached glossary.

Please return the questionnaire to [XX@worldbank.org](mailto:XX@worldbank.org) no later than [XXX, 2016].

**Section 1: Contributor Information****Primary Contributor Information**

*This information is for validation purpose only. It will not be publicly disclosed.*

<b>Name</b>	
Title (Mr., Ms., Dr.)	[ ]
First Name	[ ]
Last Name	[ ]
Professional title	[ ]
<b>Contact details</b>	
Agency name	[ ]
Department/office name	[ ]
Website	[ ]
E-mail address	[ ]
Phone	[ ]
Mobile phone	[ ]
<b>Agency Address</b>	
Street	[ ]

City	[ ]
Postal code	[ ]
Municipality	[ ]
Region	[ ]
Country	[ ]

#### Additional contributor(s) who worked on the questionnaire

Name	Occupation	Email	Phone
[title, name]	[agency] [professional title]	[ ]	[phone] [mobile]
[title, name]	[agency] [professional title]	[ ]	[phone] [mobile]
[title, name]	[agency] [professional title]	[ ]	[phone] [mobile]

#### Mandate of responding agency/ministry

Which of the following regulatory functions describe best the role or mandate of your unit or agency?  
(Select all that apply)

- ☐ Regulator (preparing and issuing laws and regulation)
- ☐ Regulatory oversight and control (quality assurance of draft laws and regulations, i.e. in terms of the legal quality or estimated economic impacts)
- ☐ Inspection and enforcement (assuring that regulatory standards and requirements are adhered to)
- ☐ Other, please explain: [ ]

#### Section 2: Authority and division of responsibilities

*This section asks how regulatory responsibilities are divided between different levels of government. As the assignment of responsibilities may vary across regulatory domains you are kindly asked to focus on the division of responsibilities in the area of food safety.*

##### 2.1. How is authority divided between the different levels of government in your country when issuing, guiding and enforcing food safety regulation? (Select all that apply)

	European Union	National Government	Regional Government	Local Government
Authority to issue primary/framework legislation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to issue secondary legislation/bylaws	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to issue technical standards and procedures in addition to what is prescribed in primary and secondary legislation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to issue binding guidance to regulated entities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to issue non-binding guidance to regulated entities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Authority to inspect and enforce regulatory compliance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--	--------------------------	--------------------------	--------------------------	--------------------------

## 2.2. Are the responsibilities of national, regional and local governments in the area of food safety regulation established in a law? – Click to Select -

If yes, please provide the name of the law(s)

If yes, please provide link to website where the law can be found: [ ]

## Section 3: Design of Legislation and Regulation

*This section covers the administrative procedures through which legislation and regulations are developed, consulted, assessed and adopted.*

### 3.1. Transparency and Access

#### 3.1.1. Do ministries/regulatory agencies in your country maintain a publicly available online database of current laws and regulations? – Click to Select - (if no, please go to 3.1.2.)

If yes, please provide link to website: [ ]

3.1.1.1. Does the database cover laws and regulations issued by all levels of government with regulatory powers?

- ☐ Yes
- ☐ No, only partial coverage of laws and regulations issued at the sub-national level (regional and local)
- ☐ No, it only covers laws and regulations issued at the national level
- ☐ The regions maintain their own database

Please provide any additional comments: [ ]

3.1.1.2. Does the database cover all regulatory domains?

- ☐ It covers all regulatory domains (food safety, environmental regulations, etc.)
- ☐ Some regulatory domains are better covered than others

Please provide any additional comments: [ ]

#### 3.1.2. Do ministries/regulatory agencies in your country publish a separate plan of regulations to be prepared, modified, reformed or repealed in the next six months or more? – Click to Select - (if no, please go to 3.2.)

If yes, please provide link to website: [ ]

3.1.2.1. Does the plan cover regulatory changes initiated by all levels of government with regulatory powers (national, regional, local)?

- ☐ Yes – there is one plan covering all planned regulatory changes at all levels of government
- ☐ No – planned regulatory changes at the subnational level are not included
- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

### 3.2. Consultation

**3.2.1. Do ministries/regulatory agencies in your country consult with the general public and/or targeted stakeholders on proposed regulation? – Click to Select - (if no, please go to 3.2.2.)**

**3.2.1.1. How are consultations conducted?**

- ☐ Feedback requested through a unified website for all proposed regulations  
Please provide link to website: [  ]
- ☐ Feedback requested through the website of the relevant ministry or regulator  
Please provide link to website: [  ]
- ☐ Targeted consultations with business associations and/or other stakeholders
- ☐ Public meetings
- ☐ Other, please specify: [  ]

**3.2.1.2. Is written guidance on how to conduct consultations available to regulators and the public? –**

[Click to Select -](#)

If available online, please provide link to website: [  ]

**3.2.1.3. Does the above consultation practice apply to all regulatory domains?**

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation

**3.2.1.4. Does the above practice for consultation apply to all regions in your country, or are there regional variations?**

- ☐ It applies uniformly to all regions of the country
- ☐ Regions apply different practices

Please provide any additional comments: [  ]

**3.2.2. Do ministries/regulatory agencies in your country provide responses to the feedback received through consultations? – Click to Select - (If no, please go to section 3)**

**3.2.2.1. How are the responses provided?**

- ☐ As one consolidated response published online
- ☐ As one consolidated response distributed to all consultation participants
- ☐ Separate responses for each comment published online
- ☐ Separate responses for each comment distributed directly to the author of the comment
- ☐ Other, please specify: [  ]

**3.2.2.2. Does the above practice for responding to feedback apply to all regulatory domains?**

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation.

**3.2.2.3. Does the above practice for providing responses apply to all regions in your country, or are there regional variations?**

- ☐ It applies uniformly to all regions of the country
- ☐ Regions apply different practices

Please provide any additional comments: [  ]

**3.3. Impact Assessment**

**3.3.1. Do ministries/regulatory agencies in your country conduct impact assessments of proposed regulations? – Click to Select - (if no, please go to 3.3.2.)**

**3.3.1.1. What impacts are typically assessed?**

- ☐ Economic impact

- ☐ Environmental impact
- ☐ Impact on regional development
- ☐ Impact on the public sector (Incl. administrative costs)
- ☐ Impact on the private sector (Incl. administrative costs)
- ☐ Other (please specify): [ ]

3.3.1.2. Is written guidance on how to conduct impact assessments available to regulators? – Click to Select -

If available online, please provide link to website: [ ]

3.3.1.3. Are impact assessments made publically available online? – Click to Select -

If yes, please provide link to website: [ ]

3.3.1.4. Please list at least and attach to your response three examples of impact assessment on food safety laws/regulations conducted in the past 3 years: [ ]

3.3.1.5. Does the above practice for conducting impact assessments apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation.

3.3.1.6. Does the above practice for impact assessment apply to all regions in your country, or are there regional variations?

- ☐ It applies uniformly to all regions of the country
- ☐ Regions apply different practices

Please provide any additional comments: [ ]

**3.3.2. Are there regional or national guidelines for how ministries and regulatory agencies implement EU legislation (either transposing an EU Directive or introducing legislation to implement and enforce EU regulation)?** – Click to Select - (if no, please go to section 4)

If yes, please provide link to guidelines: [ ]

3.2.2.1. What, if any, is included in the guidelines? (Select all that apply)

- ☐ A prohibition to add regulatory requirements beyond EU minimum requirements
- ☐ An obligation to justify any regulatory requirement going beyond EU minimum requirements
- ☐ An obligation to ensure that domestic firms are not put at a competitive disadvantage compared with their European counterparts
- ☐ An obligation to seek to implement EU policies through non-regulatory alternatives where possible
- ☐ An obligation to include a statutory duty for review of the legislation after at least 5 years

Please provide any additional comments: [ ]

#### **Section 4: Delivery: Implementation and Enforcement of Regulation**

*This section covers tools and approaches to “making regulation happen”, i.e. the implementation of regulation by regulatory agencies vis-à-vis regulated entities (citizens/businesses). Unless otherwise specified, this sections looks exclusively at implementation of **food safety regulation**.*

#### **4.1. Transparency and Communication of Standards and Practices**

**4.1.1. Do ministries/regulatory agencies in your country provide guidance to businesses on how to interpret and implement food safety regulatory requirements?** – Click to Select - (if no, please go to 4.1.2.)

4.1.1.1. What is included in the guidance? (Select all that apply)

- ☐ Illustrations of how to apply laws/regulations using real examples
- ☐ A section with frequently asked questions
- ☐ Discussion on the underlying objectives of the regulation
- ☐ Other (please specify): [ ]

4.1.1.2. Does the above practice for issuing guidance apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation.

4.1.1.3. Does the above practice for providing guidance apply to all regions in your country, or are there regional variations?

- ☐ It applies uniformly to all regions of the country
- ☐ Regions apply different practices

Please provide any additional comments: [ ]

**4.1.2. Do ministries/regulatory agencies in your country have a system for rating food businesses based on the outcomes of inspection visits? – Click to Select - (if no, please go to 4.1.3.)**

4.1.2.1. Which type of food businesses are rated?

- ☐ Food retail (grocery stores, restaurants, etc.)
- ☐ Other (please specify): [ ]

4.1.2.2. How are these ratings made publicly available?

- ☐ Ratings are not made public
- ☐ Mandatory display at the premises of food business
- ☐ Voluntary display at the premises of food business
- ☐ In an online registry or application. Please provide link: [ ]
- ☐ Other (please specify): [ ]

4.1.2.3. Does the above rating practice apply to all regions in your country, or are there regional variations?

- ☐ It applies uniformly to all regions of the country
- ☐ Regions apply different practices

Please provide any additional comments: [ ]

**4.1.3. Do ministries or regulatory agencies in your country publish a document explaining the methodologies and approaches used for inspections? – Click to Select - (if no, please go to 4.1.4.)**

4.1.3.1. Which of the following aspects are included in the document

- ☐ How to select businesses for inspection
- ☐ Method to be followed by inspectors during inspections
- ☐ Method for taking enforcement decisions
- ☐ Other (please specify): [ ]

4.1.3.2. Does the above practice for publishing inspection methodologies apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation

4.1.3.3. Does the above publishing practice apply to all regions in your country, or are there regional variations?

- ☐ It applies uniformly to all regions of the country
- ☐ Regions apply different practices

Please provide any additional comments: [ ]

**4.1.4. Do ministries/regulatory agencies country provide channels through which food businesses can submit feedback on the way inspections take place? – Click to Select - (if no, please go to 4.1.5.)**

**4.1.4.2. Through which channels can feedback be submitted?**

- ☐ Online system. Please provide website address: [ ]
- ☐ Hotline
- ☐ SMS
- ☐ Letter
- ☐ Personal visit to regulator
- ☐ Other (please specify): [ ]

**4.1.4.3. Please estimate the annual number of communications of feedback received:**

- ☐ 0
- ☐ 1-50
- ☐ 51-100
- ☐ More than 100

Please provide any additional comments: [ ]

**4.1.4.4. Do regulatory agencies report (at least periodically) on measures taken based upon the feedback received? – Click to Select -**

Please provide any additional comments: [ ]

**4.1.5. Do ministries/regulatory agencies in your country provide any mechanisms to food businesses through which they can appeal enforcement decisions? – Click to Select - (if no, please go to 4.2.)**

**4.1.5.2. Which appeals mechanisms are available?**

- ☐ Independent administrative appeals process
- ☐ Judicial review (decision reviewed by the judiciary)
- ☐ Ombudsman
- ☐ Other, please specify: [ ]

**4.1.5.2. Does the above practice for appeals apply to all regulatory domains?**

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation

**4.1.5.3. Does the above practice for appeals apply to all regions in your country, or are there regional variations?**

- ☐ It applies uniformly to all regions of the country
- ☐ Regions apply different practices

Please provide any additional comments: [ ]

**4.2. Risk Management and Compliance Promotion**

**4.2.1. What is required for the following categories of food businesses to start operations?**

	Mandatory prior inspections and approval of activity license	Simple registration or notice of economic activity (no inspection or approval)	Prior inspections and approval in some cases
Slaughterhouses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



			Please specify
Processing of meat and dairy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify
Processing of food of plant origin (fruits, cereals etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify
Food warehouses for foods which do not require temperature control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify
Bakeries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify
Restaurants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify
Butchers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify
Retail food stores (excluding butchers)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify

#### 4.2.2. How do regulatory enforcement agencies in your country decide on which businesses to inspect?

- ☐ Plans are developed based on a risk assessment of which sectors and business types could cause most damage
- ☐ Inspections are conducted based on complaints and incidents
- ☐ A combination of the above
- ☐ Other, please specify: [ ]

##### 4.2.2.1. If risk assessment is conducted, what type of information is used to inform the risk rating?

- ☐ Information on business operations (type products produced, material used in production, etc.)
- ☐ Scale of business operations
- ☐ Past inspection records
- ☐ Other (please specify): [ ]

##### 4.2.2.3. Does the above practice for planning inspection visits apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation.

##### 4.2.2.4. Does the above practice for planning inspections apply to all regions in your country, or are there regional variations?

- ☐ It applies uniformly to all regions of the country
- ☐ Regions apply different practices

Please provide any additional comments: [ ]

#### 4.2.3. Which enforcement measures are available to regulatory enforcement agencies? (Select all that apply)

- ☐ Oral warning
- ☐ Written warning (officially recorded)

- ☐ Notice of improvement with specific delay
- ☐ Notice of improvement with specific delay *and* temporary suspension of some/all activities
- ☐ Order to withdraw specific goods/services from the market
- ☐ Fines
- ☐ Suspension of license to operate
- ☐ Permanent withdrawal of license to operate
- ☐ Criminal prosecution
- ☐ Other (please specify):

4.2.3.1. Does the above range of enforcement measures apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation.

4.2.3.2. Does the above practice for enforcement measures apply to all regions in your country, or are there regional variations?

- ☐ It applies uniformly to all regions of the country
- ☐ Regions apply different practices

Please provide any additional comments: [  ]

### 4.3. Accountability and Independence of regulatory enforcement agencies

#### 4.3.1. Are regulatory enforcement agencies in your country subject to formal performance reviews? –

[Click to Select](#) - (if no, please go to 4.3.2.)

4.3.1.1. Who is responsible for conducting the performance review?

- ☐ An internal evaluation unit
- ☐ An independent evaluator (such as the Courts of Accounts)?
- ☐ Other, please specify: [  ]

4.3.1.2. How frequently are the agency performance reviews done? – [Click to Select](#) -

4.3.1.3. Does the above practice for performance review apply to all regions in your country, or are there regional variations?

- ☐ It applies uniformly to all regions of the country
- ☐ Regions apply different practices

Please provide any additional comments: [  ]

#### 4.3.2. Can the government (national, regional or local) issue instructions or guidance to the regulatory enforcement agency regarding its decisions? – [Click to Select](#) -

4.3.2.1. For which decisions can the government (at any level) issue instructions/guidance?

- ☐ Long-term strategy
- ☐ Operational planning
- ☐ Decisions to conduct inspections
- ☐ Individual enforcement decisions
- ☐ Appeals
- ☐ Other (please specify):

4.3.2.2. If the government issues instructions/guidance on individual cases and/or appeals, is there a legal requirement to make these instructions public? – [Click to Select](#) -

Please provide any additional comments: [  ]

#### 4.4. Institutional integration and coordination of inspection functions

**4.4.1. Is more than one regulatory enforcement agency responsible for food safety inspections in your country?** – [Click to Select](#) - (If no, please go to section 5.)

4.4.1.1. If yes, please list the name of the agencies: [  ]

4.4.1.2. At which level of governments do the regulatory enforcement agencies operate?

- ☐ Only the national level
- ☐ Only regional/local
- ☐ A mix of both

Please provide any additional comments: [  ]

**4.4.2. Is there a formal structure or agency with the responsibility of coordinating inspections in your Country?** – [Click to Select](#) - (if no, please go to section 5)

4.4.2.1. If yes, what aspects of inspection does it coordinate?

- ☐ Planning and targeting
- ☐ Methods, practices, enforcement decisions
- ☐ Information sharing and guidance
- ☐ Feedback/appeals case management
- ☐ Other (please specify): [  ]

4.4.1.2. Is there a formal document specifying the role and responsibilities of different regulators? – [Click to Select](#) -

4.4.1.3. Is there a joint plan for inspections by all inspecting agencies? – [Click to Select](#) -

4.4.1.4. Is there a rule prohibiting re-inspection? – [Click to Select](#) -

4.4.1.5. How is information shared across the different agencies?

- ☐ There is a unified database and information system for inspection planning and record keeping
- ☐ Some information systems are shared but other differ across agencies
- ☐ Each regulatory agency uses its own system

If databases/systems are separate: what mechanism are used for information exchange? Please explain [  ]

Please provide any additional comments: [  ]

#### Section 5: Regulatory Coordination and Oversight

*This section covers regulatory coordination and oversight between and across levels of government aimed at ensuring consistency in the way regulation is prepared, consulted and communicated.*

##### 5.1. Coordination

**5.1.1. Are there any formal regulatory co-ordination mechanisms between the national and sub-national governments to ensure regulatory consistency and avoid duplication or conflict of regulations?** – [Click to Select](#) - (if no, please go to section 5.2.)

5.1.1.1. What form of coordination mechanism exist?

- ☐ Network of regulatory agencies from across the country
- ☐ Coordination committee with representatives from different levels of government
- ☐ Other (please specify): [  ]

5.1.1.2. What aspects of regulatory coordination does the mechanism address?

- ☐ Consistency - ensure that national and regional regulations are not contradictory
- ☐ Roles and responsibilities between levels of government (to avoid overlaps)
- ☐ Inspections and enforcement planning and implementation
- ☐ Information sharing
- ☐ Dissemination of innovative regulatory practices across jurisdictions
- ☐ Other (please specify): [ ]

Please provide any additional comments: [ ]

**5.1.2. Recent regulatory reviews: In the past 3 years, has your region been involved in specific efforts to reduce overlaps of regulation between different levels of government in your country?** – Click to

Select -

If yes, please explain: [ ]

## 5.2. Oversight

**5.2.1. Is there within your country a unit responsible for regulatory oversight or quality assurance across the country?** – Click to Select - (if no, please go to section 6)

5.2.1.1. What is the name of this unit? [ ]

5.2.1.2. What is the organizational location (Governor's Office/ within a certain Department /etc.) of the unit? [ ]

5.2.1.3. What functions does this regulatory oversight unit have?

- ☐ Quality control of impact assessments
- ☐ Quality control of legal drafts
- ☐ Training on impact assessment
- ☐ Monitoring and reporting to Parliament on regulatory reform
- ☐ Coordination of ex post evaluation for policy revision
- ☐ Other (please specify): [ ]

Please provide any additional comments: [ ]

## Section 6: Ex-post Review of the Impact of Regulations

**This section covers tools to review regulatory performance of existing regulations.**

### 6.1. Practices and Requirements

**6.1.1. Do ministries/regulatory agencies in your country conduct reviews of *existing* food safety regulations?** – Click to Select - (if no, please go to 6.2.)

6.1.1.2. On what basis are these reviews conducted?

- ☐ Periodic ex-post evaluations of existing regulations are mandatory
- ☐ Ex-post evaluations are prompted by "*sunsetting*" clauses in some regulations
- ☐ Other, please specify: [ ]

6.1.1.3. What impacts are typically assessed?

- ☐ Comparison of actual vs. predicted impacts
- ☐ Unintended consequences
- ☐ Achievement of underlying policy objectives
- ☐ Other, please specify: [ ]

6.1.1.4. Is written guidance on how to conduct ex-post evaluations available to regulatory officials and the public? – Click to Select -

6.1.1.5. Are ex-post reviews made publically available online? – Click to Select -

If yes, please provide link to website: [ ]

6.1.1.6. Does the above practice for ex-post reviews apply to all regulatory domains?

☐ It applies to all regulatory domains

☐ There are separate practices in the area of food safety regulation

6.1.1.7. Does the above practice for ex-post review apply to all regions in your country, or are there regional variations?

☐ It applies uniformly to all regions of the country

☐ Regions apply different practices

Please provide any additional comments: [ ]

**6.1.3. Ex-post review in practice: In the past 5 years, have any major reviews of existing food safety regulations been conducted?** – Click to Select -

If yes, please list an example: [ ]

## 6.2. Feedback mechanisms

**6.2.1. Are there any mechanisms through which the public can make recommendations to modify or provide feedback on existing food safety regulations?** – Click to Select - (if no, you have completed this questionnaire)

6.2.1.1. Please specify the channels through which feedback can be provided:

☐ Online system

☐ Ombudsman

☐ Judicial system

☐ Petitions

☐ Other (please specify): [ ]

6.2.1.2. Do ministries/regulatory agencies use communication materials or conduct public outreach to inform the public about the feedback channels stated above? – Click to Select -

6.2.1.3. Does the above practice for soliciting feedback apply to all regulatory domains?

☐ It applies to all regulatory domains

☐ There are separate practices in the area of food safety regulation

6.2.1.4. Does the above practice for soliciting feedback apply to all regions in your country, or are there regional variations?

☐ It applies uniformly to all regions of the country

☐ Regions apply different practices

Please provide any additional comments: [ ]

**Thank you for completing the questionnaire!**

For questions or feedback on this questionnaire please contact:

**[Name]**

[Title]

World Bank Group

Phone:

Email:

## Actionable Regulatory Governance Indicators for EU Regions – Food Safety, Regional

### QUESTIONNAIRE

September, 2016

Assessment of regulatory management capacities to produce and enforce high-quality regulation

Food Safety Regulation  
Regional Regulators

**Background:**

This questionnaire is developed under the **EU Actionable Regulatory Governance Indicator** initiative, which is funded by the European Commission and implemented by the World Bank Group.

The initiative is developing and testing a new set of indicators to measure the capacity of **regions within the EU** to prepare, assess, consult, disseminate and enforce high-quality regulation. It is a unique effort to gather data focused on good regulatory practices as applied at the regional level in the EU. The aim is that these new indicators will provide policy-makers with an actionable assessment framework for regulatory reform that take regional variations into account.

[Insert name of region] has been selected to take part in the first pilot of this questionnaire. As a regulatory expert in [name of region], your contribution to this pilot program is critical to making sure that the data we collect for your region is accurate and comprehensive. Our staff would be happy to answer any questions you may have about this project or the questionnaire.

The information collected through this questionnaire will be kept confidential and the identity of the respondents will not be disclosed.

**How to answer the questionnaire:**

- Please save this document as a MS Word file and fill it out on the computer.
- Please tick the appropriate boxes or provide the information requested for each question.
- Some questions ask for the precise legal text or examples of documents. Please attach these separately when you return the questionnaire.
- The questions refer to regulatory practices as they are applied at the regional level. Such regional practices may in some cases be the same as nation-wide practices. In such cases the questions should simply reflect national practices as applied at the regional level.
- Respondents may wish to refer to the definitions of terms used in the attached glossary.

**Please return the questionnaire to** [XX@worldbank.org](mailto:XX@worldbank.org) no later than [XXX, 2016].

**Section 1: Contributor Information****Primary Contributor Information**

*This information is for validation purpose only. It will not be publicly disclosed.*

<b>Name</b>	
Title (Mr., Ms., Dr.)	[ ]
First Name	[ ]
Last Name	[ ]
Professional title	[ ]
<b>Contact details</b>	
Agency name	[ ]
Department/office name	[ ]
Website	[ ]
E-mail address	[ ]
Phone	[ ]
Mobile phone	[ ]



<b>Agency Address</b>	
Street	[ ]
City	[ ]
Postal code	[ ]
Municipality	[ ]
Region	[ ]
Country	[ ]

**Additional contributor(s) who worked on the questionnaire**

Name	Occupation	Email	Phone
[title, name]	[agency] [professional title]	[ ]	[phone] [mobile]
[title, name]	[agency] [professional title]	[ ]	[phone] [mobile]
[title, name]	[agency] [professional title]	[ ]	[phone] [mobile]

**Mandate of responding agency/ministry**

Which of the following regulatory functions describe best the role or mandate of your unit or agency?  
(Select all that apply)

- ☐ Regulator (preparing and issuing laws and regulation)
- ☐ Regulatory oversight and control (quality assurance of draft laws and regulations, i.e. in terms of the legal quality or estimated economic impacts)
- ☐ Inspection and enforcement (assuring that regulatory standards and requirements are adhered to)
- ☐ Other, please explain: [ ]

**Section 2: Authority and division of responsibilities**

*This section asks how regulatory responsibilities are divided between different levels of government. As the assignment of responsibilities may vary across regulatory domains you are kindly asked to focus on the division of responsibilities in the area of food safety.*

**2.1. How is authority divided between the different levels of government in your country when issuing, guiding and enforcing food safety regulation? (Select all that apply)**

	European Union	National Government	Regional Government	Local Government
Authority to issue primary/framework legislation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to issue secondary legislation/bylaws	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to issue technical standards and procedures in addition to what is prescribed in primary and secondary legislation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to issue binding guidance to regulated entities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Authority to issue non-binding guidance to regulated entities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to inspect and enforce regulatory compliance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## 2.2. Are the responsibilities of national, regional and local governments in the area of food safety regulation established in a law? – Click to Select -

If yes, please provide the name of the law(s)

If yes, please provide link to website where the law can be found: [ ]

## Section 3: Design of Legislation and Regulation

*This section covers the administrative procedures through which legislation and regulations are developed, consulted, assessed and adopted.*

### 3.1. Transparency and Access

#### 3.1.1. Do ministries/regulatory agencies *in your region* maintain a publicly available online database of current laws and regulations? – Click to Select - (if no, please go to 3.1.1.3.)

If yes, please provide link to website: [ ]

3.1.1.1. If yes, in what way does the regional database complement database(s) administered by the central government?

- ☐ It includes regulation and guidelines issued at the regional level
- ☐ It includes complementary guidelines for national-level regulation
- ☐ Other, please specify: [ ]

3.1.1.2. Does the above practice of making of laws and regulations available apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation

3.1.1.3. If no, please explain why your region does not maintain a database of laws and regulation

- ☐ Ministries/regulatory agencies in my region do not issue regulation
- ☐ Regulations issued by my region are included in a national database

Please provide link to website: [ ]

- ☐ There is no systematic practice for maintaining a database of laws and regulations

- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

#### 3.1.2. Do ministries/regulatory agencies *in your region* publish a separate *plan of regulations* to be prepared, modified, reformed or repealed in the next six months or more? – Click to Select - (if no, please go to 3.1.2.3.)

3.1.2.1. If yes, in what way does your region's practice vary from the national practice?

- ☐ My region communicates its own plan for future *regional* regulatory initiatives
- ☐ My region communicates the *national plan* with additional *commentary on regional implications*
- ☐ Other, please specify: [ ]

3.1.2.2. Does the above communication practice apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation

3.1.2.3. If no, please explain why your region does not publish a plan for future regulatory initiatives

- ☐ Ministries/regulatory agencies in my region do not issue regulation
- ☐ My regions' future regulatory initiatives are included in national plans
- ☐ There is no systematic practice communicating plans for future regulatory initiatives
- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

### 3.2. Consultation

**3.2.1. Do ministries/regulatory agencies in your region consult with the general public and/or targeted stakeholders on proposed regulation?** – Click to Select - (if no, please go to 3.2.2.5.)

3.2.1.1. If yes, in what way does your region's practice vary from the national practice? (Select all that apply)

- ☐ Regional consultations are carried out for regulations issued by the region
- ☐ Regional consultations are carried out for national laws/regulations on behalf of the central government
- ☐ Regional consultation practices are subject to formal consultation guidelines issued by the region

If so, please provide link to website where these can be found: [ ]

- ☐ Regional consultation practices are subject to formal consultation guidelines issued by the national government

If so, please provide link to website where these can be found: [ ]

3.2.1.2. How are consultations conducted? (Select all that apply)

- ☐ Feedback requested through a unified website for all proposed regulations  
Please provide link to website: [ ]
- ☐ Feedback requested through the website of the relevant ministry or regulator  
Please provide link to website: [ ]
- ☐ Targeted consultations with business associations and/or other stakeholders
- ☐ Public meetings
- ☐ Other, please specify: [ ]

3.2.1.3. Is written guidance on how to conduct consultations available to regulators and the public? –

Click to Select -

If available online, please provide link to website: [ ]

3.2.1.4. Does the above consultation practice apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation

3.2.1.5. If no, please explain why your region does not conduct public consultations for proposed regulation

- ☐ Ministries/regulatory agencies in my region do not issue regulation
- ☐ There is no systematic practice for public consultation on proposed regulation
- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

**3.2.2. Do ministries/regulatory agencies in your region provide responses to the feedback received through consultations?** – Click to Select - (If no, please go to question 3.2.2.4.)

3.2.2.1. If yes, in what way does your region's practice vary from the national practice?

- ☐ Responses are provided to feedback on regulation issued by regional agencies
  - ☐ Responses are provided to feedback on regulation issued by national agencies
  - ☐ Other, please specify: [ ]
- 3.2.2.2. How are the responses provided?
- ☐ As one consolidated response published online
  - ☐ As one consolidated response distributed to all consultation participants
  - ☐ Separate responses for each comment published online
  - ☐ Separate responses for each comment distributed directly to the author of the comment
  - ☐ Other, please specify: [ ]
- 3.2.2.3. Does the above practice for responding to feedback apply to all regulatory domains?
- ☐ It applies to all regulatory domains
  - ☐ There are separate practices in the area of food safety regulation
- 3.2.2.4. If no, please explain why your region does not respond to feedback on proposed regulation
- ☐ Ministries/regulatory agencies in my region do not issue regulation
  - ☐ There is no systematic practice for responding to feedback on proposed regulation
  - ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

### 3.3. Impact Assessment

**3.3.1. Do ministries/regulatory agencies *in your region* conduct impact assessments of proposed regulations?** – Click to Select - (if no, please go to 3.3.1.6.)

3.3.1.1. If yes, in what way does your region's practice vary from the national practice? (Select all that apply)

- ☐ Impact assessments are carried out for regulations issued by the region
- ☐ Impact assessments are carried out for national law/regulation on behalf of the central government
- ☐ Regional impact assessments are subject to formal impact assessment guidelines issued by the region?

If yes, please provide link to website: [ ]

- ☐ Regional impact assessments are subject to formal impact assessment guidelines issued by the national government?

If yes, please provide link to website: [ ]

3.3.1.2. What impacts are typically assessed?

- ☐ Economic impact
- ☐ Environmental impact
- ☐ Impact on regional development
- ☐ Impact on the public sector (Incl. administrative costs)
- ☐ Impact on the private sector (Incl. administrative costs)
- ☐ Other (please specify): [ ]

3.3.1.3. Are impact assessments made publically available online? – Click to Select -

If yes, please provide link to website: [ ]

3.3.1.4. Please list and attach to your response at least three examples of impact assessment on food safety laws/regulations conducted in the past 3 years: [ ]

3.3.1.5. Does the above practice for conducting impact assessments apply to all regulatory domains?

- ☐ It applies to all regulatory domains

- ☐ There are separate practices in the area of food safety regulation.
- 3.3.1.6. If no, please clarify why your region does not conduct impact assessments of proposed regulation
- ☐ Ministries/regulatory agencies in my region do not issue regulation
- ☐ There is no systematic practice for conducting impact assessment of proposed regional regulation
- ☐ Other, please specify: [ ]
- Please provide any additional comments: [ ]

**3.3.2. Are there regional or national guidelines for how ministries and regulatory agencies implement EU legislation (either transposing an EU Directive or introducing legislation to implement and enforce EU regulation)?** – Click to Select – (if no, please go to section 4)

If yes, please provide link to guidelines: [ ]

3.2.2.1. What, if any, is included in the guidelines? (Select all that apply)

- ☐ A prohibition to add regulatory requirements beyond EU minimum requirements
- ☐ An obligation to justify any regulatory requirement going beyond EU minimum requirements
- ☐ An obligation to ensure that domestic firms are not put at a competitive disadvantage compared with their European counterparts
- ☐ An obligation to seek to implement EU policies through non-regulatory alternatives where possible
- ☐ An obligation to include a statutory duty for review of the legislation after at least 5 years

Please provide any additional comments: [ ]

**Section 4: Delivery: Implementation and Enforcement of Regulation**

*This section covers tools and approaches to “making regulation happen”, i.e. the implementation of regulation by regulatory agencies vis-à-vis regulated entities (citizens/businesses). Unless otherwise specified, this sections looks exclusively at implementation of **food safety regulation**.*

**4.1. Transparency and Communication of Standards and Practices**

**4.1.1. Do ministries/regulatory agencies in your region provide guidance to businesses on how to interpret and implement food safety regulatory requirements?** – Click to Select – (if no, please go to

4.1.1.4)

4.1.1.1. If yes, in what way does your region’s practice vary from the national practice?

- ☐ Implementation guidance is provided for regulation issued by the region
- ☐ Implementation guidance is provided for regulation issued at the national level
- ☐ Other, please specify: [ ]

4.1.1.2. What is included in the guidance? (Select all that apply)

- ☐ Illustrations of how to apply laws/regulations using real examples
- ☐ A section with frequently asked questions
- ☐ Discussion on the underlying objectives of the regulation
- ☐ Other (please specify): [ ]

4.1.1.3. Does the above practice for issuing guidance apply to all regulatory domains?

- ☐ It applies to all regulatory domains

☐ There are separate practices in the area of food safety regulation.

Please explain: [ ]

4.1.1.4. If no, please clarify why your region does not provide implementation guidance on regulation

☐ My region is not responsible for implementation and inspection of regulation

☐ There is no systematic practice in my region for issuing implementation guidance for food safety regulation

☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

**4.1.2. Do ministries/regulatory agencies in your region have a system for rating food businesses based on the outcomes of inspection visits? – Click to Select - (if no, please go to 4.1.2.4)**

4.1.2.1. If yes, in what way does your region's practice vary from the national practice?

☐ Ratings are provided on compliance with regulation issued by the region

☐ Ratings are provided on compliance with regulation issued nationally or by the EU on behalf of the central government

☐ Other, please specify: [ ]

4.1.2.2. Which type of food businesses are rated?

☐ Food retail (grocery stores, restaurants, etc.)

☐ Other (please specify): [ ]

4.1.2.3. How are these ratings made publicly available?

☐ Ratings are not publicly available

☐ Mandatory display at the premises of food business

☐ Voluntary display at the premises of food business

☐ In an online registry or application. Please provide link: [ ]

☐ Other (please specify): [ ]

4.1.2.4. If no, please explain why your region does not rate outcomes of inspection visits

☐ My region is not responsible for inspections

☐ There is a nationwide rating system administered by the central government

☐ There is no systematic regional practice for ratings based on inspection visit outcomes

☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

**4.1.3. Do ministries or regulatory agencies in your region publish a document explaining the methodologies and approaches used for inspections? – Click to Select - (if no, please go to 4.1.3.4.)**

4.1.3.1. If yes, in what way does your region's practice vary from the national practice?

☐ Methods used for inspections conducted by regional agencies are published

☐ Methods used for inspections conducted by regional agencies on behalf of the central government are published

☐ Other, please specify: [ ]

4.1.3.2. Which of the following aspects are included in the document

☐ How to select businesses for inspection

☐ Method to be followed by inspectors during inspections

☐ Method for taking enforcement decisions

☐ Other (please specify): [ ]

4.1.3.3. Does the above practice for publishing inspection methodologies apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation

Please explain: [ ]

4.1.3.4. If no, please explain why your region does not publish its methodologies used inspection

- ☐ Methodologies are published by the national government
- ☐ There is no systematic practice for publishing methodologies
- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

**4.1.4. Do ministries/regulatory agencies *in your region* provide channels through which food businesses can submit feedback on the way inspections take place?** – Click to Select - (if no, please go to 4.1.4.6.)

4.1.4.1. If yes, in what way does your region's practice vary from the national practice?

- ☐ Feedback is solicited on inspections conducted by regional agencies
- ☐ Feedback is solicited on inspections conducted by central agencies
- ☐ Other, please specify: [ ]

4.1.4.2. Through which channels can feedback be submitted?

- ☐ Online system. Please provide website address: [ ]
- ☐ Hotline
- ☐ SMS
- ☐ Letter
- ☐ Personal visit to regulator
- ☐ Other (please specify): [ ]

4.1.4.3. Please estimate the annual number of communications of feedback received:

- ☐ 0
- ☐ 1-50
- ☐ 51-100
- ☐ More than 100

Please provide any additional comments: [ ]

4.1.4.4. Do regulatory agencies report (at least periodically) on measures taken based upon the feedback received? – Click to Select -

4.1.4.5. Does the above practice for soliciting feedback apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation

4.1.4.6. If no, please clarify why your region does not solicit feedback on inspection visits

- ☐ Regional agencies are not responsible for inspections
- ☐ There is no systematic practice for soliciting feedback on inspection visits
- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

**4.1.5. Do ministries/regulatory agencies *in your region* provide any mechanisms to food businesses through which they can appeal enforcement decisions?** – Click to Select - (if no, please go to 4.1.5.4.)

4.1.5.1. If yes, in what way does your region's practice vary from the national practice?

- ☐ The appeals process only cover enforcement decision taken by regional agencies
- ☐ The region handles appeals of decisions taken by central agencies on behalf of the central government
- ☐ Other, please specify: [ ]

4.1.5.2. Which appeals mechanisms are available?

- ☐ Independent administrative appeals process
- ☐ Judicial review (decision reviewed by the judiciary)
- ☐ Ombudsman
- ☐ Other, please specify: [ ]

4.1.5.3. Does the above practice for handling appeals apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation.

4.1.5.4. If no, please clarify why your region does not have its own appeals mechanism

- ☐ Regional agencies are not responsible for enforcement decisions
- ☐ There is no systematic practice for handling appeals of enforcement decisions
- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

## 4.2. Risk Management and Compliance Promotion

### 4.2.1. What is required for the following categories of food businesses to start operations?

	Mandatory <u>prior</u> inspections and approval of activity license	Simple registration or <u>notice</u> of economic activity (no inspection or approval)	Prior inspections and approval in <u>some cases</u>
Slaughterhouses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify
Processing of meat and dairy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify
Processing of food of plant origin (fruits, cereals etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify
Food warehouses for foods which do not require temperature control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify
Bakeries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify
Restaurants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify
Butchers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify
Retail food stores (excluding butchers)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify

### 4.2.2. How do regulatory enforcement agencies in your region decide on which businesses to inspect?

- ☐ Plans are developed based on a risk assessment of which sectors and business types could cause most damage



- ☐ Inspections are conducted based on complaints and incidents
  - ☐ A combination of the above
  - ☐ Other, please specify: [ ]
- 4.2.2.1. If risk assessment is conducted, what type of information is used to inform the risk rating?
- ☐ Information on business operations (type products produced, material used in production, etc.)
  - ☐ Scale of business operations
  - ☐ Past inspection records
  - ☐ Other (please specify): [ ]
- 4.2.2.2. In what way does your region's practices for planning inspection visits differ from the practices applied nationally?
- ☐ My region has its own inspection planning practices
  - ☐ My region follows national practices for planning inspections
  - ☐ Other, please specify: [ ]
- 4.2.2.3. Does the above practice for planning inspection visits apply to all regulatory domains?
- ☐ It applies to all regulatory domains
  - ☐ There are separate practices in the area of food safety regulation.
- Please provide any additional comments: [ ]

**4.2.3. Which enforcement measures are available to regulatory enforcement agencies *in your region*?**

(Select all that apply)

- ☐ Oral warning
  - ☐ Written warning (officially recorded)
  - ☐ Notice of improvement with specific delay
  - ☐ Notice of improvement with specific delay *and* temporary suspension of some/all activities
  - ☐ Order to withdraw specific goods/services from the market
  - ☐ Fines
  - ☐ Suspension of license to operate
  - ☐ Permanent withdrawal of license to operate
  - ☐ Criminal prosecution
  - ☐ Other (please specify):
- 4.2.3.1. In what way does your region's enforcement measures differ from those applied nationally?
- ☐ My region has its own range of enforcement measures
  - ☐ My region has the same range of enforcement measures as the national level
  - ☐ Other, please specify: [ ]
- 4.2.3.2. Does the above range of enforcement measures apply to all regulatory domains?
- ☐ It applies to all regulatory domains
  - ☐ There are separate practices in the area of food safety regulation.
- Please provide any additional comments: [ ]

**4.3. Accountability and Independence of regulatory enforcement agencies**

**4.3.1. Are regulatory enforcement agencies *in your region* subject to formal performance reviews? –**

Click to Select - (if no, please go directly to 4.3.1.5.)

- 4.3.1.1. If yes, in what way does your region's practice vary from the national practice?
- ☐ My region has its own practices for reviewing the performance of enforcement agencies
  - ☐ My region follow national practices for performance reviews of enforcement agencies
  - ☐ Other, please specify: [ ]
- 4.3.1.2. Who is responsible for conducting the performance review?
- ☐ An internal evaluation unit
  - ☐ An independent evaluator (such as the Courts of Accounts)?
  - ☐ Other, please specify: [ ]
- 4.3.1.3. How frequently are the agency performance reviews done? – [Click to Select](#) -
- 4.3.1.4. Does the above practice for performance reviews apply to all regulatory domains?
- ☐ It applies to all regulatory domains
  - ☐ There are separate practices in the area of food safety regulation.
- 4.3.1.5. If no, please clarify why your region does not conduct performance reviews
- ☐ Performance reviews are handled by the central government
  - ☐ There is no systematic practice for performance reviews
  - ☐ Other, please specify: [ ]
- Please provide any additional comments: [ ]

**4.3.2. Can the government (national, regional or local) issue instructions or guidance to the regulatory enforcement agency regarding its decisions?** – [Click to Select](#) -

- 4.3.2.1. For which decisions can the government (at any level) issue instructions/guidance?
- ☐ Long-term strategy
  - ☐ Operational planning
  - ☐ Decisions to conduct inspections
  - ☐ Individual enforcement decisions
  - ☐ Appeals
  - ☐ Other (please specify):
- 4.3.2.2. If the government issues instructions/guidance on individual cases and/or appeals, is there a legal requirement to make these instructions public? – [Click to Select](#) -
- Please provide any additional comments: [ ]

**4.4. Institutional integration and coordination of inspection functions**

**4.4.1. Is more than one regulatory enforcement agency responsible for food safety inspections in your region?** – [Click to Select](#) - (If no, please go to section 5.)

- 4.4.1.1. If yes, please list the name of the agencies: [ ]
- 4.4.1.2. At which level of governments do the regulatory enforcement agencies operate?
- ☐ Only the national level
  - ☐ Only regional/local
  - ☐ A mix of both
- Please provide any additional comments: [ ]

**4.4.2. Is there a formal structure or agency with the responsibility of coordinating inspections in your region?** – [Click to Select](#) - (if no, please go to section 5)

- 4.4.2.1. If yes, what aspects of inspection does it coordinate?

- ☐ Planning and targeting
- ☐ Methods, practices, enforcement decisions
- ☐ Information sharing and guidance
- ☐ Feedback/appeals case management
- ☐ Other (please specify): [ ]

4.4.1.2. Is there a formal document specifying the role and responsibilities of different regulators? – Click to Select -

4.4.1.3. Is there a joint plan for inspections by all inspecting agencies? – Click to Select -

4.4.1.4. Is there a rule prohibiting re-inspection? – Click to Select -

4.4.1.5. How is information shared across the different agencies?

- ☐ There is a unified database and information system for inspection planning and record keeping
- ☐ Some information systems are shared but other differ across agencies
- ☐ Each regulatory agency uses its own system

If databases/systems are separate: what mechanism are used for information exchange? Please explain: [ ]

Please provide any additional comments: [ ]

## Section 5: Regulatory Coordination and Oversight

*This section covers regulatory coordination and oversight between and across levels of government aimed at ensuring consistency in the way regulation is prepared, consulted and communicated.*

### 5.1. Coordination

**5.1.1. Are there any formal regulatory co-ordination mechanisms between the national and sub-national governments to ensure regulatory consistency and avoid duplication or conflict of regulations?** – Click to Select - (if no, please go to section 5.2.)

5.1.1.1. What form of coordination mechanism exist?

- ☐ Network of regulatory agencies from across the country
- ☐ Coordination committee with representatives from different levels of government
- ☐ Other (please specify): [ ]

5.1.1.2. What aspects of regulatory coordination does the mechanism address?

- ☐ Consistency - ensure that national and regional regulations are not contradictory
- ☐ Roles and responsibilities between levels of government (to avoid overlaps)
- ☐ Inspections and enforcement planning and implementation
- ☐ Information sharing
- ☐ Dissemination of innovative regulatory practices across jurisdictions
- ☐ Other (please specify): [ ]

Please provide any additional comments: [ ]

5.1.2. In the past 3 years, has your region been involved in specific efforts to reduce overlaps of **regulation between different levels of government in your country?** – Click to Select -

If yes, please explain: [ ]

### 5.2. Oversight

**5.2.1. Is there within your region's government a unit responsible for regulatory oversight and quality assurance across the region?** – Click to Select - (if no, please go to section 6)

- 5.2.1.1. What is the name of this unit? [ ]
- 5.2.1.2. What is the organizational location (Governor's Office/ within a certain Department /etc.) of the unit? [ ]
- 5.2.1.3. What functions does this regulatory oversight unit have?
- ☐ Quality control of impact assessments
  - ☐ Quality control of legal drafts
  - ☐ Training on impact assessment
  - ☐ Monitoring and reporting to Parliament on regulatory reform
  - ☐ Coordination of ex post evaluation for policy revision
  - ☐ Other (please specify): [ ]
- Please provide any additional comments: [ ]

## Section 6: Ex-post Review of the Impact of Regulations

*This section covers tools to review regulatory performance of existing regulations.*

### 6.1. Practices and Requirements

**6.1.1. Does your region conduct reviews of existing food safety regulations?** – Click to Select - (if no, please go to 6.1.1.7.)

6.1.1.1. If yes, in what way does your region's practice vary from the national practice?

- ☐ Ex-post reviews are conducted for regulations issued by regional agencies
- ☐ Ex-post reviews are conducted on behalf of the central government
- ☐ Other, please specify: [ ]

6.1.1.2. On what basis are these reviews conducted?

- ☐ Periodic ex-post evaluations of existing regulations are mandatory
- ☐ Ex-post evaluations are prompted by "sunsetting" clauses in some regulations
- ☐ Other, please specify: [ ]

6.1.1.3. What impacts are typically assessed?

- ☐ Comparison of actual vs. predicted impacts
- ☐ Unintended consequences
- ☐ Achievement of underlying policy objectives
- ☐ Other, please specify: [ ]

6.1.1.4. Is written guidance on how to conduct ex-post evaluations available to regulatory officials and the public? – Click to Select -

6.1.1.5. Are ex-post reviews made publically available online? – Click to Select -

If yes, please provide link to website: [ ]

6.1.1.6. Does the above practice for ex-post reviews apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation.

6.1.1.7. If no, please clarify why your region does not conduct ex-post reviews

- ☐ Ex-post reviews are conducted by the central government
- ☐ There is no systematic practice for ex-post reviews
- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

**6.1.3. Ex-post review in practice: In the past 5 years, have any major reviews of existing food safety regulations been conducted?** – Click to Select -

If yes, please list an example: [ ]

## **6.2. Feedback mechanisms**

**6.2.1. Are there regional mechanisms through which the public can make recommendations to modify or provide feedback on existing food safety regulations?** – Click to Select - (if no, please go directly to 6.2.1.5.)

6.2.1.1. If yes, in what way does your region's practice vary from the national practice?

- ☐ My region solicits feedback on existing regulation issued by the region
- ☐ My region solicits feedback on existing regulation on behalf of the central government
- ☐ Other, please specify: [ ]

6.2.1.2. Please specify the channels through which feedback can be provided:

- ☐ Online system
- ☐ Ombudsman
- ☐ Judicial system
- ☐ Petitions
- ☐ Other (please specify): [ ]

6.2.1.3. Does your region use communication materials or conduct public outreach to inform the public about the feedback channels stated above? – Click to Select -

6.2.1.4. Does the above practice for soliciting feedback apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation

6.2.1.5. If no, please clarify why your region does not solicit feedback on existing regulation

- ☐ My region does not issue regulation
- ☐ There is no systematic practice for soliciting feedback on existing regional regulation
- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

**Thank you for completing the questionnaire!**

For questions or feedback on this questionnaire please contact:

**[Name]**

[Title]

World Bank Group

Phone:

Email:

## Actionable Regulatory Governance Indicators for EU Regions – Private Sector

### QUESTIONNAIRE September, 2016

Assessment of regulatory management capacities to produce and enforce  
high-quality regulation  
Food Safety Regulation

**Private Sector**

**Background:**

This questionnaire is developed under the **EU Actionable Regulatory Governance Indicator** initiative, which is funded by the European Commission and implemented by the World Bank Group.

The initiative is developing and testing a new set of indicators to measure the capacity at the national and regional level within the EU to prepare, assess, consult, disseminate and enforce high-quality regulation. It is a unique effort to gather data focused on not only national, but also subnational regulatory management capacities. The aim is that these new indicators will provide policy-makers with an actionable assessment framework for regulatory reform that take regional variations into account.

Your organization [name of organization] has been selected to take part in the first pilot of this questionnaire. As a representative of the private sector within your country, your contribution to this pilot program is critical to making sure that the data we collect for your country is accurate and reflect the private sector perspective on the regulatory environment. Our staff would be happy to answer any questions you may have about this project or the questionnaire.

The information collected through this questionnaire will be kept confidential and the identity of the respondents will not be disclosed.

**How to answer the questionnaire:**

- Please save this document as a MS Word file and fill it out on the computer.
- Please tick the appropriate boxes or provide the information requested for each question.
- Some questions ask for the precise legal text or examples of documents. Please attach these separately when you return the questionnaire.
- Respondents may wish to refer to the definitions of terms used in the attached glossary.

**Please return the questionnaire to [XX@worldbank.org](mailto:XX@worldbank.org) no later than [XXX, 2016].**

**Section 1: Contributor Information****Primary Contributor Information**

*This information is for validation purpose only. It will not be publically disclosed.*

<b>Name</b>	
Title (Mr., Ms., Dr.)	[ ]
First Name	[ ]
Last Name	[ ]
Professional title	[ ]
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Firm/organization name	[ ]
Department/office name	[ ]
Website	[ ]
E-mail address	[ ]
Phone	[ ]
Mobile phone	[ ]
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Street	[ ]
City	[ ]
Postal code	[ ]
Municipality	[ ]
Region	[ ]
Country	[ ]

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[title, name]	[Department/Unit] [professional title]	[ ]	[phone] [mobile]
[title, name]	[Department/Unit] [professional title]	[ ]	[phone] [mobile]

## Section 2: Design of Legislation and Regulation

*This section covers the administrative procedures through which legislation and regulations are developed, consulted, assessed and adopted.*

### 2.1. Transparency and Access

#### 2.1.1. Do ministries/regulatory agencies in your country maintain a publicly available online database of current laws and regulations? – Click to Select - (if no, please go to 2.1.2.)

If yes, please provide link to website: [ ]

2.1.1.1. Does the database cover laws and regulations issued by all levels of government?

- ☐ Yes
- ☐ No, only partial coverage of laws and regulations issued at the sub-national level (regional and local)
- ☐ No, it only covers laws and regulations issued at the national level
- ☐ The regions maintain their own databases
- ☐ Other (please specify): [ ]

2.1.1.2. Does the database cover all regulatory domains?

- ☐ It cover all regulatory domains (food safety, environmental regulations, etc.)
- ☐ Some regulatory domains are better covered than others

Please provide any additional comments: [ ]

#### 2.1.2. Do ministries/regulatory agencies in your country publish a separate *plan of regulations* to be prepared, modified, reformed or repealed in the next six months or more? – Click to Select - (if no, please go to 2.2.)

2.1.2.1. Does the plan cover regulatory changes initiated by all levels of government with regulatory powers (national, regional, local)?

- ☐ Yes – there is one plan covering all regulatory changes at all levels of government
- ☐ No – it is up to the subnational governments to issue their own plans
- ☐ Other, please specify: [ ]



Please provide any additional comments: [ ]

## 2.2. Consultation

### 2.2.1. Do ministries/regulatory agencies in your country *consult* with the general public and/or targeted stakeholders on proposed regulation? – Click to Select - (if no, please go to 2.2.2.)

#### 2.2.1.1. How are consultations conducted?

☐ Feedback requested through a unified website for all proposed regulations

Please provide link to website: [ ]

☐ Feedback requested through the website of the relevant ministry or regulator

Please provide link to website: [ ]

☐ Targeted consultations with business associations and/or other stakeholders

☐ Public meetings

☐ Other, please specify: [ ]

#### 2.2.1.2. Does the above consultation practice apply to all regulatory domains?

☐ It applies to all regulatory domains

☐ There are separate practices in the area of food safety regulation.

Please provide any additional comments: [ ]

### 2.2.2. Do ministries/regulatory agencies in your country provide *responses to the feedback* received through consultations? – Click to Select - (If no, please go to section 2.3.)

#### 2.2.2.1. How are the responses provided?

☐ As one consolidated response published online

☐ As one consolidated response distributed to all consultation participants

☐ Separate responses for each comment published online

☐ Separate responses for each comment distributed directly to the author of the comment

☐ Other, please specify: [ ]

#### 2.2.2.2. Does the above practice for responding to feedback apply to all regulatory domains?

☐ It applies to all regulatory domains

☐ There are separate practices in the area of food safety regulation.

Please provide any additional comments: [ ]

## 2.3. Impact Assessment

### 2.3.1. Do ministries/regulatory agencies in your country conduct *impact assessments* of proposed regulations? – Click to Select - (if no, please go to Section 3.)

#### 2.3.1.1. What impacts are typically assessed?

☐ Economic impact

☐ Environmental impact

☐ Impact on regional development

☐ Impact on the public sector (Incl. administrative costs)

☐ Impact on the private sector (Incl. administrative costs)

☐ Other (please specify): [ ]

#### 2.3.1.2. Are impact assessments made publically available online? – Click to Select -

If yes, please provide link to website: [ ]

2.3.1.3. Does the above practice for conducting impact assessments apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation.

Please provide any additional comments: [ ]

### **Section 3: Delivery: Implementation and Enforcement of Regulation**

*This section covers tools and approaches to “making regulation happen”, i.e. the implementation of regulation by regulatory agencies vis-à-vis regulated entities (citizens/businesses). Unless otherwise specified, this sections looks exclusively at implementation of **food safety regulation**.*

#### **3.1. Transparency and Communication of Standards and Practices**

**3.1.1. Do ministries/regulatory agencies in your country provide guidance to businesses on how to interpret and implement food safety regulatory requirements?** – Click to Select - (if no, please go to 3.1.2.)

3.1.1.1. What is included in the guidance? (Select all that apply)

- ☐ Illustrations of how to apply laws/regulations using real examples
- ☐ A section with frequently asked questions
- ☐ Discussion on the underlying objectives of the regulation
- ☐ Other (please specify): [ ]

3.1.1.2. Does the above practice for issuing guidance apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation

Please provide any additional comments: [ ]

**3.1.2. Do ministries/regulatory agencies in your country have a system for rating food businesses based on the outcomes of inspection visits?** – Click to Select - (if no, please go to 3.1.3.)

3.1.2.1. Which type of food businesses are rated?

- ☐ Food retail (grocery stores, restaurants, etc.)
- ☐ Other (please specify): [ ]

3.1.2.2. How are these ratings made publicly available?

- ☐ Mandatory display at the premises of food business
- ☐ Voluntary display at the premises of food business
- ☐ In an online registry or application. Please provide link: [ ]
- ☐ Other (please specify): [ ]

Please provide any additional comments: [ ]

**3.1.3. Do ministries or regulatory agencies in your country publish a document explaining the methodologies and approaches used for inspections?** – Click to Select - (if no, please go to 3.1.4.)

3.1.3.1. Which of the following aspects are included in the document

- ☐ How to select businesses for inspection
- ☐ Method to be followed by inspectors during inspections
- ☐ Method for taking enforcement decisions

☐ Other (please specify): [ ]

3.1.3.2. Does the above practice for publishing inspection methodologies apply to all regulatory domains?

☐ It applies to all regulatory domains

☐ There are separate practices in the area of food safety regulation

Please provide any additional comments: [ ]

**3.1.4. Do ministries/regulatory agencies country provide channels through which food businesses can submit feedback on the way inspections take place?** – Click to Select - (if no, please go to 3.1.5.)

3.1.4.2. Through which channels can feedback be submitted?

☐ Online system. Please provide website address: [ ]

☐ Hotline

☐ SMS

☐ Letter

☐ Personal visit to regulator

☐ Other (please specify): [ ]

3.1.4.3. Do regulatory agencies report (at least periodically) on measures taken based upon the feedback received? – Click to Select -

Please provide any additional comments: [ ]

**3.1.5. Do ministries/regulatory agencies in your country provide any mechanisms to food business through which they can appeal enforcement decisions?** – Click to Select - (if no, please go to 3.2.)

3.1.5.2. Which appeals mechanisms are available?

☐ Independent administrative appeals process

☐ Judicial review (decision reviewed by the judiciary)

☐ Ombudsman

☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

## 3.2. Risk Management and Compliance Promotion

**3.2.1. What is required for the following categories of food businesses to start operations?**

	<u>Mandatory</u> prior inspections and approval of activity license	Simple registration or <u>notice</u> of economic activity (no inspection or approval)	Prior inspections and approval in <u>some cases</u>
Slaughterhouses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify
Processing of meat and dairy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify
Processing of food of plant origin (fruits, cereals etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify

Food warehouses for foods which do not require temperature control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify
Bakeries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify
Restaurants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify
Butchers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify
Retail food stores (excluding butchers)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Please specify

### 3.2.2. How do regulatory enforcement agencies in your country decide on which businesses to inspect?

- ☐ Inspection is based on a risk assessment of which sectors and businesses that could cause most damage
- ☐ Inspections are conducted based on complaints and incidents
- ☐ A combination of the above
- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

### 3.2.3. Which enforcement measures are available to *regulatory enforcement agencies*? (Select all that apply)

- ☐ Oral warning
- ☐ Written warning (officially recorded)
- ☐ Notice of improvement with specific delay
- ☐ Notice of improvement with specific delay *and* temporary suspension of some/all activities
- ☐ Order to withdraw specific goods/services from the market
- ☐ Fines
- ☐ Suspension of license to operate
- ☐ Permanent withdrawal of license to operate
- ☐ Criminal prosecution
- ☐ Other (please specify):

Please provide any additional comments: [ ]

### 3.3.4. Is more than one regulatory enforcement agency responsible for food safety inspections in your country? – Click to Select - (If no, please go to section 4.)

3.3.4.1. If yes, please list the name of the agencies: [ ]

Please provide any additional comments: [ ]

## Section 4: Ex-post Review of the Impact of Regulations

*This section covers tools to review regulatory performance of existing regulations.*

### 4.1. Practices and Requirements

**4.1.1. Do ministries/regulatory agencies in your country conduct reviews of *existing* food safety regulations?** – Click to Select - (if no, please go to 4.2.)

4.1.1.1. On what basis are these reviews conducted?

- ☐ Periodic ex-post evaluations of existing regulations are mandatory
- ☐ Ex-post evaluations are prompted by “*sunsetting*” clauses in some regulations
- ☐ Other, please specify: [ ]

4.1.1.2. What impacts are typically assessed?

- ☐ Comparison of actual vs. predicted impacts
- ☐ Unintended consequences
- ☐ Achievement of underlying policy objectives
- ☐ Other, please specify: [ ]

4.1.1.3. Are ex-post reviews made publically available online? – Click to Select -  
If yes, please provide link to website: [ ]

4.1.1.4. Does the above practice for ex-post reviews apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation

Please provide any additional comments: [ ]

**4.1.2. Ex-post review in practice: In the past 5 years, have any major reviews of existing food safety regulations been conducted?** – Click to Select -

If yes, please list an example: [ ]

**4.2. Feedback mechanisms**

**4.2.1. Are there any mechanisms through which the public can make recommendations to modify or provide feedback on existing food safety regulations?** – Click to Select - (if no, you have completed this questionnaire)

4.2.1.1. Please specify the channels through which feedback can be provided:

- ☐ Online system
- ☐ Ombudsman
- ☐ Judicial system
- ☐ Petitions
- ☐ Other (please specify): [ ]

4.2.1.2. Do ministries/regulatory agencies use communication materials or conduct public outreach to inform the public about the feedback channels stated above? – Click to Select -

4.2.1.3. Does the above practice for soliciting feedback apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of food safety regulation

Please provide any additional comments: [ ]

**4.3. Regional variations**

**4.3.1. Are the above practices covered by this questionnaire applied uniformly across the country or are there regional variations?**

☐ It applies uniformly to all regions of the country

☐ Regions apply different practices

If there are regional differences, please explain: [  ]

**Thank you for completing the questionnaire!**

For questions or feedback on this questionnaire please contact:

**[Name]**

[Title]

World Bank Group

Phone:

Email:

Actionable Regulatory Governance Indicators for EU Regions –  
National, IED

**QUESTIONNAIRE**

**September, 2016**

Assessment of regulatory management capacities to produce and enforce  
high-quality regulation

**National level regulators**

**Environmental regulations related to industrial emissions**

**Background:**

This questionnaire is developed under the **EU Actionable Regulatory Governance Indicator** initiative, which is funded by the European Commission and implemented by the World Bank Group.

The initiative is developing and testing a new set of indicators to measure the capacity at the national and regional level within the EU to prepare, assess, consult, disseminate and enforce high-quality regulation. It is a unique effort to gather data focused on not only national, but also subnational regulatory management capacities. The aim is that these new indicators will provide policy-makers with an actionable assessment framework for regulatory reform that take regional variations into account.

[Insert name of country] has been selected to take part in the first pilot of this questionnaire. As a regulatory expert in [name of country], your contribution to this pilot program is critical to making sure that the data we collect for your country is accurate and comprehensive. Our staff would be happy to answer any questions you may have about this project or the questionnaire.

The information collected through this questionnaire will be kept confidential and the identity of the respondents will not be disclosed.

**How to answer the questionnaire:**

- Please save this document as a MS Word file and fill it out on the computer.
- Please tick the appropriate boxes or provide the information requested for each question.
- Some questions ask for the precise legal text or examples of documents. Please attach these separately when you return the questionnaire.
- Respondents may wish to refer to the definitions of terms used in the attached glossary.

**Please return the questionnaire to** XX@worldbank.org **no later than** [XXX, 2016].

**Section 1: Contributor Information****Primary Contributor Information**

*This information is for validation purpose only. It will not be publically disclosed.*

<b>Name</b>	
Title (Mr., Ms., Dr.)	[ ]
First Name	[ ]
Last Name	[ ]
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Website	[ ]
E-mail address	[ ]
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Mobile phone	[ ]
<b>Agency Address</b>	
Street	[ ]



City	[ ]
Postal code	[ ]
Municipality	[ ]
Region	[ ]
Country	[ ]

#### Additional contributor(s) who worked on the questionnaire

Name	Occupation	Email	Phone
[title, name]	[agency] [professional title]	[ ]	[phone] [mobile]
[title, name]	[agency] [professional title]	[ ]	[phone] [mobile]
[title, name]	[agency] [professional title]	[ ]	[phone] [mobile]

#### Mandate of responding agency/ministry

Which of the following regulatory functions describe best the role or mandate of your unit or agency?  
(Select all that apply)

- ☐ Regulator (preparing and issuing laws and regulation)
- ☐ Regulatory oversight and control (quality assurance of draft laws and regulations, i.e. in terms of the legal quality or estimated economic impacts)
- ☐ Inspection and enforcement (assuring that regulatory standards and requirements are adhered to)
- ☐ Other, please explain: [ ]

#### Section 2: Authority and division of responsibilities

*This section asks how regulatory responsibilities are divided between different levels of government. As the assignment of responsibilities may vary across regulatory domains you are kindly asked to focus on the division of responsibilities in the area of environmental regulations related to industrial emissions.*

##### 2.1. How is authority divided between the different levels of government in your country when issuing, guiding and enforcing food safety regulation? (Select all that apply)

	European Union	National Government	Regional Government	Local Government
Authority to issue primary/framework legislation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to issue secondary legislation/bylaws	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to issue technical standards and procedures in addition to what is prescribed in primary and secondary legislation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to issue binding guidance to regulated entities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to issue non-binding guidance to regulated entities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Authority to inspect and enforce regulatory compliance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--	--------------------------	--------------------------	--------------------------	--------------------------

**2.2. Are the responsibilities of national, regional and local governments in the area of environmental regulations related to industrial emissions established in a law?** – Click to Select -

If yes, please provide the name of the law(s)

If yes, please provide link to website where the law can be found: [ ]

**Section 3: Design of Legislation and Regulation**

*This section covers the administrative procedures through which legislation and regulations are developed, consulted, assessed and adopted.*

**3.1. Transparency and Access**

**3.1.1. Do ministries/regulatory agencies in your country maintain a publicly available online database of current laws and regulations?** – Click to Select - (if no, please go to 3.1.2.)

If yes, please provide link to website: [ ]

3.1.1.1. Does the database cover laws and regulations issued by all levels of government with regulatory powers?

- ☐ Yes
- ☐ No, only partial coverage of laws and regulations issued at the sub-national level (regional and local)
- ☐ No, it only covers laws and regulations issued at the national level
- ☐ The regions maintain their own database

Please provide any additional comments: [ ]

3.1.1.2. Does the database cover all regulatory domains?

- ☐ It cover all regulatory domains (food safety, environmental regulations, etc.)
- ☐ Some regulatory domains are better covered than others

Please provide any additional comments: [ ]

**3.1.2. Do ministries/regulatory agencies in your country publish a separate plan of regulations to be prepared, modified, reformed or repealed in the next six months or more?** – Click to Select - (if no, please go to 3.2.)

If yes, please provide link to website: [ ]

3.1.2.1. Does the plan cover regulatory changes initiated by all levels of government with regulatory powers (national, regional, local)?

- ☐ Yes – there is one plan covering all planned regulatory changes at all levels of government
- ☐ No – planned regulatory changes at the subnational level are not included
- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

**3.2. Consultation**

**3.2.1. Do ministries/regulatory agencies in your country consult with the general public and/or targeted stakeholders on proposed regulation? – Click to Select - (if no, please go to 3.2.2.)**

3.2.1.1. How are consultations conducted?

☐ Feedback requested through a unified website for all proposed regulations

Please provide link to website: [ ]

☐ Feedback requested through the website of the relevant ministry or regulator

Please provide link to website: [ ]

☐ Targeted consultations with business associations and/or other stakeholders

☐ Public meetings

☐ Other, please specify: [ ]

3.2.1.2. Is written guidance on how to conduct consultations available to regulators and the public? –

Click to Select -

If available online, please provide link to website: [ ]

3.2.1.3. Does the above consultation practice apply to all regulatory domains?

☐ It applies to all regulatory domains

☐ There are separate practices in the area of environmental regulations related to industrial emissions

3.2.1.4. Does the above practice for consultation apply to all regions in your country, or are there regional variations?

☐ It applies uniformly to all regions of the country

☐ Regions apply different practices

Please provide any additional comments: [ ]

**3.2.2. Do ministries/regulatory agencies in your country provide responses to the feedback received through consultations? – Click to Select - (If no, please go to section 3)**

3.2.2.1. How are the responses provided?

☐ As one consolidated response published online

☐ As one consolidated response distributed to all consultation participants

☐ Separate responses for each comment published online

☐ Separate responses for each comment distributed directly to the author of the comment

☐ Other, please specify: [ ]

3.2.2.2. Does the above practice for responding to feedback apply to all regulatory domains?

☐ It applies to all regulatory domains

☐ There are separate practices in the area of environmental regulations related to industrial emissions

3.2.2.3. Does the above practice for providing responses apply to all regions in your country, or are there regional variations?

☐ It applies uniformly to all regions of the country

☐ Regions apply different practices

Please provide any additional comments: [ ]

**3.3. Impact Assessment**

**3.3.1. Do ministries/regulatory agencies in your country conduct impact assessments of proposed regulations? – Click to Select - (if no, please go to 3.3.2.)**

3.3.1.1. What impacts are typically assessed?

- ☐ Economic impact
- ☐ Environmental impact
- ☐ Impact on regional development
- ☐ Impact on the public sector (Incl. administrative costs)
- ☐ Impact on the private sector (Incl. administrative costs)
- ☐ Other (please specify): [ ]

3.3.1.2. Is written guidance on how to conduct impact assessments available to regulators? – Click to Select -

If available online, please provide link to website: [ ]

3.3.1.3. Are impact assessments made publically available online? – Click to Select -

If yes, please provide link to website: [ ]

3.3.1.4. Please list at least and attach to your response three examples of impact assessment on environmental regulations related to industrial emissions conducted in the past 3 years: [ ]

3.3.1.5. Does the above practice for conducting impact assessments apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of environmental regulations related to industrial emissions

3.3.1.6. Does the above practice for impact assessment apply to all regions in your country, or are there regional variations?

- ☐ It applies uniformly to all regions of the country
- ☐ Regions apply different practices

Please provide any additional comments: [ ]

**3.3.2. Are there regional or national guidelines for how ministries and regulatory agencies implement EU legislation (either transposing an EU Directive or introducing legislation to implement and enforce EU regulation)?** – Click to Select - (if no, please go to section 4)

If yes, please provide link to guidelines: [ ]

3.2.2.1. What, if any, is included in the guidelines? (Select all that apply)

- ☐ A prohibition to add regulatory requirements beyond EU minimum requirements
- ☐ An obligation to justify any regulatory requirement going beyond EU minimum requirements
- ☐ An obligation to ensure that domestic firms are not put at a competitive disadvantage compared with their European counterparts
- ☐ An obligation to seek to implement EU policies through non-regulatory alternatives where possible
- ☐ An obligation to include a statutory duty for review of the legislation after at least 5 years

Please provide any additional comments: [ ]

#### **Section 4: Delivery: Implementation and Enforcement of Regulation**

This section covers tools and approaches to “making regulation happen”, i.e. the implementation of **regulation by regulatory agencies vis-à-vis regulated entities (citizens/businesses)**. Unless otherwise specified, this sections looks exclusively at implementation of environmental regulations related to industrial emissions.

#### 4.1. Transparency and Communication of Standards and Practices

**4.1.1. Do ministries/regulatory agencies in your country provide guidance to industries on how to interpret and implement environmental regulations related to industrial emissions?** – Click to Select - (if no, please go to 4.1.2.)

4.1.1.1. What is included in the guidance? (Select all that apply)

- ☐ Illustrations of how to apply laws/regulations using real examples
- ☐ A section with frequently asked questions
- ☐ Discussion on the underlying objectives of the regulation
- ☐ Other (please specify): [ ]

4.1.1.2. Does the above practice for issuing guidance apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of environmental regulations related to industrial emissions

4.1.1.3. Does the above practice for providing guidance apply to all regions in your country, or are there regional variations?

- ☐ It applies uniformly to all regions of the country
- ☐ Regions apply different practices

Please provide any additional comments: [ ]

**4.1.3. Do ministries or regulatory agencies in your country publish a document explaining the methodologies and approaches used for inspections?** – Click to Select - (if no, please go to 4.1.4.)

4.1.3.1. Which of the following aspects are included in the document

- ☐ How to select businesses for inspection
- ☐ Method to be followed by inspectors during inspections
- ☐ Method for taking enforcement decisions
- ☐ Other (please specify): [ ]

4.1.3.2. Does the above practice for publishing inspection methodologies apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of environmental regulations related to industrial emissions

4.1.3.3. Does the above publishing practice apply to all regions in your country, or are there regional variations?

- ☐ It applies uniformly to all regions of the country
- ☐ Regions apply different practices

Please provide any additional comments: [ ]

**4.1.4. Do ministries/regulatory agencies country provide channels through which industries can submit feedback on the way inspections take place?** – Click to Select - (if no, please go to 4.1.5.)

4.1.4.2. Through which channels can feedback be submitted?

- ☐ Online system. Please provide website address: [ ]
- ☐ Hotline
- ☐ SMS
- ☐ Letter

- ☐ Personal visit to regulator  
☐ Other (please specify): [ ]

4.1.4.3. Please estimate the annual number of communications of feedback received:

- ☐ 0  
☐ 1-50  
☐ 51-100  
☐ More than 100

Please provide any additional comments: [ ]

4.1.4.4. Do regulatory agencies report (at least periodically) on measures taken based upon the feedback received? – Click to Select -

Please provide any additional comments: [ ]

**4.1.5. Do ministries/regulatory agencies in your country provide any mechanisms to industries through which they can appeal enforcement decisions?** – Click to Select - (if no, please go to 4.2.)

4.1.5.2. Which appeals mechanisms are available?

- ☐ Independent administrative appeals process  
☐ Judicial review (decision reviewed by the judiciary)  
☐ Ombudsman  
☐ Other, please specify: [ ]

4.1.5.2. Does the above practice for appeals apply to all regulatory domains?

- ☐ It applies to all regulatory domains  
☐ There are separate practices in the area of environmental regulations related to industrial emissions

4.1.5.3. Does the above practice for appeals apply to all regions in your country, or are there regional variations?

- ☐ It applies uniformly to all regions of the country  
☐ Regions apply different practices

Please provide any additional comments: [ ]

## 4.2. Risk Management and Compliance Promotion

**4.2.1. What is required for industries carrying out the following activities to start operating in accordance with environmental regulations related to industrial emissions?**

	No registration, notification or permit needed	Notification of intent to operate to competent environmental authority	One single environmental permit covering all aspects of pollution and environmental hazards	Multiple environmental permits covering different aspects of pollution and environmental hazards
Refining of mineral, oil and gas	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Production of pulp from timber	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Manufacturing of glass	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Production of chemicals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Waste management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dry cleaning (using volatile organic solvents); Footwear manufacture; Vegetable oil extraction and refining activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Slaughterhouse with capacity of less than 50 tons per day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**4.2.2. How do regulatory enforcement agencies in your country decide on which industries to inspect?**

- ☐ Plans are developed based on a risk assessment of which sectors and business types could cause most damage
- ☐ Inspections are conducted based on complaints and incidents
- ☐ A combination of the above
- ☐ Other, please specify: [ ]

**4.2.2.1. If risk assessment is conducted, what type of information is used to inform the risk rating?**

- ☐ Information on business operations (type products produced, material used in production, etc.)
- ☐ Scale of business operations
- ☐ Past inspection records
- ☐ Other (please specify): [ ]

**4.2.2.3. Does the above practice for planning inspection visits apply to all regulatory domains?**

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of environmental regulations related to industrial emissions

**4.2.2.4. Does the above practice for planning inspections apply to all regions in your country, or are there regional variations?**

- ☐ It applies uniformly to all regions of the country
- ☐ Regions apply different practices

Please provide any additional comments: [ ]

**4.2.3. Which enforcement measures are available to regulatory enforcement agencies? (Select all that apply)**

- ☐ Oral warning
- ☐ Written warning (officially recorded)
- ☐ Notice of improvement with specific delay
- ☐ Notice of improvement with specific delay *and* temporary suspension of some/all activities
- ☐ Order to withdraw specific goods/services from the market

- ☐ Fines
- ☐ Suspension of license to operate
- ☐ Permanent withdrawal of license to operate
- ☐ Criminal prosecution
- ☐ Other (please specify):

4.2.3.1. Does the above range of enforcement measures apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of environmental regulations related to industrial emissions

4.2.3.2. Does the above practice for enforcement measures apply to all regions in your country, or are there regional variations?

- ☐ It applies uniformly to all regions of the country
- ☐ Regions apply different practices

Please provide any additional comments: [ ]

#### **4.3. Accountability and Independence of regulatory enforcement agencies**

**4.3.1. Are regulatory enforcement agencies in your country subject to formal performance reviews? –**

[Click to Select](#) - (if no, please go to 4.3.2.)

4.3.1.1. Who is responsible for conducting the performance review?

- ☐ An internal evaluation unit
- ☐ An independent evaluator (such as the Courts of Accounts)?
- ☐ Other, please specify: [ ]

4.3.1.2. How frequently are the agency performance reviews done? – [Click to Select](#) -

4.3.1.3. Does the above practice for performance review apply to all regions in your country, or are there regional variations?

- ☐ It applies uniformly to all regions of the country
- ☐ Regions apply different practices

Please provide any additional comments: [ ]

**4.3.2. Can the government (national, regional or local) issue instructions or guidance to the regulatory enforcement agency regarding its decisions? – [Click to Select](#) -**

4.3.2.1. For which decisions can the government (at any level) issue instructions/guidance?

- ☐ Long-term strategy
- ☐ Operational planning
- ☐ Decisions to conduct inspections
- ☐ Individual enforcement decisions
- ☐ Appeals
- ☐ Other (please specify):

4.3.2.2. If the government issues instructions/guidance on individual cases and/or appeals, is there a legal requirement to make these instructions public? – [Click to Select](#) -

Please provide any additional comments: [ ]

#### **4.4. Institutional integration and coordination of inspection functions**



**4.4.1. Is more than one regulatory enforcement agency responsible for industrial emissions inspections in your country?** – Click to Select - (If no, please go to section 5.)

4.4.1.1. If yes, please list the name of the agencies: [ ]

4.4.1.2. At which level of governments do the regulatory enforcement agencies operate?

- ☐ Only the national level
- ☐ Only regional/local
- ☐ A mix of both

Please provide any additional comments: [ ]

**4.4.2. Is there a formal structure or agency with the responsibility of coordinating inspections in your Country?** – Click to Select - (if no, please go to section 5)

4.4.2.1. If yes, what aspects of inspection does it coordinate?

- ☐ Planning and targeting
- ☐ Methods, practices, enforcement decisions
- ☐ Information sharing and guidance
- ☐ Feedback/appeals case management
- ☐ Other (please specify): [ ]

4.4.1.2. Is there a formal document specifying the role and responsibilities of different regulators? – Click to Select -

4.4.1.3. Is there a joint plan for inspections by all inspecting agencies? – Click to Select -

4.4.1.4. Is there a rule prohibiting re-inspection? – Click to Select -

4.4.1.5. How is information shared across the different agencies?

- ☐ There is a unified database and information system for inspection planning and record keeping
- ☐ Some information systems are shared but other differ across agencies
- ☐ Each regulatory agency uses its own system

If databases/systems are separate: what mechanism are used for information exchange? Please explain [ ]

Please provide any additional comments: [ ]

**Section 5: Regulatory Coordination and Oversight**

*This section covers regulatory coordination and oversight between and across levels of government aimed at ensuring consistency in the way regulation is prepared, consulted and communicated.*

**5.1. Coordination**

**5.1.1. Are there any formal regulatory co-ordination mechanisms between the national and sub-national governments to ensure regulatory consistency and avoid duplication or conflict of regulations?** – Click to Select - (if no, please go to section 5.2.)

5.1.1.1. What form of coordination mechanism exist?

- ☐ Network of regulatory agencies from across the country
- ☐ Coordination committee with representatives from different levels of government
- ☐ Other (please specify): [ ]

5.1.1.2. What aspects of regulatory coordination does the mechanism address?

- ☐ Consistency - ensure that national and regional regulations are not contradictory
- ☐ Roles and responsibilities between levels of government (to avoid overlaps)

- ☐ Inspections and enforcement planning and implementation
- ☐ Information sharing
- ☐ Dissemination of innovative regulatory practices across jurisdictions
- ☐ Other (please specify): [ ]

Please provide any additional comments: [ ]

**5.1.2. In the past 3 years, has your region been involved in specific efforts to reduce overlaps of regulation between different levels of government in your country?** – Click to Select -

If yes, please explain: [ ]

## 5.2. Oversight

**5.2.1. Is there within your country a unit responsible for regulatory oversight or quality assurance across the country?** – Click to Select - (if no, please go to section 6)

5.2.1.1. What is the name of this unit? [ ]

5.2.1.2. What is the organizational location (Governor's Office/ within a certain Department /etc.) of the unit? [ ]

5.2.1.3. What functions does this regulatory oversight unit have?

- ☐ Quality control of impact assessments
- ☐ Quality control of legal drafts
- ☐ Training on impact assessment
- ☐ Monitoring and reporting to Parliament on regulatory reform
- ☐ Coordination of ex post evaluation for policy revision
- ☐ Other (please specify): [ ]

Please provide any additional comments: [ ]

## Section 6: Ex-post Review of the Impact of Regulations

*This section covers tools to review regulatory performance of existing regulations.*

### 6.1. Practices and Requirements

**6.1.1. Do ministries/regulatory agencies in your country conduct reviews of existing environmental regulations related to industrial emissions?** – Click to Select - (if no, please go to 6.2.)

6.1.1.2. On what basis are these reviews conducted?

- ☐ Periodic ex-post evaluations of existing regulations are mandatory
- ☐ Ex-post evaluations are prompted by “*sunsetting*” clauses in some regulations
- ☐ Other, please specify: [ ]

6.1.1.3. What impacts are typically assessed?

- ☐ Comparison of actual vs. predicted impacts
- ☐ Unintended consequences
- ☐ Achievement of underlying policy objectives
- ☐ Other, please specify: [ ]

6.1.1.4. Is written guidance on how to conduct ex-post evaluations available to regulatory officials and the public? – Click to Select -

6.1.1.5. Are ex-post reviews made publically available online? – Click to Select -

If yes, please provide link to website: [ ]

6.1.1.6. Does the above practice for ex-post reviews apply to all regulatory domains?

- ☐ It applies to all regulatory domains

☐ There are separate practices in the area of environmental regulations related to industrial emissions

6.1.1.7. Does the above practice for ex-post review apply to all regions in your country, or are there regional variations?

☐ It applies uniformly to all regions of the country

☐ Regions apply different practices

Please provide any additional comments: [ ]

**6.1.3. Ex-post review in practice: In the past 5 years, have any major reviews of existing environmental regulations related to industrial emissions been conducted?** – Click to Select -

If yes, please list an example: [ ]

## 6.2. Feedback mechanisms

**6.2.1. Are there any mechanisms through which the public can make recommendations to modify or provide feedback on existing environmental regulations related to industrial emissions?** – Click to Select - (if no, you have completed this questionnaire)

6.2.1.1. Please specify the channels through which feedback can be provided:

☐ Online system

☐ Ombudsman

☐ Judicial system

☐ Petitions

☐ Other (please specify): [ ]

6.2.1.2. Do ministries/regulatory agencies use communication materials or conduct public outreach to inform the public about the feedback channels stated above? – Click to Select -

6.2.1.3. Does the above practice for soliciting feedback apply to all regulatory domains?

☐ It applies to all regulatory domains

☐ There are separate practices in the area of environmental regulations related to industrial emissions

6.2.1.4. Does the above practice for soliciting feedback apply to all regions in your country, or are there regional variations?

☐ It applies uniformly to all regions of the country

☐ Regions apply different practices

Please provide any additional comments: [ ]

**Thank you for completing the questionnaire!**

For questions or feedback on this questionnaire please contact:

**[Name]**

[Title]

World Bank Group

Phone:

Email:

Actionable Regulatory Governance Indicators for EU Regions – IED,  
Regional

**QUESTIONNAIRE**

**September, 2016**

Assessment of regulatory management capacities to produce and enforce  
high-quality regulation

**Environmental Regulations related to industrial emissions**  
**Regional regulators**

**Background:**

This questionnaire is developed under the **EU Actionable Regulatory Governance Indicator** initiative, which is funded by the European Commission and implemented by the World Bank Group.

The initiative is developing and testing a new set of indicators to measure the capacity at the national and regional level within the EU to prepare, assess, consult, disseminate and enforce high-quality regulation. It is a unique effort to gather data focused on good regulatory practices as applied at the regional level in the EU. The aim is that these new indicators will provide policy-makers with an actionable assessment framework for regulatory reform that take regional variations into account.

[Insert name of region] has been selected to take part in the first pilot of this questionnaire. As a regulatory expert in [name of region], your contribution to this pilot program is critical to making sure that the data we collect for your region is accurate and comprehensive. Our staff would be happy to answer any questions you may have about this project or the questionnaire.

The information collected through this questionnaire will be kept confidential and the identity of the respondents will not be disclosed.

**How to answer the questionnaire:**

- Please save this document as a MS Word file and fill it out on the computer.
- Please tick the appropriate boxes or provide the information requested for each question.
- Some questions ask for the precise legal text or examples of documents. Please attach these separately when you return the questionnaire.
- The questions refer to regulatory practices as they are applied at the regional level. Such regional practices may in some cases be the same as nation-wide practices. In such cases the questions should simply reflect national practices as applied at the regional level.
- Respondents may wish to refer to the definitions of terms used in the attached glossary.

**Please return the questionnaire to [XX@worldbank.org](mailto:XX@worldbank.org) no later than [XXX, 2016].**

**Section 1: Contributor Information****Primary Contributor Information**

*This information is for validation purpose only. It will not be publically disclosed.*

<b>Name</b>	
Title (Mr., Ms., Dr.)	[ ]
First Name	[ ]
Last Name	[ ]
Professional title	[ ]
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#### Additional contributor(s) who worked on the questionnaire

Name	Occupation	Email	Phone
[title, name]	[agency] [professional title]	[ ]	[phone] [mobile]
[title, name]	[agency] [professional title]	[ ]	[phone] [mobile]
[title, name]	[agency] [professional title]	[ ]	[phone] [mobile]

#### Mandate of responding agency/ministry

Which of the following regulatory functions describe best the role or mandate of your unit or agency?  
(Select all that apply)

- ☐ Regulator (preparing and issuing laws and regulation)
- ☐ Regulatory oversight and control (quality assurance of draft laws and regulations, i.e. in terms of the legal quality or estimated economic impacts)
- ☐ Inspection and enforcement (assuring that regulatory standards and requirements are adhered to)
- ☐ Other, please explain: [ ]

#### Section 2: Authority and division of responsibilities

*This section asks how regulatory responsibilities are divided between different levels of government. As the assignment of responsibilities may vary across regulatory domains you are kindly asked to focus on the division of responsibilities in the area of environmental regulations related to industrial emissions.*

##### 2.1. How is authority divided between the different levels of government in your country when issuing, guiding and enforcing environmental regulations related to industrial emissions? (Select all that apply)

	European Union	National Government	Regional Government	Local Government
Authority to issue primary/framework legislation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to issue secondary legislation/bylaws	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to issue technical standards and procedures in addition to what is prescribed in primary and secondary legislation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Authority to issue binding guidance to regulated entities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to issue non-binding guidance to regulated entities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authority to inspect and enforce regulatory compliance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## 2.2. Are the responsibilities of national, regional and local governments in the area of environmental regulations related to industrial emissions established in a law? – Click to Select -

If yes, please provide the name of the law(s)

If yes, please provide link to website where the law can be found: [  ]

## Section 3: Design of Legislation and Regulation

*This section covers the administrative procedures through which legislation and regulations are developed, consulted, assessed and adopted.*

### 3.1. Transparency and Access

#### 3.1.1. Do ministries/regulatory agencies *in your region* maintain a publicly available online database of current laws and regulations? – Click to Select - (if no, please go to 3.1.1.3.)

If yes, please provide link to website: [  ]

3.1.1.1. If yes, in what way does the regional database complement database(s) administered by the central government?

- ☐ It includes regulation and guidelines issued at the regional level
- ☐ It includes complementary guidelines for national-level regulation
- ☐ Other, please specify: [  ]

3.1.1.2. Does the above practice of making of laws and regulations available apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of environmental regulations related to industrial emissions

3.1.1.3. If no, please explain why your region does not maintain a database of laws and regulation

- ☐ Ministries/regulatory agencies in my region do not issue regulation
- ☐ Regulations issued by my region are included in a national database

Please provide link to website: [  ]

- ☐ There is no systematic practice for maintaining a database of laws and regulations
- ☐ Other, please specify: [  ]

Please provide any additional comments: [  ]

#### 3.1.2. Do ministries/regulatory agencies *in your region* publish a separate *plan of regulations* to be prepared, modified, reformed or repealed in the next six months or more? – Click to Select - (if no, please go to 3.1.2.3.)

3.1.2.1. If yes, in what way does your region's practice vary from the national practice?

- ☐ My region communicates its own plan for future *regional* regulatory initiatives
- ☐ My region communicates the *national plan with additional commentary on regional implications*

- ☐ Other, please specify: [ ]
- 3.1.2.2. Does the above communication practice apply to all regulatory domains?
- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of environmental regulations related to industrial emissions
- 3.1.2.3. If no, please explain why your region does not publish a plan for future regulatory initiatives
- ☐ Ministries/regulatory agencies in my region do not issue regulation
- ☐ My regions' future regulatory initiatives are included in national plans
- ☐ There is no systematic practice communicating plans for future regulatory initiatives
- ☐ Other, please specify: [ ]
- Please provide any additional comments: [ ]

### 3.2. Consultation

#### 3.2.1. Do ministries/regulatory agencies in your region consult with the general public and/or targeted stakeholders on proposed regulation? – Click to Select - (if no, please go to 3.2.2.5.)

3.2.1.1. If yes, in what way does your region's practice vary from the national practice? (Select all that apply)

- ☐ Regional consultations are carried out for regulations issued by the region
- ☐ Regional consultations are carried out for national laws/regulations on behalf of the central government
- ☐ Regional consultation practices are subject to formal consultation guidelines issued by the region

If so, please provide link to website where these can be found: [ ]

- ☐ Regional consultation practices are subject to formal consultation guidelines issued by the national government

If so, please provide link to website where these can be found: [ ]

3.2.1.2. How are consultations conducted? (Select all that apply)

- ☐ Feedback requested through a unified website for all proposed regulations  
Please provide link to website: [ ]
- ☐ Feedback requested through the website of the relevant ministry or regulator  
Please provide link to website: [ ]
- ☐ Targeted consultations with business associations and/or other stakeholders
- ☐ Public meetings
- ☐ Other, please specify: [ ]

3.2.1.3. Is written guidance on how to conduct consultations available to regulators and the public? – Click to Select -

If available online, please provide link to website: [ ]

3.2.1.4. Does the above consultation practice apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of environmental regulations related to industrial emissions

3.2.1.5. If no, please explain why your region does not conduct public consultations for proposed regulation

- ☐ Ministries/regulatory agencies in my region do not issue regulation
- ☐ There is no systematic practice for public consultation on proposed regulation



☐ Other, please specify: [ ]  
Please provide any additional comments: [ ]

**3.2.2. Do ministries/regulatory agencies *in your region* provide responses to the feedback received through consultations?** – Click to Select - (If no, please go to question 3.2.2.4.)

3.2.2.1. If yes, in what way does your region's practice vary from the national practice?

- ☐ Responses are provided to feedback on regulation issued by regional agencies
- ☐ Responses are provided to feedback on regulation issued by national agencies
- ☐ Other, please specify: [ ]

3.2.2.2. How are the responses provided?

- ☐ As one consolidated response published online
- ☐ As one consolidated response distributed to all consultation participants
- ☐ Separate responses for each comment published online
- ☐ Separate responses for each comment distributed directly to the author of the comment
- ☐ Other, please specify: [ ]

3.2.2.3. Does the above practice for responding to feedback apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of environmental regulations related to industrial emissions

3.2.2.4. If no, please explain why your region does not respond to feedback on proposed regulation

- ☐ Ministries/regulatory agencies in my region do not issue regulation
- ☐ There is no systematic practice for responding to feedback on proposed regulation
- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

**3.3. Impact Assessment**

**3.3.1. Do ministries/regulatory agencies *in your region* conduct impact assessments of proposed regulations?** – Click to Select - (if no, please go to 3.3.1.6.)

3.3.1.1. If yes, in what way does your region's practice vary from the national practice? (Select all that apply)

- ☐ Impact assessments are carried out for regulations issued by the region
- ☐ Impact assessments are carried out for national law/regulation on behalf of the central government
- ☐ Regional impact assessments are subject to formal impact assessment guidelines issued by the region?

If yes, please provide link to website: [ ]

- ☐ Regional impact assessments are subject to formal impact assessment guidelines issued by the national government?

If yes, please provide link to website: [ ]

3.3.1.2. What impacts are typically assessed? (Select all that apply)

- ☐ Economic impact
- ☐ Environmental impact
- ☐ Impact on regional development
- ☐ Impact on the public sector (Incl. administrative costs)
- ☐ Impact on the private sector (Incl. administrative costs)

☐ Other (please specify): [ ]

3.3.1.3. Are impact assessments made publically available online? – Click to Select -

If yes, please provide link to website: [ ]

3.3.1.4. Please list and attach to your response at least three examples of impact assessment on environmental regulations related to industrial emissions conducted in the past 3 years: [ ]

3.3.1.5. Does the above practice for conducting impact assessments apply to all regulatory domains?

☐ It applies to all regulatory domains

☐ There are separate practices in the area of environmental regulations related to industrial emissions

3.3.1.6. If no, please clarify why your region does not conduct impact assessments of proposed regulation

☐ Ministries/regulatory agencies in my region do not issue regulation

☐ There is no systematic practice for conducting impact assessment of proposed regional regulation

☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

**3.3.2. Are there regional or national guidelines for how ministries and regulatory agencies implement EU legislation (either transposing an EU Directive or introducing legislation to implement and enforce EU regulation)?** – Click to Select - (if no, please go to section 4)

If yes, please provide link to guidelines: [ ]

3.2.2.1. What, if any, is included in the guidelines? (Select all that apply)

☐ A prohibition to add regulatory requirements beyond EU minimum requirements

☐ An obligation to justify any regulatory requirement going beyond EU minimum requirements

☐ An obligation to ensure that domestic firms are not put at a competitive disadvantage compared with their European counterparts

☐ An obligation to seek to implement EU policies through non-regulatory alternatives where possible

☐ An obligation to include a statutory duty for review of the legislation after at least 5 years

Please provide any additional comments: [ ]

#### **Section 4: Delivery: Implementation and Enforcement of Regulation**

*This section covers tools and approaches to “making regulation happen”, i.e. the implementation of regulation by regulatory agencies vis-à-vis regulated entities (citizens/businesses). Unless otherwise specified, this sections looks exclusively at implementation of **environmental regulations related to industrial emissions**.*

##### **4.1. Transparency and Communication of Standards and Practices**

**4.1.1. Do ministries/regulatory agencies in your region provide guidance to businesses on how to interpret and implement regulatory requirements related to industrial emissions?** – Click to Select - (if no, please go to 4.1.1.4)

4.1.1.1. If yes, in what way does your region’s practice vary from the national practice?

☐ Implementation guidance is provided for regulation issued by the region

☐ Implementation guidance is provided for regulation issued at the national level

☐ Other, please specify: [ ]

4.1.1.2. What is included in the guidance? (Select all that apply)

- ☐ Illustrations of how to apply laws/regulations using real examples
- ☐ A section with frequently asked questions
- ☐ Discussion on the underlying objectives of the regulation
- ☐ Other (please specify): [ ]

4.1.1.3. Does the above practice for issuing guidance apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of *environmental regulations related to industrial emissions*

Please explain: [ ]

4.1.1.4. If no, please clarify why your region does not provide implementation guidance on regulation

- ☐ My region is not responsible for implementation and inspection of regulation
- ☐ There is no systematic practice in my region for issuing implementation guidance for *environmental regulations related to industrial emissions*
- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

**4.1.2. Do ministries/regulatory agencies *in your region* publish a document explaining the methodologies and approaches used for inspections?** – Click to Select - (if no, please go to 4.1.2.4.)

4.1.2.1. If yes, in what way does your region's practice vary from the national practice?

- ☐ Methods used for inspections conducted by regional agencies are published
- ☐ Methods used for inspections conducted by regional agencies on behalf of the central government are published
- ☐ Other, please specify: [ ]

4.1.2.2. Which of the following aspects are included in the document

- ☐ How to select businesses for inspection
- ☐ Method to be followed by inspectors during inspections
- ☐ Method for taking enforcement decisions
- ☐ Other (please specify): [ ]

4.1.2.3. Does the above practice for publishing inspection methodologies apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of environmental regulations related to industrial emissions

Please explain: [ ]

4.1.2.4. If no, please explain why your region does not publish its methodologies used inspection

- ☐ Methodologies are published by the national government
- ☐ There is no systematic practice for publishing methodologies
- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

**4.1.3. Do ministries/regulatory agencies *in your region* provide channels through which food businesses can submit feedback on the way inspections take place?** – Click to Select - (if no, please go to 4.1.3.6.)

4.1.3.1. If yes, in what way does your region's practice vary from the national practice?

- ☐ Feedback is solicited on inspections conducted by regional agencies

- ☐ Feedback is solicited on inspections conducted by central agencies
- ☐ Other, please specify: [ ]
- 4.1.3.2. Through which channels can feedback be submitted?
  - ☐ Online system. Please provide website address: [ ]
  - ☐ Hotline
  - ☐ SMS
  - ☐ Letter
  - ☐ Personal visit to regulator
  - ☐ Other (please specify): [ ]
- 4.1.3.3. Please estimate the annual number of communications of feedback received:
  - ☐ 0
  - ☐ 1-50
  - ☐ 51-100
  - ☐ More than 100
 Please provide any additional comments: [ ]
- 4.1.3.4. Do regulatory agencies report (at least periodically) on measures taken based upon the feedback received? – [Click to Select](#) -
- 4.1.3.5. Does the above practice for soliciting feedback apply to all regulatory domains?
  - ☐ It applies to all regulatory domains
  - ☐ There are separate practices in the area of environmental regulations related to industrial emissions
- 4.1.3.6. If no, please clarify why your region does not solicit feedback on inspection visits
  - ☐ Regional agencies are not responsible for inspections
  - ☐ There is no systematic practice for soliciting feedback on inspection visits
  - ☐ Other, please specify: [ ]
 Please provide any additional comments: [ ]

**4.1.4. Do ministries/regulatory agencies *in your region* provide any mechanisms to industries through which they can appeal enforcement decisions?** – [Click to Select](#) - (if no, please go to 4.1.4.4.)

- 4.1.4.1. If yes, in what way does your region's practice vary from the national practice?
  - ☐ The appeals process only cover enforcement decision taken by regional agencies
  - ☐ The region handles appeals of decisions taken by central agencies on behalf of the central government
  - ☐ Other, please specify: [ ]
- 4.1.4.2. Which appeals mechanisms are available?
  - ☐ Independent administrative appeals process
  - ☐ Judicial review (decision reviewed by the judiciary)
  - ☐ Ombudsman
  - ☐ Other, please specify: [ ]
- 4.1.4.3. Does the above practice for handling appeals apply to all regulatory domains?
  - ☐ It applies to all regulatory domains
  - ☐ There are separate practices in the area of environmental regulations related to industrial emissions
- 4.1.4.4. If no, please clarify why your region does not have its own appeals mechanism

- ☐ Regional agencies are not responsible for enforcement decisions
- ☐ There is no systematic practice for handling appeals of enforcement decisions
- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

#### 4.2. Risk Management and Compliance Promotion

##### 4.2.1. What is required for industries carrying out the following activities to start operating in accordance with environmental regulations related to industrial emissions?

	No registration, notification or permit needed	Notification of intent to operate to competent environmental authority	One single environmental permit covering all aspects of pollution and environmental hazards	Multiple environmental permits covering different aspects of pollution and environmental hazards
Refining of mineral, oil and gas	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Production of pulp from timber	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Manufacturing of glass	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Production of chemicals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Waste management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dry cleaning (using volatile organic solvents); Footwear manufacture; Vegetable oil extraction and refining activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Slaughterhouse with capacity of less than 50 tons per day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

##### 4.2.2. How do regulatory enforcement agencies *in your region* decide on which businesses to inspect?

- ☐ Plans are developed based on a risk assessment of which sectors and business types could cause most damage
- ☐ Inspections are conducted based on complaints and incidents
- ☐ A combination of the above
- ☐ Other, please specify: [ ]

##### 4.2.2.1. If risk assessment is conducted, what type of information is used to inform the risk rating?

- ☐ Information on business operations (type products produced, material used in production, etc.)
- ☐ Scale of business operations

- ☐ Past inspection records
- ☐ Other (please specify): [ ]

4.2.2.2. In what way does your region's practices for planning inspection visits differ from the practices applied nationally?

- ☐ My region has its own inspection planning practices
- ☐ My region follows national practices for planning inspections
- ☐ Other, please specify: [ ]

4.2.2.3. Does the above practice for planning inspection visits apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of environmental regulations related to industrial emissions

Please provide any additional comments: [ ]

#### **4.2.3. Which enforcement measures are available to regulatory enforcement agencies *in your region*?**

(Select all that apply)

- ☐ Oral warning
- ☐ Written warning (officially recorded)
- ☐ Notice of improvement with specific delay
- ☐ Notice of improvement with specific delay *and* temporary suspension of some/all activities
- ☐ Order to withdraw specific goods/services from the market
- ☐ Fines
- ☐ Suspension of license to operate
- ☐ Permanent withdrawal of license to operate
- ☐ Criminal prosecution
- ☐ Other (please specify):

4.2.3.1. In what way does your region's enforcement measures differ from the practices applied nationally?

- ☐ My region has its own range of enforcement measures
- ☐ My region has the same range of enforcement measures as the national level
- ☐ Other, please specify: [ ]

4.2.3.2. Does the above range of enforcement measures apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of environmental regulations related to industrial emissions

Please provide any additional comments: [ ]

#### **4.3. Accountability and Independence of regulatory enforcement agencies**

##### **4.3.1. Are regulatory enforcement agencies *in your region* subject to formal performance reviews? –**

Click to Select - (if no, please go directly to 4.3.1.5.)

4.3.1.1. If yes, in what way does your region's practice vary from the national practice?

- ☐ My region has its own practices for reviewing the performance of enforcement agencies
- ☐ My region follow national practices for performance reviews of enforcement agencies
- ☐ Other, please specify: [ ]

4.3.1.2. Who is responsible for conducting the performance review?

- ☐ An internal evaluation unit
- ☐ An independent evaluator (such as the Courts of Accounts)?
- ☐ Other, please specify: [ ]

4.3.1.3. How frequently are the agency performance reviews done? – [Click to Select](#) -

4.3.1.4. Does the above practice for performance reviews apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of environmental regulations related to industrial emissions

4.3.1.5. If no, please clarify why your region does not conduct performance reviews

- ☐ Performance reviews are handled by the central government
- ☐ There is no systematic practice for performance reviews
- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

#### **4.3.2. Can the government (national, regional or local) issue instructions or guidance to the regulatory enforcement agency regarding its decisions?** – [Click to Select](#) -

4.3.2.1. For which decisions can the government (at any level) issue instructions/guidance?

- ☐ Long-term strategy
- ☐ Operational planning
- ☐ Decisions to conduct inspections
- ☐ Individual enforcement decisions
- ☐ Appeals
- ☐ Other (please specify):

4.3.2.2. If the government issues instructions/guidance on individual cases and/or appeals, is there a legal requirement to make these instructions public? – [Click to Select](#) -

Please provide any additional comments: [ ]

#### **4.4. Institutional integration and coordination of inspection functions**

##### **4.4.1. Is more than one regulatory enforcement agency responsible for industrial emissions inspections in your region?** – [Click to Select](#) - (If no, please go to section 5.)

4.4.1.1. If yes, please list the name of the agencies: [ ]

4.4.1.2. At which level of governments do the regulatory enforcement agencies operate?

- ☐ Only the national level
- ☐ Only regional/local
- ☐ A mix of both

Please provide any additional comments: [ ]

##### **4.4.2. Is there a formal structure or agency with the responsibility of coordinating inspections in your region?** – [Click to Select](#) - (if no, please go to section 5)

4.4.2.1. If yes, what aspects of inspection does it coordinate?

- ☐ Planning and targeting
- ☐ Methods, practices, enforcement decisions
- ☐ Information sharing and guidance
- ☐ Feedback/appeals case management

☐ Other (please specify): [ ]

4.4.1.2. Is there a formal document specifying the role and responsibilities of different regulators? – Click to Select -

4.4.1.3. Is there a joint plan for inspections by all inspecting agencies? – Click to Select -

4.4.1.4. Is there a rule prohibiting re-inspection? – Click to Select -

4.4.1.5. How is information shared across the different agencies?

☐ There is a unified database and information system for inspection planning and record keeping

☐ Some information systems are shared but other differ across agencies

☐ Each regulatory agency uses its own system

If databases/systems are separate: what mechanism are used for information exchange? Please explain [ ]

Please provide any additional comments: [ ]

## Section 5: Regulatory Coordination and Oversight

*This section covers regulatory coordination and oversight between and across levels of government aimed at ensuring consistency in the way regulation is prepared, consulted and communicated.*

### 5.1. Coordination

**5.1.1. Are there any formal regulatory co-ordination mechanisms between the national and sub-national governments to ensure regulatory consistency and avoid duplication or conflict of regulations?** – Click to Select - (if no, please go to section 5.2.)

5.1.1.1. What form of coordination mechanism exist?

☐ Network of regulatory agencies from across the country

☐ Coordination committee with representatives from different levels of government

☐ Other (please specify): [ ]

5.1.1.2. What aspects of regulatory coordination does the mechanism address?

☐ Consistency - ensure that national and regional regulations are not contradictory

☐ Roles and responsibilities between levels of government (to avoid overlaps)

☐ Inspections and enforcement planning and implementation

☐ Information sharing

☐ Dissemination of innovative regulatory practices across jurisdictions

☐ Other (please specify): [ ]

Please provide any additional comments: [ ]

5.1.2. Recent regulatory reviews: In the past 3 years, has your region been involved in specific efforts to reduce overlaps of regulation between different levels of government in your country? – Click to Select -  
If yes, please explain: [ ]

### 5.2. Oversight

**5.2.1. Is there within your region's government a unit responsible for regulatory oversight or quality assurance across the region?** – Click to Select - (if no, please go to section 6)

5.2.1.1. What is the name of this unit? [ ]

5.2.1.2. What is the organizational location (Governor's Office/ within a certain Department /etc.) of the unit? [ ]

5.2.1.3. What functions does this regulatory oversight unit have?



- ☐ Quality control of impact assessments
- ☐ Quality control of legal drafts
- ☐ Training on impact assessment
- ☐ Monitoring and reporting to Parliament on regulatory reform
- ☐ Coordination of ex post evaluation for policy revision
- ☐ Other (please specify): [ ]

Please provide any additional comments: [ ]

## **Section 6: Ex-post Review of the Impact of Regulations**

*This section covers tools to review regulatory performance of existing regulations.*

### **6.1. Practices and Requirements**

**6.1.1. Does your region conduct reviews of *existing* environmental regulations related to industrial emissions?** – Click to Select - (if no, please go to 6.1.1.7.)

6.1.1.1. If yes, in what way does your region's practice vary from the national practice?

- ☐ Ex-post reviews are conducted for regulations issued by regional agencies
- ☐ Ex-post reviews are conducted on behalf of the central government
- ☐ Other, please specify: [ ]

6.1.1.2. On what basis are these reviews conducted?

- ☐ Periodic ex-post evaluations of existing regulations are mandatory
- ☐ Ex-post evaluations are prompted by “*sunsetting*” clauses in some regulations
- ☐ Other, please specify: [ ]

6.1.1.3. What impacts are typically assessed?

- ☐ Comparison of actual vs. predicted impacts
- ☐ Unintended consequences
- ☐ Achievement of underlying policy objectives
- ☐ Other, please specify: [ ]

6.1.1.4. Is written guidance on how to conduct ex-post evaluations available to regulatory officials and the public? – Click to Select -

6.1.1.5. Are ex-post reviews made publically available online? – Click to Select -

If yes, please provide link to website: [ ]

6.1.1.6. Does the above practice for ex-post reviews apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of environmental regulations related to industrial emissions

6.1.1.7. If no, please clarify why your region does not conduct ex-post reviews

- ☐ Ex-post reviews are conducted by the central government
- ☐ There is no systematic practice for ex-post reviews
- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

**6.1.3. Ex-post review in practice: In the past 5 years, have any major reviews of existing environmental regulations related to industrial emissions been conducted?** – Click to Select -

If yes, please list an example: [ ]

### **6.2. Feedback mechanisms**

**6.2.1. Are there regional mechanisms through which the public can make recommendations to modify or provide feedback on existing environmental regulations related to industrial emissions? – Click to**

Select - (if no, please go directly to 6.2.1.5.)

6.2.1.1. If yes, in what way does your region's practice vary from the national practice?

- ☐ My region solicits feedback on existing regulation issued by the region
- ☐ My region solicits feedback on existing regulation on behalf of the central government
- ☐ Other, please specify: [ ]

6.2.1.2. Please specify the channels through which feedback can be provided:

- ☐ Online system
- ☐ Ombudsman
- ☐ Judicial system
- ☐ Petitions
- ☐ Other (please specify): [ ]

6.2.1.3. Does your region use communication materials or conduct public outreach to inform the public about the feedback channels stated above? – Click to Select -

6.2.1.4. Does the above practice for soliciting feedback apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of environmental regulations related to industrial emissions

6.2.1.5. If no, please clarify why your region does not solicit feedback on existing regulation

- ☐ My region does not issue regulation
- ☐ There is no systematic practice for soliciting feedback on existing regional regulation
- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

**Thank you for completing the questionnaire!**

For questions or feedback on this questionnaire please contact:

**[Name]**

[Title]

World Bank Group

Phone:

Email:

# Actionable Regulatory Governance Indicators for EU Regions – Private Sector

## **QUESTIONNAIRE** **September, 2016**

Assessment of regulatory management capacities to produce and enforce  
high-quality regulation  
IED

**Private Sector**

**Background:**

This questionnaire is developed under the **EU Actionable Regulatory Governance Indicator** initiative, which is funded by the European Commission and implemented by the World Bank Group.

The initiative is developing and testing a new set of indicators to measure the capacity at the national and regional level within the EU to prepare, assess, consult, disseminate and enforce high-quality regulation. It is a unique effort to gather data focused on not only national, but also subnational regulatory management capacities. The aim is that these new indicators will provide policy-makers with an actionable assessment framework for regulatory reform that take regional variations into account.

Your organization [name of organization] has been selected to take part in the first pilot of this questionnaire. As a representative of the private sector within your country, your contribution to this pilot program is critical to making sure that the data we collect for your country is accurate and reflect the private sector perspective on the regulatory environment. Our staff would be happy to answer any questions you may have about this project or the questionnaire.

The information collected through this questionnaire will be kept confidential and the identity of the respondents will not be disclosed.

**How to answer the questionnaire:**

- Please save this document as a MS Word file and fill it out on the computer.
- Please tick the appropriate boxes or provide the information requested for each question.
- Some questions ask for the precise legal text or examples of documents. Please attach these separately when you return the questionnaire.
- Respondents may wish to refer to the definitions of terms used in the attached glossary.

**Please return the questionnaire to** [XX@worldbank.org](mailto:XX@worldbank.org) **no later than** [XXX, 2016].

**Section 1: Contributor Information****Primary Contributor Information**

*This information is for validation purpose only. It will not be publically disclosed.*

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#### Additional contributor(s) who worked on the questionnaire

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[title, name]	[Department/Unit] [professional title]	[ ]	[phone] [mobile]
[title, name]	[Department/Unit] [professional title]	[ ]	[phone] [mobile]
[title, name]	[Department/Unit] [professional title]	[ ]	[phone] [mobile]

## Section 2: Design of Legislation and Regulation

*This section covers the administrative procedures through which legislation and regulations are developed, consulted, assessed and adopted.*

### 2.1. Transparency and Access

#### 2.1.1. Do ministries/regulatory agencies in your country maintain a publicly available online database of current laws and regulations? – Click to Select - (if no, please go to 2.1.2.)

If yes, please provide link to website: [ ]

2.1.1.1. Does the database cover laws and regulations issued by all levels of government?

- ☐ Yes
- ☐ No, only partial coverage of laws and regulations issued at the sub-national level (regional and local)
- ☐ No, it only covers laws and regulations issued at the national level
- ☐ The regions maintain their own database
- ☐ Other (please specify): [ ]

2.1.1.2. Does the database cover all regulatory domains?

- ☐ It covers all regulatory domains (food safety, environmental regulations, etc.)
- ☐ Some regulatory domains are better covered than others

Please provide any additional comments: [ ]

#### 2.1.2. Do ministries/regulatory agencies in your country publish a separate *plan of regulations* to be prepared, modified, reformed or repealed in the next six months or more? – Click to Select - (if no, please go to 2.2.)

2.1.2.1. Does the plan cover regulatory changes initiated by all levels of government with regulatory powers (national, regional, local)?

- ☐ Yes – there is one plan covering all regulatory changes at all levels of government
- ☐ No – it is up to the subnational governments to issue their own plans
- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

### 2.2. Consultation

**2.2.1. Do ministries/regulatory agencies in your country *consult* with the general public and/or targeted stakeholders on proposed regulation?** – Click to Select - (if no, please go to 2.2.2.)

2.2.1.1. How are consultations conducted?

- ☐ Feedback requested through a unified website for all proposed regulations  
Please provide link to website: [  ]
- ☐ Feedback requested through the website of the relevant ministry or regulator  
Please provide link to website: [  ]
- ☐ Targeted consultations with business associations and/or other stakeholders
- ☐ Public meetings
- ☐ Other, please specify: [  ]

2.2.1.2. Does the above consultation practice apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of *environmental regulations related to industrial emissions*

Please provide any additional comments: [  ]

**2.2.2. Do ministries/regulatory agencies in your country provide *responses to the feedback* received through consultations?** – Click to Select - (If no, please go to section 2.3.)

2.2.2.1. How are the responses provided?

- ☐ As one consolidated response published online
- ☐ As one consolidated response distributed to all consultation participants
- ☐ Separate responses for each comment published online
- ☐ Separate responses for each comment distributed directly to the author of the comment
- ☐ Other, please specify: [  ]

2.2.2.2. Does the above practice for responding to feedback apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of *environmental regulations related to industrial emissions*

Please provide any additional comments: [  ]

**2.3. Impact Assessment**

**2.3.1. Do ministries/regulatory agencies in your country conduct *impact assessments* of proposed regulations?** – Click to Select - (if no, please go to Section 3.)

2.3.1.1. What impacts are typically assessed?

- ☐ Economic impact
- ☐ Environmental impact
- ☐ Impact on regional development
- ☐ Impact on the public sector (Incl. administrative costs)
- ☐ Impact on the private sector (Incl. administrative costs)
- ☐ Other (please specify): [  ]

2.3.1.2. Are impact assessments made publically available online? – Click to Select -

If yes, please provide link to website: [  ]

2.3.1.3. Does the above practice for conducting impact assessments apply to all regulatory domains?

- ☐ It applies to all regulatory domains

- ☐ There are separate practices in the area of *environmental regulations related to industrial emissions*

Please provide any additional comments: [  ]

### **Section 3: Delivery: Implementation and Enforcement of Regulation**

*This section covers tools and approaches to “making regulation happen”, i.e. the implementation of regulation by regulatory agencies vis-à-vis regulated entities (citizens/businesses). Unless otherwise specified, this sections looks exclusively at implementation of **environmental regulations related to industrial emissions**.*

#### **3.1. Transparency and Communication of Standards and Practices**

**3.1.1. Do ministries/regulatory agencies in your country provide guidance to businesses on how to interpret and implement environmental regulations related to industrial emissions?** – Click to Select - (if no, please go to 3.1.2.)

3.1.1.1. What is included in the guidance? (Select all that apply)

- ☐ Illustrations of how to apply laws/regulations using real examples  
☐ A section with frequently asked questions  
☐ Discussion on the underlying objectives of the regulation  
☐ Other (please specify): [  ]

3.1.1.2. Does the above practice for issuing guidance apply to all regulatory domains?

- ☐ It applies to all regulatory domains  
☐ There are separate practices in the area of environmental regulations related to industrial emissions

Please provide any additional comments: [  ]

**3.1.3. Do ministries or regulatory agencies in your country publish a document explaining the methodologies and approaches used for inspections?** – Click to Select - (if no, please go to 3.1.4.)

3.1.3.1. Which of the following aspects are included in the document

- ☐ How to select businesses for inspection  
☐ Method to be followed by inspectors during inspections  
☐ Method for taking enforcement decisions  
☐ Other (please specify): [  ]

3.1.3.2. Does the above practice for publishing inspection methodologies apply to all regulatory domains?

- ☐ It applies to all regulatory domains  
☐ There are separate practices in the area of environmental regulations related to industrial emissions

Please provide any additional comments: [  ]

**3.1.4. Do ministries/regulatory agencies country provide channels through which industries can submit feedback on the way inspections take place?** – Click to Select - (if no, please go to 3.1.5.)

3.1.4.2. Through which channels can feedback be submitted?

- ☐ Online system. Please provide website address: [  ]  
☐ Hotline  
☐ SMS  
☐ Letter

- ☐ Personal visit to regulator  
☐ Other (please specify): [ ]

3.1.4.3. Do regulatory agencies report (at least periodically) on measures taken based upon the feedback received? – Click to Select -

Please provide any additional comments: [ ]

**3.1.5. Do ministries/regulatory agencies in your country provide any mechanisms to industries through which they can appeal enforcement decisions?** – Click to Select - (if no, please go to 3.2.)

3.1.5.2. Which appeals mechanisms are available?

- ☐ Independent administrative appeals process  
☐ Judicial review (decision reviewed by the judiciary)  
☐ Ombudsman  
☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

### 3.2. Risk Management and Compliance Promotion

**3.2.1. What is required for industries carrying out the following activities to start operating in accordance with environmental regulations related to industrial emissions?**

	No registration, notification or permit needed	Notification of intent to operate to competent environmental authority	One single environmental permit covering all aspects of pollution and environmental hazards	Multiple environmental permits covering different aspects of pollution and environmental hazards
Refining of mineral, oil and gas	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Production of pulp from timber	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Manufacturing of glass	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Production of chemicals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Waste management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dry cleaning (using volatile organic solvents); Footwear manufacture; Vegetable oil extraction and refining activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Slaughterhouse with capacity of less than 50 tons per day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



**3.2.2. How do regulatory enforcement agencies in your country decide on which businesses to inspect?**

- ☐ Inspection is based on a risk assessment of which sectors and businesses that could cause most damage
- ☐ Inspections are conducted based on complaints and incidents
- ☐ A combination of the above
- ☐ Other, please specify: [ ]

Please provide any additional comments: [ ]

**3.2.3. Which enforcement measures are available to *regulatory enforcement agencies*? (Select all that apply)**

- ☐ Oral warning
- ☐ Written warning (officially recorded)
- ☐ Notice of improvement with specific delay
- ☐ Notice of improvement with specific delay *and* temporary suspension of some/all activities
- ☐ Order to withdraw specific goods/services from the market
- ☐ Fines
- ☐ Suspension of license to operate
- ☐ Permanent withdrawal of license to operate
- ☐ Criminal prosecution
- ☐ Other (please specify):

Please provide any additional comments: [ ]

**3.3.4. Is more than one regulatory enforcement agency responsible for food safety inspections in your country? – Click to Select - (If no, please go to section 4.)**

3.3.4.1. If yes, please list the name of the agencies: [ ]

Please provide any additional comments: [ ]

**Section 4: Ex-post Review of the Impact of Regulations**

*This section covers tools to review regulatory performance of existing regulations.*

**4.1. Practices and Requirements**

**4.1.1. Do ministries/regulatory agencies in your country conduct reviews of existing environmental regulations related to industrial emissions? – Click to Select - (if no, please go to 4.2.)**

4.1.1.1. On what basis are these reviews conducted?

- ☐ Periodic ex-post evaluations of existing regulations are mandatory
- ☐ Ex-post evaluations are prompted by “*sunsetting*” clauses in some regulations
- ☐ Other, please specify: [ ]

4.1.1.2. What impacts are typically assessed?

- ☐ Comparison of actual vs. predicted impacts
- ☐ Unintended consequences
- ☐ Achievement of underlying policy objectives
- ☐ Other, please specify: [ ]

4.1.1.3. Are ex-post reviews made publically available online? – Click to Select -

If yes, please provide link to website: [ ]

4.1.1.4. Does the above practice for ex-post reviews apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of environmental regulations related to industrial emissions

Please provide any additional comments: [ ]

**4.1.2. Ex-post review in practice: In the past 5 years, have any major reviews of existing environmental regulations related to industrial emissions been conducted?** – Click to Select -

If yes, please list an example: [ ]

## 4.2. Feedback mechanisms

**4.2.1. Are there any mechanisms through which the public can make recommendations to modify or provide feedback on existing environmental regulations related to industrial emissions regulations?** –

Click to Select - (if no, you have completed this questionnaire)

4.2.1.1. Please specify the channels through which feedback can be provided:

- ☐ Online system
- ☐ Ombudsman
- ☐ Judicial system
- ☐ Petitions
- ☐ Other (please specify): [ ]

4.2.1.2. Do ministries/regulatory agencies use communication materials or conduct public outreach to inform the public about the feedback channels stated above? – Click to Select -

4.2.1.3. Does the above practice for soliciting feedback apply to all regulatory domains?

- ☐ It applies to all regulatory domains
- ☐ There are separate practices in the area of environmental regulations related to industrial emissions

Please provide any additional comments: [ ]

## 4.3. Regional variations

**4.3.1. Are the above practices covered by this questionnaire applied uniformly across the country or are there regional variations?**

- ☐ It applies uniformly to all regions of the country
- ☐ Regions apply different practices

If there are regional differences, please explain: [ ]

Thank you for completing the questionnaire!

For questions or feedback on this questionnaire please contact:

[Name]

[Title]

World Bank Group

Phone:

Email:

## XIV. Annex 11: Weighting of Responses

This annex includes the weights applied to individual responses in the construction of the four sub-indicators of regulatory governance. Where questions vary for food safety and industrial emissions, weights for responses in both regulatory domains are provided.

### 3.1. Transparency and Access

≤ 1		<b>3.1.1. Do ministries/regulatory agencies <i>in your region</i> maintain a publicly available online database of current laws and regulations?</b> – Click to Select - (if no, please go to 3.1.1.3.)
		If yes, please provide link to website: [            ]
≤ 0.5		3.1.1.1. If yes, in what way does the regional database complement database(s) administered by the central government?
	0.5	<input type="checkbox"/> It includes regulation and guidelines issued at the regional level
	0.25	<input type="checkbox"/> It includes complementary guidelines for national-level regulation
		<input type="checkbox"/> Other, please specify: [            ]
		3.1.1.2. Does the above practice of making of laws and regulations available apply to all regulatory domains?
	0.5	<input type="checkbox"/> It applies to all regulatory domains
≤ 0.5	0	<input type="checkbox"/> There are separate practices in the area of food safety regulation
		3.1.1.3. If no, please explain why your region does not maintain a database of laws and regulation
≤ 1		<input type="checkbox"/> Ministries/regulatory agencies in my region do not issue regulation
	1	<input type="checkbox"/> Regulations issued by my region are included in a national database
	1	Please provide link to website: [            ]
		<input type="checkbox"/> There is no systematic practice for maintaining a database of laws and regulations
	0	<input type="checkbox"/> Other, please specify: [            ]
		Please provide any additional comments: [            ]

$\leq 1$	<b>3.1.2. Do ministries/regulatory agencies <i>in your region</i> publish a separate <i>plan of regulations to be prepared, modified, reformed or repealed in the next six months or more?</i> – Click to Select - (if no, please go to 3.1.2.3.)</b>	
$\leq 0.5$	0.25 0.5	3.1.2.1. If yes, in what way does your region's practice vary from the national practice? <input type="checkbox"/> My region communicates its own plan for future <i>regional</i> regulatory initiatives <input type="checkbox"/> My region communicates the <i>national plan with additional commentary on regional implications</i> <input type="checkbox"/> Other, please specify: [ ]
$\leq 0.5$	0.5 0	3.1.2.2. Does the above communication practice apply to all regulatory domains? <input type="checkbox"/> It applies to all regulatory domains <input type="checkbox"/> There are separate practices in the area of food safety regulation
$\leq 1$	1 1 0	3.1.2.3. If no, please explain why your region does not publish a plan for future regulatory initiatives <input type="checkbox"/> Ministries/regulatory agencies in my region do not issue regulation <input type="checkbox"/> My regions' future regulatory initiatives are included in national plans <input type="checkbox"/> There is no systematic practice communicating plans for future regulatory initiatives <input type="checkbox"/> Other, please specify: [ ] Please provide any additional comments: [ ]

## 3.2. Consultation

≤ 1	<b>3.2.1. Do ministries/regulatory agencies <i>in your region</i> consult with the general public and/or targeted stakeholders on proposed regulation?</b> – Click to Select - (if no, please go to 3.2.2.5.)	
≤ 0.2	3.2.1.1. If yes, in what way does your region's practice vary from the national practice? (Select all that apply)	
	0.1	<input type="checkbox"/> Regional consultations are carried out for regulations issued by the region
	0.1	<input type="checkbox"/> Regional consultations are carried out for national laws/regulations on behalf of the central government
	0	<input type="checkbox"/> Regional consultation practices are subject to formal consultation guidelines issued by the region If so, please provide link to website where these can be found: [            ]
	0.1	<input type="checkbox"/> Regional consultation practices are subject to formal consultation guidelines issued by the national government If so, please provide link to website where these can be found: [            ]
	3.2.1.2. How are consultations conducted? (Select all that apply)	
	0.4	<input type="checkbox"/> Feedback requested through a unified website for all proposed regulations Please provide link to website: [            ]
	0.3	<input type="checkbox"/> Feedback requested through the website of the relevant ministry or regulator Please provide link to website: [            ]
	0.2	<input type="checkbox"/> Targeted consultations with business associations and/or other stakeholders
	0.1	<input type="checkbox"/> Public meetings
		<input type="checkbox"/> Other, please specify: [            ]
≤ 0.2	3.2.1.3. Is written guidance on how to conduct consultations available to regulators and the public? – Click to Select - If available online, please provide link to website: [            ]	
	3.2.1.4. Does the above consultation practice apply to all regulatory domains?	
	0.2	<input type="checkbox"/> It applies to all regulatory domains
	0	<input type="checkbox"/> There are separate practices in the area of food safety regulation
	3.2.1.5. If no, please explain why your region does not conduct public consultations for proposed regulation	
	1	<input type="checkbox"/> Ministries/regulatory agencies in my region do not issue regulation
	0	<input type="checkbox"/> There is no systematic practice for public consultation on proposed regulation <input type="checkbox"/> Other, please specify: [            ]
	Please provide any additional comments: [    ]	

≤ 1		<b>3.2.2. Do ministries/regulatory agencies <i>in your region</i> provide responses to the feedback received through consultations?</b> – Click to Select - (If no, please go to question 3.2.2.4.)
≤ 0.2	0.2	3.2.2.1. If yes, in what way does your region's practice vary from the national practice?
	0.1	<input type="checkbox"/> Responses are provided to feedback on <u>regulation issued by regional agencies</u>
		<input type="checkbox"/> Responses are provided to feedback on <u>regulation issued by national agencies</u>
		<input type="checkbox"/> Other, please specify: [            ]
≤ 0.6		3.2.2.2. How are the responses provided?
	0.3	<input type="checkbox"/> As one consolidated response published online
	0.25	<input type="checkbox"/> As one consolidated response distributed to all consultation participants
	0.6	<input type="checkbox"/> Separate responses for each comment published online
	0.6	<input type="checkbox"/> Separate responses for each comment distributed directly to the author of the comment
		<input type="checkbox"/> Other, please specify: [            ]
≤ 0.2		3.2.2.3. Does the above practice for responding to feedback apply to all regulatory domains?
		<input type="checkbox"/> It applies to all regulatory domains
		<input type="checkbox"/> There are separate practices in the area of food safety regulation.
	0.2	3.2.2.4. If no, please explain why your region does not respond to feedback on proposed regulation
	0	
≤ 1		<input type="checkbox"/> Ministries/regulatory agencies in my region do not issue regulation
		<input type="checkbox"/> There is no systematic practice for responding to feedback on proposed regulation
	1	<input type="checkbox"/> Other, please specify: [            ]
	0	Please provide any additional comments: [            ]

### 3.3. Impact Assessment

≤ 1	<b>3.3.1. Do ministries/regulatory agencies <i>in your region</i> conduct <u>impact assessments</u> of proposed regulations?</b> – Click to Select - (if no, please go to 3.3.1.6.)	
≤ 0.2	3.3.1.1. If yes, in what way does your region's practice vary from the national practice? (Select all that apply)	
0.1	<input type="checkbox"/>	Impact assessments are carried out for regulations issued by the region
0.1	<input type="checkbox"/>	Impact assessments are carried out for national law/regulation on behalf of the central government
0	<input type="checkbox"/>	Regional impact assessments are subject to formal impact assessment guidelines issued by the region?
		If yes, please provide link to website: [ <input type="text"/> ]
0.1	<input type="checkbox"/>	Regional impact assessments are subject to formal impact assessment guidelines issued by the national government?
		If yes, please provide link to website: [ <input type="text"/> ]
	3.3.1.2. What impacts are typically assessed?	
	<input type="checkbox"/>	Economic impact
	<input type="checkbox"/>	Environmental impact
	<input type="checkbox"/>	Impact on regional development
	<input type="checkbox"/>	Impact on the public sector (Incl. administrative costs)
	<input type="checkbox"/>	Impact on the private sector (Incl. administrative costs)
	<input type="checkbox"/>	Other (please specify): [ <input type="text"/> ]
≤ 0.6	3.3.1.3. Are impact assessments made publically available online? – Click to Select - If yes, please provide link to website: [ <input type="text"/> ]	
	3.3.1.4. Please list and attach to your response at least three examples of impact assessment on food safety laws/regulations conducted in the past 3 years: [ <input type="text"/> ]	
≤ 0.2	3.3.1.5. Does the above practice for conducting impact assessments apply to all regulatory domains?	
	<input type="checkbox"/>	It applies to all regulatory domains
0.2	<input type="checkbox"/>	There are separate practices in the area of food safety regulation.
0	3.3.1.6. If no, please clarify why your region does not conduct impact assessments of proposed regulation	
≤ 1	<input type="checkbox"/>	Ministries/regulatory agencies in my region do not issue regulation
	<input type="checkbox"/>	There is no systematic practice for conducting impact assessment of proposed regional regulation
1	<input type="checkbox"/>	Other, please specify: [ <input type="text"/> ]
0	Please provide any additional comments: [ <input type="text"/> ]	

≤ 1

**3.3.2. Are there regional or national guidelines for how ministries and regulatory agencies implement EU legislation (either transposing an EU Directive or introducing legislation to implement and enforce EU regulation)?** – Click to Select - (if no, please go to section 4)

If yes, please provide link to guidelines: [ ]

3.2.2.1. What, if any, is included in the guidelines? (Select all that apply)

- ☐ A prohibition to add regulatory requirements beyond EU minimum requirements
- ☐ An obligation to justify any regulatory requirement going beyond EU minimum requirements
- ☐ An obligation to ensure that domestic firms are not put at a competitive disadvantage compared with their European counterparts
- ☐ An obligation to seek to implement EU policies through non-regulatory alternatives where possible
- ☐ An obligation to include a statutory duty for review of the legislation after at least 5 years

Please provide any additional comments: [ ]



## Section 4: Delivery: Implementation and Enforcement of Regulation

This section covers tools and approaches to “making regulation happen”, i.e. the implementation of regulation by regulatory agencies vis-à-vis regulated entities (citizens/businesses). Unless otherwise specified, this section looks exclusively at implementation of **food safety regulation**.

### 4.1. Transparency and Communication of Standards and Practices

$\leq 1$	<b>4.1.1. Do ministries/regulatory agencies <i>in your region</i> provide <u>guidance to businesses on how to interpret and implement food safety regulatory requirements</u>?</b> – Click to Select - (if no, please go to 4.1.1.4)
$\leq 0.2$	4.1.1.1. If yes, in what way does your region’s practice vary from the national practice?
0.2 0.1	<input type="checkbox"/> Implementation guidance is provided for regulation issued by the region <input type="checkbox"/> Implementation guidance is provided for regulation issued at the national level <input type="checkbox"/> Other, please specify: [ ]
$\leq 0.6$	4.1.1.2. What is included in the guidance? (Select all that apply)
0.35 0.125 0.125 0.125	<input type="checkbox"/> Illustrations of how to apply laws/regulations using real examples <input type="checkbox"/> A section with frequently asked questions <input type="checkbox"/> Discussion on the underlying objectives of the regulation <input type="checkbox"/> Other (please specify): [ ]
$\leq 0.2$	4.1.1.3. Does the above practice for issuing guidance apply to all regulatory domains?
0.2 0	<input type="checkbox"/> It applies to all regulatory domains <input type="checkbox"/> There are separate practices in the area of food safety regulation. Please explain: [ ]
$\leq 1$	4.1.1.4. If no, please clarify why your region does not provide implementation guidance on regulation
1 0	<input type="checkbox"/> My region is not responsible for implementation and inspection of regulation <input type="checkbox"/> There is no systematic practice in my region for issuing implementation guidance for food safety regulation <input type="checkbox"/> Other, please specify: [ ] Please provide any additional comments: [ ]

≤ 1		<p><b>4.1.3. Do ministries or regulatory agencies <i>in your region</i> publish a document explaining the methodologies and approaches used for inspections?</b> – Click to Select - (if no, please go to 4.1.3.4.)</p>
≤ 0.2	0.2	4.1.3.1. If yes, in what way does your region's practice vary from the national practice?
	0.2	<input type="checkbox"/> Methods used for inspections <u>conducted by regional agencies</u> are published
		<input type="checkbox"/> Methods used for inspections conducted by regional agencies <u>on behalf of the central government</u> are published
		<input type="checkbox"/> Other, please specify: [            ]
≤ 0.6	0.2	4.1.3.2. Which of the following aspects are included in the document
	0.2	<input type="checkbox"/> How to select businesses for inspection
	0.2	<input type="checkbox"/> Method to be followed by inspectors during inspections
	0.2	<input type="checkbox"/> Method for taking enforcement decisions
		<input type="checkbox"/> Other (please specify): [            ]
≤ 0.2		4.1.3.3. Does the above practice for publishing inspection methodologies apply to all regulatory domains?
		<input type="checkbox"/> It applies to all regulatory domains
	0.2	<input type="checkbox"/> There are separate practices in the area of food safety regulation
	0	Please explain: [            ]
≤ 1		4.1.3.4. If no, please explain why your region does not publish its methodologies used inspection
	1	<input type="checkbox"/> Methodologies are published by the national government
	0	<input type="checkbox"/> There is no systematic practice for publishing methodologies
		<input type="checkbox"/> Other, please specify: [            ]
		Please provide any additional comments: [            ]
		 <b>4.1.4. Do ministries/regulatory agencies <i>in your region</i> provide channels through which food businesses can submit feedback on the way inspections take place?</b> – Click to Select - (if no, please go to 4.1.4.6.)
≤ 1		4.1.4.1. If yes, in what way does your region's practice vary from the national practice?
		<input type="checkbox"/> Feedback is solicited on inspections conducted by regional agencies
≤ 0.2		<input type="checkbox"/> Feedback is solicited on inspections conducted by central agencies
	0.2	<input type="checkbox"/> Other, please specify: [            ]
	0.2	4.1.4.2. Through which channels can feedback be submitted?
		<input type="checkbox"/> Online system. Please provide website address: [            ]
≤ 0.25		<input type="checkbox"/> Hotline
	0.05	<input type="checkbox"/> SMS
	0.05	<input type="checkbox"/> Letter
	0.05	<input type="checkbox"/> Personal visit to regulator
	0.05	<input type="checkbox"/> Other (please specify): [            ]
	0.05	4.1.4.3. Please estimate the annual number of communications of feedback received:
		<input type="checkbox"/> 0
		<input type="checkbox"/> 1-50
≤ 0.15	0.1	
	0.15	

≤ 0.2	<input type="checkbox"/> 51-100 <input type="checkbox"/> More than 100 Please provide any additional comments: [            ]
≤0.2	4.1.4.4. Do regulatory agencies report (at least periodically) on measures taken based upon the feedback received? – <a href="#">Click to Select</a> -
0.2	4.1.4.5. Does the above practice for soliciting feedback apply to all regulatory domains?
≤ 1	<input type="checkbox"/> It applies to all regulatory domains <input type="checkbox"/> There are separate practices in the area of food safety regulation
1	4.1.4.6. If no, please clarify why your region does not solicit feedback on inspection visits
0	<input type="checkbox"/> Regional agencies are not responsible for inspections <input type="checkbox"/> There is no systematic practice for soliciting feedback on inspection visits <input type="checkbox"/> Other, please specify: [            ]
≤1	Please provide any additional comments: [            ]
≤0.2	<b>4.1.5. Do ministries/regulatory agencies <u>in your region</u> provide any mechanisms to food businesses through which they can <u>appeal enforcement decisions</u>? – <a href="#">Click to Select</a> - (if no, please go to 4.1.5.4.)</b>
0.2	4.1.5.1. If yes, in what way does your region's practice vary from the national practice?
0.2	<input type="checkbox"/> The appeals process only cover enforcement decision taken by regional agencies <input type="checkbox"/> The region handles appeals of decisions taken by central agencies on behalf of the central government
≤0.6	<input type="checkbox"/> Other, please specify: [            ]
0.6	4.1.5.2. Which appeals mechanisms are available?
0.6	<input type="checkbox"/> Independent administrative appeals process <input type="checkbox"/> Judicial review (decision reviewed by the judiciary) <input type="checkbox"/> Ombudsman
≤0.2	<input type="checkbox"/> Other, please specify: [            ]
0.2	4.1.5.3. Does the above practice for handling appeals apply to all regulatory domains?
0	<input type="checkbox"/> It applies to all regulatory domains <input type="checkbox"/> There are separate practices in the area of food safety regulation
≤1	4.1.5.4. If no, please clarify why your region does not have its own appeals mechanism
1	<input type="checkbox"/> Regional agencies are not responsible for enforcement decisions <input type="checkbox"/> There is no systematic practice for handling appeals of enforcement decisions <input type="checkbox"/> Other, please specify: [            ]
0	Please provide any additional comments: [            ]

## 4.2. Risk Management and Compliance Promotion

### 4.2.1. What is required for the following categories of food businesses to start operations?

	Mandatory prior inspections and approval of activity license	Simple registration or notice of economic activity (no inspection or approval)	Prior inspections and approval in some cases
Slaughterhouses	0.125 <input type="checkbox"/>	0 <input type="checkbox"/>	<input type="checkbox"/> Please specify
Processing of meat and dairy	0.125 <input type="checkbox"/>	0 <input type="checkbox"/>	<input type="checkbox"/> Please specify
Processing of food of plant origin (fruits, cereals etc.)	0 <input type="checkbox"/>	0.125 <input type="checkbox"/>	<input type="checkbox"/> Please specify
Food warehouses for foods which do not require temperature control	0 <input type="checkbox"/>	0.125 <input type="checkbox"/>	<input type="checkbox"/> Please specify
Bakeries	0 <input type="checkbox"/>	0.125 <input type="checkbox"/>	<input type="checkbox"/> Please specify
Restaurants	0 <input type="checkbox"/>	0.125 <input type="checkbox"/>	<input type="checkbox"/> Please specify
Butchers	0 <input type="checkbox"/>	0.125 <input type="checkbox"/>	<input type="checkbox"/> Please specify
Retail food stores (excluding butchers)	0 <input type="checkbox"/>	0.125 <input type="checkbox"/>	<input type="checkbox"/> Please specify

≤1		<b>4.2.2. How do regulatory enforcement agencies <u>in your region</u> decide on <u>which businesses to inspect</u>?</b>
≤ 0.6	0.6	<input type="checkbox"/> Plans are developed based on a risk assessment of which sectors and business types could cause most damage
	0.4	<input type="checkbox"/> Inspections are conducted based on complaints and incidents
	0.6	<input type="checkbox"/> A combination of the above
		<input type="checkbox"/> Other, please specify: [            ]
		4.2.2.1. If risk assessment is conducted, what type of information is used to inform the risk rating?
		<input type="checkbox"/> Information on business operations (type products produced, material used in production, etc.)
		<input type="checkbox"/> Scale of business operations
		<input type="checkbox"/> Past inspection records
		<input type="checkbox"/> Other (please specify): [            ]
≤ 0.2		4.2.2.2. In what way does your region's practices for planning inspection visits differ from the practices applied nationally?
	0	<input type="checkbox"/> My region has its own inspection planning practices
	0.2	<input type="checkbox"/> My region follows national practices for planning inspections
		<input type="checkbox"/> Other, please specify: [            ]
		4.2.2.3. Does the above practice for planning inspection visits apply to all regulatory domains?
≤0.2		<input type="checkbox"/> It applies to all regulatory domains
	0.2	<input type="checkbox"/> There are separate practices in the area of food safety regulation.
	0	Please provide any additional comments: [            ]
		<b>4.2.3. Which <u>enforcement measures</u> are available to regulatory enforcement agencies <u>in your region</u>?</b> (Select all that apply)
≤ 0.6		<input type="checkbox"/> Oral warning
		<input type="checkbox"/> Written warning (officially recorded)
	0.16	<input type="checkbox"/> Notice of improvement with specific delay
	0.16	<input type="checkbox"/> Notice of improvement with specific delay <i>and</i> temporary suspension of some/all activities
	0.16	<input type="checkbox"/> Order to withdraw specific goods/services from the market
	0.16	<input type="checkbox"/> Fines
	0.16	<input type="checkbox"/> Suspension of license to operate
	0.16	<input type="checkbox"/> Permanent withdrawal of license to operate
	0.16	<input type="checkbox"/> Criminal prosecution
	0.16	<input type="checkbox"/> Other (please specify) : [            ]
	0.16	4.2.3.1. In what way does your region's enforcement measures differ from those applied nationally?
	0.16	<input type="checkbox"/> My region has its own range of enforcement measures
≤0.2		<input type="checkbox"/> My region has the same range of enforcement measures as the national level
	0	<input type="checkbox"/> Other, please specify: [            ]
≤0.2		

<div style="display: flex; align-items: center;"> <div style="width: 40px; text-align: right;">0.2</div> <div style="width: 40px; text-align: right;">0</div> </div>	<p>4.2.3.2. Does the above range of enforcement measures apply to all regulatory domains?</p> <div style="margin-left: 20px;"> <input type="checkbox"/> It applies to all regulatory domains         </div> <div style="margin-left: 20px;"> <input type="checkbox"/> There are separate practices in the area of food safety regulation.         </div> <p>Please provide any additional comments: [            ]</p>
<div style="display: flex; align-items: center;"> <div style="width: 40px; text-align: right;">≤1</div> </div>	<p>4.3. Accountability and Independence of regulatory enforcement agencies</p>
<div style="display: flex; align-items: center;"> <div style="width: 40px; text-align: right;">≤0.2</div> <div style="width: 40px; text-align: right;">0</div> </div>	<p><b>4.3.1. Are regulatory enforcement agencies <i>in your region</i> subject to formal performance reviews?</b> – Click to Select - (if no, please go directly to 4.3.1.5.)</p>
<div style="display: flex; align-items: center;"> <div style="width: 40px; text-align: right;">0.2</div> </div>	<p>4.3.1.1. If yes, in what way does your region's practice vary from the national practice?</p> <div style="margin-left: 20px;"> <input type="checkbox"/> My region has its own practices for reviewing the performance of enforcement agencies         </div> <div style="margin-left: 20px;"> <input type="checkbox"/> My region follow national practices for performance reviews of enforcement agencies         </div>
<div style="display: flex; align-items: center;"> <div style="width: 40px; text-align: right;">≤0.4</div> <div style="width: 40px; text-align: right;">0.4</div> </div>	<div style="margin-left: 20px;"> <input type="checkbox"/> Other, please specify: [            ]         </div>
<div style="display: flex; align-items: center;"> <div style="width: 40px; text-align: right;">0.4</div> </div>	<p>4.3.1.2. Who is responsible for conducting the performance review?</p> <div style="margin-left: 20px;"> <input type="checkbox"/> An internal evaluation unit         </div> <div style="margin-left: 20px;"> <input type="checkbox"/> An independent evaluator (such as the Courts of Accounts)?         </div> <div style="margin-left: 20px;"> <input type="checkbox"/> Other, please specify: [            ]         </div>
<div style="display: flex; align-items: center;"> <div style="width: 40px; text-align: right;">≤0.2 (annually)</div> <div style="width: 40px; text-align: right;">0.2</div> </div>	<p>4.3.1.3. How frequently are the agency performance reviews done? – Click to Select -</p>
<div style="display: flex; align-items: center;"> <div style="width: 40px; text-align: right;">≤0.2</div> <div style="width: 40px; text-align: right;">0</div> </div>	<p>4.3.1.4. Does the above practice for performance reviews apply to all regulatory domains?</p> <div style="margin-left: 20px;"> <input type="checkbox"/> It applies to all regulatory domains         </div> <div style="margin-left: 20px;"> <input type="checkbox"/> There are separate practices in the area of food safety regulation.         </div>
<div style="display: flex; align-items: center;"> <div style="width: 40px; text-align: right;">≤1</div> <div style="width: 40px; text-align: right;">1</div> </div>	<p>4.3.1.5. If no, please clarify why your region does not conduct performance reviews</p> <div style="margin-left: 20px;"> <input type="checkbox"/> Performance reviews are handled by the central government         </div> <div style="margin-left: 20px;"> <input type="checkbox"/> There is no systematic practice for performance reviews         </div> <div style="margin-left: 20px;"> <input type="checkbox"/> Other, please specify: [            ]         </div>
<div style="display: flex; align-items: center;"> <div style="width: 40px; text-align: right;">0</div> </div>	<p>Please provide any additional comments: [            ]</p>
<div style="display: flex; align-items: center;"> <div style="width: 40px; text-align: right;">≤1</div> </div>	<p><b>4.3.2. Can the government (national, regional or local) issue <u>instructions or guidance to the regulatory enforcement agency regarding its decisions</u>?</b>– Click to Select -</p>
<div style="display: flex; align-items: center;"> <div style="width: 40px; text-align: right;">≤0.75</div> <div style="width: 40px; text-align: right;">0.15</div> </div>	<p>4.3.2.1. For which decisions can the government (at any level) issue instructions/guidance?</p> <div style="margin-left: 20px;"> <input type="checkbox"/> Long-term strategy         </div> <div style="margin-left: 20px;"> <input type="checkbox"/> Operational planning         </div> <div style="margin-left: 20px;"> <input type="checkbox"/> Decisions to conduct inspections         </div> <div style="margin-left: 20px;"> <input type="checkbox"/> Individual enforcement decisions         </div> <div style="margin-left: 20px;"> <input type="checkbox"/> Appeals         </div> <div style="margin-left: 20px;"> <input type="checkbox"/> Other (please specify): [            ]         </div>
<div style="display: flex; align-items: center;"> <div style="width: 40px; text-align: right;">0.15</div> </div>	
<div style="display: flex; align-items: center;"> <div style="width: 40px; text-align: right;">0.15</div> </div>	
<div style="display: flex; align-items: center;"> <div style="width: 40px; text-align: right;">0.15</div> </div>	
<div style="display: flex; align-items: center;"> <div style="width: 40px; text-align: right;">0.15</div> </div>	
<div style="display: flex; align-items: center;"> <div style="width: 40px; text-align: right;">≤0.25</div> </div>	<p>4.3.2.2. If the government issues instructions/guidance on individual cases and/or appeals, is there a legal requirement to make these instructions public? – Click to Select -</p> <p>Please provide any additional comments: [            ]</p>

#### 4.4. Institutional integration and coordination of inspection functions

1 (for no)

**4.4.1. Is more than one regulatory enforcement agency responsible for food safety inspections in your region?** – Click to Select - (If no, please go to section 5.)

4.4.1.1. If yes, please list the name of the agencies: [ ]

4.4.1.2. At which level of governments do the regulatory enforcement agencies operate?

☐ Only the national level

☐ Only regional/local

☐ A mix of both

Please provide any additional comments: [ ]

≤1

0.5 for yes (at country level)

**4.4.2. Is there a formal structure or agency with the responsibility of coordinating inspections in your region?** – Click to Select - (if no, please go to section 5)

4.4.2.1. If yes, what aspects of inspection does it coordinate?

☐ Planning and targeting

☐ Methods, practices, enforcement decisions

☐ Information sharing and guidance

☐ Feedback/appeals case management

☐ Other (please specify): [ ]

4.4.2.2. Is there a formal document specifying the role and responsibilities of different regulators? – Click to Select -

4.4.2.3. Is there a joint plan for inspections by all inspecting agencies? – Click to Select -

4.4.2.4. Is there a rule prohibiting re-inspection? – Click to Select -

4.4.2.5. How is information shared across the different agencies?

☐ There is a unified database and information system for inspection planning and record keeping

☐ Some information systems are shared but other differ across agencies

☐ Each regulatory agency uses its own system

If databases/systems are separate: what mechanism are used for information exchange?

Please explain: [ ]

Please provide any additional comments: [ ]

0.5 (unified data base)

## Section 5: Regulatory Coordination and Oversight

*This section covers regulatory coordination and oversight between and across levels of government aimed at ensuring consistency in the way regulation is prepared, consulted and communicated.*

### 5.1. Coordination

<div>≤ 1</div> <div>≤ 0.5</div> <div>0.5</div> <div>0.5</div> <div>0.5</div> <div>≤0.5</div> <div>0.5</div> <div>0.5</div> <div>0.5</div> <div>0.5</div> <div>0.5</div>	<p><b>5.1.1. Are there any formal regulatory co-ordination mechanisms <u>between the national and sub-national governments to ensure regulatory consistency and avoid duplication or conflict of regulations?</u></b> – Click to Select - (if no, please go to section 5.2.)</p> <p>5.1.1.1. What form of coordination mechanism exist?</p> <p><input type="checkbox"/> Network of regulatory agencies from across the country</p> <p><input type="checkbox"/> Coordination committee with representatives from different levels of government</p> <p><input type="checkbox"/> Other (please specify): [ ]</p> <p>5.1.1.2. What aspects of regulatory coordination does the mechanism address?</p> <p><input type="checkbox"/> Consistency - ensure that national and regional regulations are not contradictory</p> <p><input type="checkbox"/> Roles and responsibilities between levels of government (to avoid overlaps)</p> <p><input type="checkbox"/> Inspections and enforcement planning and implementation</p> <p><input type="checkbox"/> Information sharing</p> <p><input type="checkbox"/> Dissemination of innovative regulatory practices across jurisdictions</p> <p><input type="checkbox"/> Other (please specify): [ ]</p> <p>Please provide any additional comments: [ ]</p>
<div>≤ 1</div>	<p><b>5.1.2. Recent regulatory reviews: In the past 3 years, has your region been involved in specific efforts to reduce overlaps of regulation between different levels of government in your country?</b> – Click to Select -</p> <p>If yes, please explain: [ ]</p>

### 5.2. Oversight

<div>≤ 1</div>	<p><b>5.2.1. Is there <u>within your region's government</u> a unit responsible for regulatory oversight and quality assurance across the region?</b> – Click to Select - (if no, please go to section 6)</p> <p>5.2.1.1. What is the name of this unit? [ ]</p> <p>5.2.1.2. What is the organizational location (Governor's Office/ within a certain Department /etc.) of the unit? [ ]</p> <p>5.2.1.3. What functions does this regulatory oversight unit have?</p> <p><input type="checkbox"/> Quality control of impact assessments</p> <p><input type="checkbox"/> Quality control of legal drafts</p> <p><input type="checkbox"/> Training on impact assessment</p> <p><input type="checkbox"/> Monitoring and reporting to Parliament on regulatory reform</p> <p><input type="checkbox"/> Coordination of ex post evaluation for policy revision</p> <p><input type="checkbox"/> Other (please specify): [ ]</p> <p>Please provide any additional comments: [ ]</p>
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## Section 6: Ex-post Review of the Impact of Regulations

*This section covers tools to review regulatory performance of existing regulations.*

### 6.1. Practices and Requirements

≤ 1	<b>6.1.1. Does <u>your region</u> conduct reviews of existing food safety regulations?</b> – Click to Select - (if no, please go to 6.1.1.7.)
≤ 0.1	6.1.1.1. If yes, in what way does your region's practice vary from the national practice?
0.1	<input type="checkbox"/> Ex-post reviews are conducted for regulations issued by regional agencies
0.1	<input type="checkbox"/> Ex-post reviews are conducted on behalf of the central government
	<input type="checkbox"/> Other, please specify: [            ]
≤ 0.2	6.1.1.2. On what basis are these reviews conducted?
0.2	<input type="checkbox"/> Periodic ex-post evaluations of existing regulations are mandatory
0.2	<input type="checkbox"/> Ex-post evaluations are prompted by “ <i>sunsetting</i> ” clauses in some regulations
0.2	<input type="checkbox"/> Other, please specify: [            ]
	6.1.1.3. What impacts are typically assessed?
	<input type="checkbox"/> Comparison of actual vs. predicted impacts
	<input type="checkbox"/> Unintended consequences
	<input type="checkbox"/> Achievement of underlying policy objectives
	<input type="checkbox"/> Other, please specify: [            ]
≤ 0.2	6.1.1.4. Is written guidance on how to conduct ex-post evaluations available to regulatory officials and the public? – Click to Select -
≤ 0.4	6.1.1.5. Are ex-post reviews made publically available online? – Click to Select -
	If yes, please provide link to website: [            ]
≤ 0.1	6.1.1.6. Does the above practice for ex-post reviews apply to all regulatory domains?
0.1	<input type="checkbox"/> It applies to all regulatory domains
0	<input type="checkbox"/> There are separate practices in the area of food safety regulation
≤ 1	6.1.1.7. If no, please clarify why your region does not conduct ex-post reviews
1	<input type="checkbox"/> Ex-post reviews are conducted by the central government
0	<input type="checkbox"/> There is no systematic practice for ex-post reviews
	<input type="checkbox"/> Other, please specify: [            ]
	Please provide any additional comments: [            ]
≤ 1	<b>6.1.3. Ex-post review in practice: In the past 5 years, have any major reviews of existing food safety regulations been conducted?</b> – Click to Select -
	If yes, please list an example: [            ]

## 6.2. Feedback mechanisms

<div>≤ 1</div> <div>≤0.2</div> <div>0.2</div> <div>0.2</div> <div>≤0.35</div> <div>0.35</div> <div>≤0.25</div> <div>≤0.2</div> <div>0.2</div> <div>0</div> <div>≤1</div> <div>1</div> <div>0</div>	<p><b>6.2.1. Are there <u>regional mechanisms</u> through which <u>the public</u> can make <u>recommendations to modify or provide</u> feedback on <i>existing</i> food safety regulations? –</b>  <a href="#">Click to Select</a> - (if no, please go directly to 6.2.1.5.)</p> <p>6.2.1.1. If yes, in what way does your region's practice vary from the national practice?</p> <p><input type="checkbox"/> My region solicits feedback on existing regulation issued by the region</p> <p><input type="checkbox"/> My region solicits feedback on existing regulation on behalf of the central government</p> <p><input type="checkbox"/> Other, please specify: [ <input type="text"/> ]</p> <p>6.2.1.2. Please specify the channels through which feedback can be provided:</p> <p><input type="checkbox"/> Online system</p> <p><input type="checkbox"/> Ombudsman</p> <p><input type="checkbox"/> Judicial system</p> <p><input type="checkbox"/> Petitions</p> <p><input type="checkbox"/> Other (please specify): [ <input type="text"/> ]</p> <p>6.2.1.3. Does your region use communication materials or conduct public outreach to inform the public about the feedback channels stated above? – <a href="#">Click to Select</a> -</p> <p>6.2.1.4. Does the above practice for soliciting feedback apply to all regulatory domains?</p> <p><input type="checkbox"/> It applies to all regulatory domains</p> <p><input type="checkbox"/> There are separate practices in the area of food safety regulation</p> <p>6.2.1.5. If no, please clarify why your region does not solicit feedback on existing regulation</p> <p><input type="checkbox"/> My region does not issue regulation</p> <p><input type="checkbox"/> There is no systematic practice for soliciting feedback on existing regional regulation</p> <p><input type="checkbox"/> Other, please specify: [ <input type="text"/> ]</p> <p>Please provide any additional comments: [ <input type="text"/> ]</p>
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## XV. Glossary

The Glossary contains terms that are used directly in the text of the Questionnaire or which are useful for a more complete understanding of the objectives of the Questionnaire. The terms are defined for purposes of the Questionnaire and may have slightly different definitions in other contexts.

### ***Administrative burdens of regulation***

The costs involved in obtaining, reviewing and understanding regulations, time and costs spent in submission and processing of application for approval, developing compliance strategies and meeting mandated reporting requirements, including data collection, processing, reporting and storage, but *not* the public sector of administering the regulations unless explicitly so defined.

### **Consultation**

The process by which the public's input on laws and regulations affecting them is sought.

### **Cost-benefit analysis**

Process of quantifying costs and benefits of a regulation (over a certain period), and those of its alternatives (within the same period), in order to have a single scale of comparison for unbiased evaluation.

### **Food Business Operators**

Natural or legal persons responsible for ensuring that the requirements of food law and regulation are met within the food business under their control.

### **Framework legislation**

See **Primary legislation**.

### **Impact Evaluation**

Systematic process to identify and quantify important benefits and costs likely to flow from adoption of a proposed regulation or a non-regulatory policy option under consideration. May be based on benefit/cost analysis, cost effectiveness analysis, business impact analysis etc.

### **Inspection**

Visits or checks conducted by state officials (or, in some cases, duly authorized and empowered third parties) on products or premises, or checks conducted on shipments at the border or on goods in country, aimed at verifying compliance with applicable requirements with the goal of securing positive outcomes for the public.

### **Levels of government**

Describes different legal and administrative jurisdictions within a country, such as central government, state or regional government and local governments.

### **License**

See *permit*.

**Local Government**

Refer to the third tier of government within a given nation. It only has control of small geographic area within a given region, such as a municipality, county, city, or town.

**Technical standards and procedures**

Benchmarks set by a regulatory agency, created to enforce the provisions of a legislation, such as a permit or certification.

**National Government**

The highest level of government. It controls the nation as a whole.

**Permit(s)**

Any authorization required to commence activities and operate. The term “permit” includes all licenses, clearances, approvals, certificates, recommendations, authorizations, accreditations and agreements issued by any **regulator** or body with delegated authority. Permits typically impose on businesses and citizens a range of conditions, obligations and rights.

**Pre-consultations**

Consultations on how to deal with a certain issue before a decision to regulate has been taken.

**Primary legislation**

Regulations which must be approved by the parliament or congress. Set out broad principles and high level norms.

**Regulated entities**

Any individual, person, organization, or corporation that is subject to a given food safety regulation.

**Regulatory agency**

Agency, ministry or organization that are given the mandate to design, administrate, and or enforce regulations.

**Regulation**

Means any law or rule of general applicability intended to bind any individuals or companies covered by it – such as subordinated legislation, administrative formalities, decrees, circulars, and directives – in your jurisdiction. The term also includes rules proposed by the government that require final approval by the parliament or other legislative body or by the head of state.

**Regulator**

Agency, ministry or organization that is given a mandate to monitor, report, make and/or administer **regulations**. Includes regulatory agencies and regulatory institutions.

**Regulatory delivery**

“Regulatory Delivery” means *making regulation happen*. It is the use of specific methods or tools that **regulators** use to implement **regulations** that affect businesses and citizens. (In this document, it is essentially a subset of the term “regulatory enforcement and compliance”.) **Regulatory delivery** is often achieved by a direct interface between government and businesses with instruments like **inspections** and **permits/licenses**. But it also includes more indirect methods like self-regulation by businesses,

professional licensing, and promoting compliance through guidance and training. **Regulatory delivery** is a feature of all business- or citizen-facing government functions, regardless of the regulatory area or economic sector. It is also fundamentally affected by government's internal institutions, operations, and policies.

### **Regulatory enforcement and compliance**

Regulatory enforcement includes all activities of government structures (or structures delegated by the government) to ensure compliance with regulations and to address non-compliance. In the broadest sense, regulatory enforcement is intended to achieve positive outcomes (policy objectives), using **regulatory delivery** instruments such as compliance-promotion efforts (information and prevention), **inspections** and all other control activities (e.g. testing, etc.), and follow-up such as sanctions, prosecutions, etc.

### **Regulatory governance**

Describes the inter-related institutions and processes that collaborate in overseeing regulatory systems and providing **regulatory delivery**. Describes the systematic implementation of government-wide policies on how governments use their regulatory powers to produce quality **regulation** within the procedural values of the governing system (such as democratic processes). **Regulatory governance** is grounded in the view that ensuring **regulatory quality** and **regulatory delivery** is a permanent and essential role of government, not a one-off set of improvements, and that institutional capacities should be designed around a clear view of the appropriate use of **regulation** in society.

### **Regulatory management**

Describes the institutions, tools, systems and processes for managing regulatory systems, including regulatory institutions and **regulations**.

### **Regulatory officials**

Civil servants and other officials of institutions that impose and administer **regulation**. Inspectors are an example of regulatory officials.

### **Regulatory policy**

Usually a statement of intent by the government outlining the objectives, principles, processes and ways in which **regulations** will be overseen, delivered, reviewed, reformed.

### **Regulatory quality**

A regulatory framework in which government agencies seek to develop and implement **regulations** and regulatory regimes that are efficient in both a static and dynamic sense in terms of using economic, social, and environmental resources to their greatest value; effective in terms of achieving a clear public policy purpose; transparent; and accountable for results. Quality standards can also include flexibility, since regulatory rigidities in the face of a changing context and need are common and among the main contributors to regulatory failures.

### **Regulatory reform**

A structured process of change applying one or more tools and modalities that improve **regulatory quality**, that is, enhance the performance, cost-effectiveness, or legal quality of **regulation** and formalities. "Deregulation" is a subset of **regulatory reform**.

**Risk**

The likelihood of adverse effects occurring, and the potential severity and magnitude of such adverse effects. Many **regulations** and **regulators** focus on managing and reducing identified **risks** to safety, health and security.

**Risk assessment**

The task of identifying and, preferably, quantifying the types, intensities and likelihood of the (normally undesired) consequences related to a **risk**. **Risk assessment** comprises hazard identification and estimation, exposure and vulnerability assessment and **risk** estimation.

**Risk-based enforcement**

**Regulators** focus **inspection** and enforcement on high-risk activities in order to reduce compliance burdens on low-risk activities.

**Secondary legislation/bylaws**

Regulations that can be approved by the head of government, by an individual Minister or by the Cabinet - that is, by an authority other than the parliament/congress. Specify substantive and procedural regulations for implementing framework/primary legislation. They may specify detailed mandatory technical norms, prescribe the internal structure and organization of specific institutions, detailing steps and requirements in mandatory processes such as approvals.

**Sunsetting**

The automatic repeal of **regulations** a certain number of years after they have come into force.