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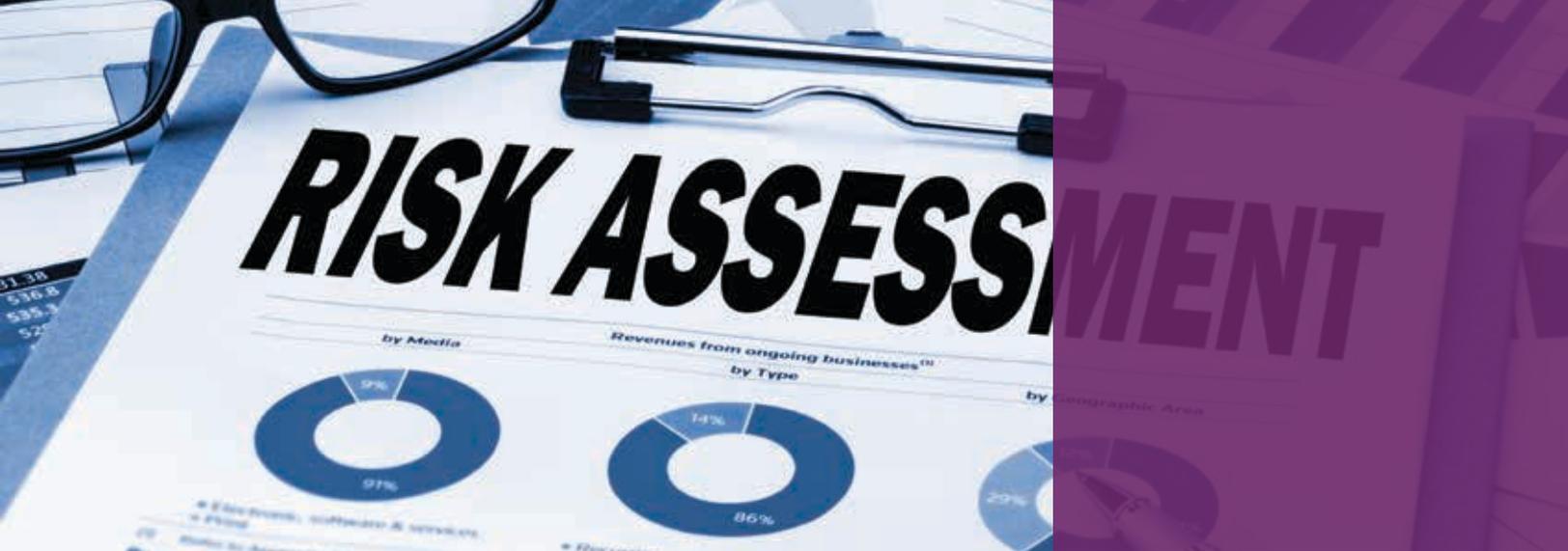
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Introduction

Governments increasingly use risk-based regulation (RBR) to adapt their degree of regulatory control to the actual risks posed by industry sectors, economic activities, and business establishments. Risk-based regulation aims to protect public goods, such as safety, health, and the environment, while at the same time avoiding unnecessary burdens on businesses. Properly implemented, a risk-based approach to regulating businesses meets four objectives:

- To attain public policy objectives, such as promoting the health and safety of the population and protecting the environment by targeting higher-risk businesses.
- To reduce the regulatory burden on low-risk businesses.
- To make better use of scarce government resources.
- To enhance accountability, transparency, predictability, and consistency in decision making.

When designing regulation and developing models for monitoring and enforcement, risk guides assessments of costs and benefits. This note presents

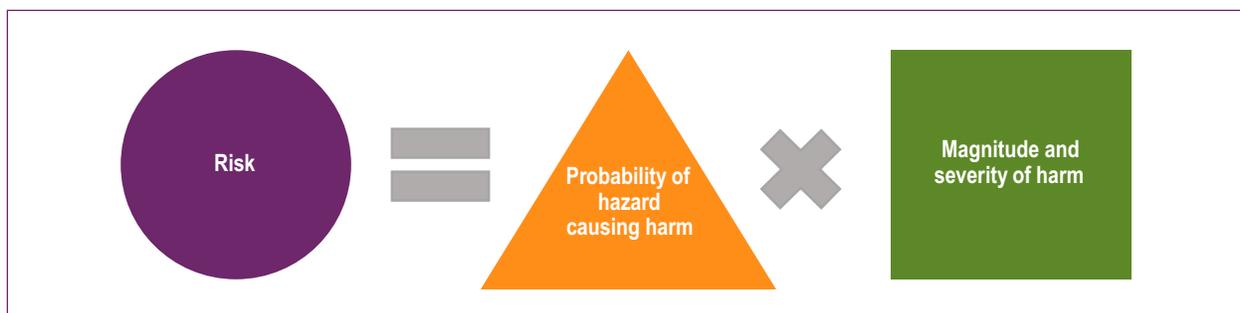
reformers and practitioners with the highlights of an approach to implementing a risk-based regulation system.

Key Concepts and Definitions

Risk combines the probability that a hazard will cause harm and the magnitude and severity of the harm caused if the hazard materializes.

Harm is any form of damage done to people (life, health, property, etc.), to the environment (natural and cultural), or to other public interests (tax fraud harms state revenue). The magnitude of that harm will depend on the scope and nature of damage.

Figure 1. The Definition of Risk



Hazard is any adverse event that may cause harm.

Probability of harm is the degree of likelihood that a hazard will occur that leads to potential harm.

In many advanced countries such as the Netherlands, the percentage of businesses inspected every year by a regulator like the tax service is 5 percent. Similar patterns exist in other EU countries, and reductions in the number of inspections have not resulted in worse outcomes. The challenge for countries is to move from quantity of inspections to quality of inspections as an objective of the risk management system.

The Levels of Risk-based Regulation

RBR can improve efficiency, effectiveness, and transparency in three ways: (1) at the strategic level (when making decisions concerning entire sectors

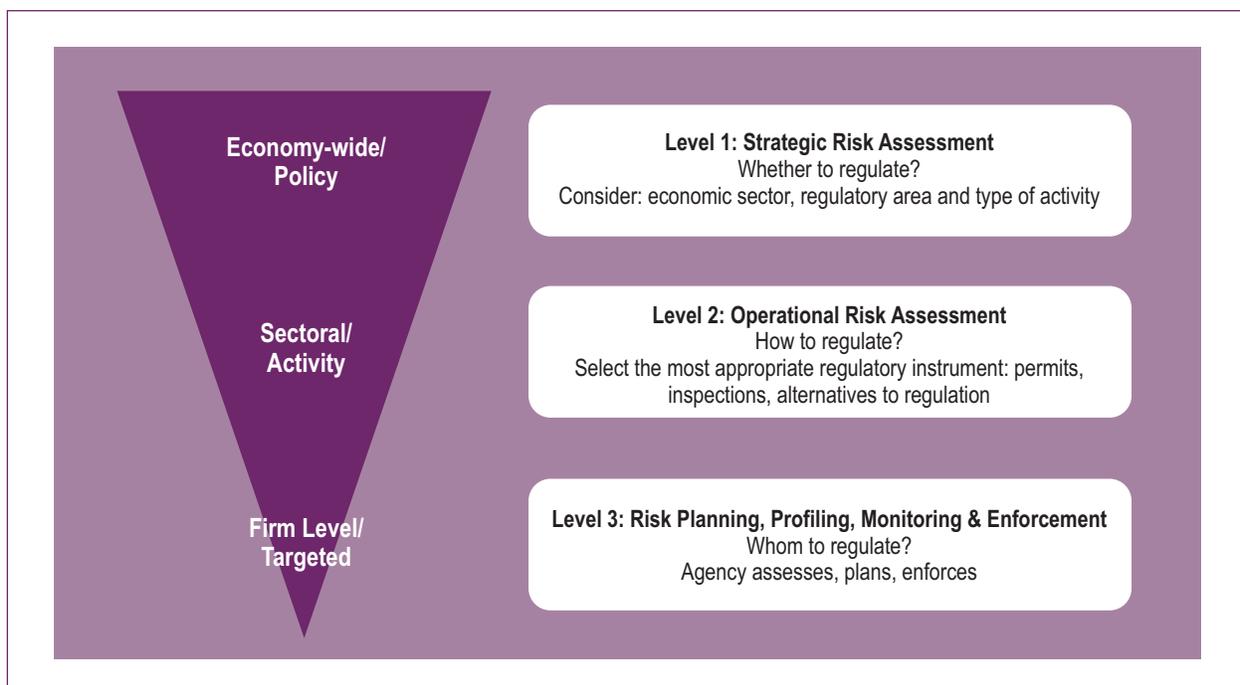
and regulatory domains); (2) at the operational level (through decisions on what instruments to use and which types of operators to focus on); and (3) at the risk planning, profiling, monitoring and enforcement level (by deciding which businesses to regulate and inspect and how to do so).

As described below, the levels of RBR are also useful for government policymakers and regulators to design their response to the Covid-19 pandemic — in terms of response, reopening and recovery.

Level 1: Strategic Risk Assessment — Whether to Regulate

Strategic risk assessment typically occurs in the initial stages of the regulatory life cycle or during a review of existing regulations, when government policy makers and decision makers are actively identifying problems and risks and designing responses. Such evidence-based assessment can inform decisions about the necessity and optimal degree of regulation needed to protect or promote public wellbeing, and it can help determine whether

Figure 2. Levels of RBR and Their Relationships



regulation is necessary for the economic sector (e.g., finance, manufacturing, agribusiness), the regulatory domain (e.g., food safety, occupational or workplace safety, environmental protection), business activity (e.g., shipping cargo, processing food, selling dry goods), or a combination of these (such as occupational safety in a specific sector).

Determining that a sector or activity requires regulation raises an important question: What is the optimal degree of regulatory intervention needed to mitigate the risks to public wellbeing?

To choose a mode of action that will, in total, generate the maximum benefit for the public, the decision maker must consider the activity's benefit, the risk it creates, and the cost of addressing that risk. The following questions are useful when considering risks and reasons for regulation, how best to respond to changing circumstances, and what improvements can be made.

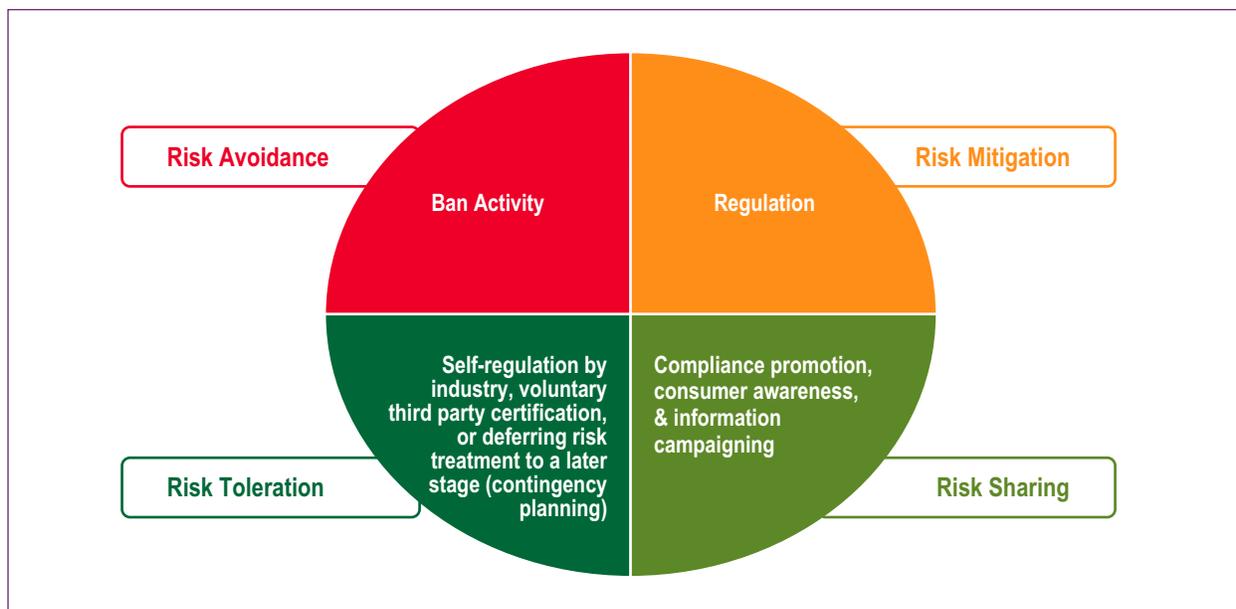
- What are the hazards posed?
- How large/serious/significant are they?
- What is the probability that the hazards will cause harm?
- What is the regulator's risk tolerance?
- What is the level of risk mitigation required?

- What regulatory and nonregulatory responses are available to address risks (e.g., taxes, charges, subsidies, information campaigns, self- or co-regulation, etc.)?
- To what extent can risks be reduced/mitigated using these possible responses?
- What are the costs and benefits of each risk-mitigation option?
- What is the best response to the risk, and how should it be implemented?

Answering these questions allows policy makers to decide on the best response — no action, regulatory solutions, or other alternatives — to the identified risks (see figure 3). For example, consider a regulator who must respond to a new economic activity, such as multisided platforms in the accommodation industry (e.g., Airbnb, HomeAway, ClickStay, Booking.com, etc.). Introducing regulation is only one of the available options, and the approach ultimately taken toward these new business models must be based on the risks they pose to consumers and the public at large. In an RBR system, the regulator first explores the risks arising from the activity and then considers risk-treatment strategies in addition to regulation.¹ One or a combination of risk-treatment strategies may be selected to manage the risks of this new activity.

¹ Taxation and subsidies are used in fiscal policy but may also be included in the category of regulation when, for example, taxation is used to influence consumer habits relating to tobacco and alcohol consumption.

Figure 3. Regulation is One of Several Risk Treatment Strategies



Source: Adapted by the authors, based on the UNECE publication, Risk Management and Regulatory Frameworks: Towards a Better Management of Risks, June 2012.

Level 2: Operational Risk Assessment — How to Regulate

“Operational risk assessment” identifies and selects the optimal intervention and regulatory instruments for managing a risk. Basing regulation on risk means that regulatory agencies can opt for alternative regulatory instruments to promote compliance and achieve regulatory outcomes. These can range from direct or constraining options (such as prior approvals and ex ante inspections) to lighter-touch instruments (such as registration requirements). The operational risk assessment may determine that a business activity or a subset of firms within a business activity pose very low risks, making a different risk treatment strategy more appropriate. In that case, alternatives to regulation, such as information campaigns, can be combined with regulatory responses. The following types of regulatory instruments can be considered as part of operational risk assessment. The instruments, arranged here broadly from greatest to least direct control, are not mutually exclusive and may overlap.

Regulatory instruments:

- **Prior approvals (mandatory ex ante controls):** registration, permits, licenses, inspections
- **Ex post controls:** inspections, audits, regular reporting, maintain compliance with minimum technical requirements
- **Mandatory third-party certification:** standards, self-regulation by industry and professional associations
- **Self-declaration of compliance:** reliance on operators’ liability as a deterrent against fraud (e.g., in EU non-food product regulations for relatively low-risk goods)

Alternatives to regulation:

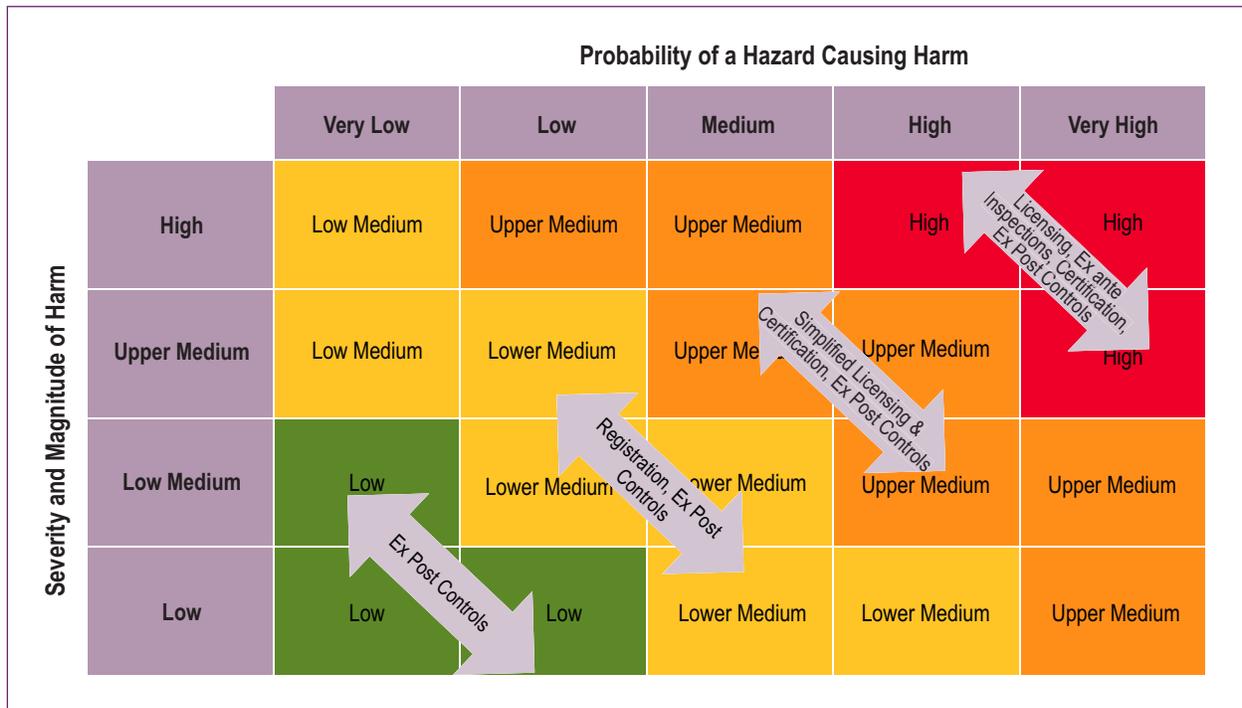
- **Voluntary third-party certification:** nonmandatory standards and self-regulation by industry and professional associations and instruments used for increasing consumer awareness and choice

- **Consumer awareness:** businesses’ public self-disclosure of information; consumer as de facto regulator; voluntary rating/grading schemes and transparency requirements
- **Compliance promotion:** information campaigns directed at businesses

RBR can use a simple but effective risk matrix to determine appropriate regulatory instruments based on the levels of risk identified to the regulators’ objectives (see figure 4). For example, if both the probability of a hazard’s occurrence and its potential severity and magnitude are high (e.g., a polluting factory without proper environmental

safeguards), a more traditional form of government command-and-control may be more appropriate; options might include licensing or inspections with stringent requirements or certifications from a certified third party. If, on the other hand, the likelihood of an adverse event and its potential severity and magnitude are both low, the activity may require only self-certification, perhaps even with no explicit requirements per se beyond those in existing legislation covering the activity (e.g., legislation governing IT firms producing software). Creating a risk matrix need not be a complex exercise. It can be done using research and/or data combined with regulators’ and experts’ experience and benchmarking with international practices.

Figure 4. Risk Matrix to Determine Regulatory Instruments



Box 1. Overhauling Business Licensing Requirements in Greece Through a Risk-Based Approach.

The Government of Greece (GoG), with the support of the World Bank, streamlined business licensing procedures in priority sectors by using a risk-based approach in 2014-2017. The objective was to reform a regulatory system that was mostly based on burdensome ex-ante licensing requirements that were ineffective in safeguarding the public interest, towards a regulatory delivery approach which leveraged both ex ante and ex post tools and was based on risk proportionality. This would lead to a risk-based, transparent, and cost-effective business licensing regime consistent with EU good practice. More than 300 business activities were reformed during the project's first phase in key economic sectors such as food and beverage manufacturing, tourism accommodation, extractive activities, logistics, waste management, and retail service activities which posed potential risks to public health.

The burdens imposed on businesses by the licensing system in Greece had grown exponentially through the years. The licensing system was based on overly prescriptive regulations and was plagued by overlap and duplications among the various line ministries and regulatory agencies. Businesses were required to obtain numerous and overlapping licenses and permits before they were allowed to operate. This included general licenses applied to all businesses irrespective of risk as well as sector-specific licenses. The licensing and inspections systems were not linked nor were they transparent or easily understandable by the private sector.

The GoG, with support from the World Bank, initiated implementation of a risk-based system in 2016 by enacting a new framework law on licensing. The 2016 law introduced risk-based approaches to regulating business activities, introduced risk-based approaches to regulating business activities, a framework for an online unified information management system known as the Integrated Licensing and Inspections Management System (ILIMS), and a framework for third-party conformity assessments as a possible tool to be used as part of the licensing procedure for high-risk activities. The GoG classified economic activities into risk categories by conducting a risk assessment of each economic activity based on its impact on health, safety and the environment, and by benchmarking against European best practice. Based on the law, mandatory licensing requirements could be applied only to specific activities that posed a high risk to public health, safety or the environment. In the case of low risk businesses, the law replaced onerous licensing requirements with a registration by only requiring business owners to notify the municipality through an online platform before commencing their business activity. The "notification" system required business operators to fill out a simple document providing the authorities with key data on their business so that the inspectorates would be able to inform their risk assessments and prioritize inspections.

Barriers to entry were removed by cancelling or streamlining several licenses, most notably the blanket licensing requirements that affected businesses across various sectors (horizontal licenses). Low risk businesses can now start immediately after notifying the government, rather than wait for a license to be issued, which could previously take weeks or several months for some business activities. Lastly, public administration efficiency is improved by allowing regulators to focus their checks on those businesses that present higher risks to public safety and the environment.

Level 3: Risk Planning, Profiling, Monitoring and Enforcement – Whom to Regulate

Risk Assessment

Risk assessment is the process of identifying, analyzing, and assessing the risks posed to regulators' objectives by economic activities, establishments, and products. It provides the means of linking the application of supervisory, monitoring, and enforcement resources to the risk scores assigned to the regulated entities (i.e., products, activities, and establishments). In short, risk assessment means

asking, "What could happen?" and "How serious would it be?"

The following series of steps will lead to a robust risk-assessment system in a given sector or regulatory domain.

Step 1: Set the Strategic Context for Risk Reduction

The regulatory agency must define the desired regulatory outcomes based on the public policy objectives it is mandated by the government to implement (e.g., environmental protection, food

safety, consumer protection, etc.). The starting point for this step is thus to identify the regulatory agency’s mandate.

The key at this stage is to articulate a strategy for the regulatory domain or the economic sector that sets out a clear mission and specific goals measurable by tangible outcomes (e.g., 30 percent reduction in food poisoning incidents by 2025), not outputs (e.g., number of inspections conducted or fines issued). The strategic goals and outcomes for risk reduction must be realistic based on existing levels of compliance. This analysis must be done at the outset and should be reviewed only once a year, except when an event occurs that requires reassessment of priorities; examples include an international public health crisis, such as COVID-19, or a domestic event that suggests the system is failing, such as a major incident involving multiple casualties. This strategy provides the context for the rest of the risk process.

Step 2: Compile a Database of the Regulated Entities (Objects)

The second step entails defining the regulatory agency’s scope of work. The regulatory agency must take stock of all regulated entities that pose a risk to its objectives and that fall within its regulatory mandate

and jurisdiction. The comprehensive database must contain the objects that must be monitored to safeguard against the identified risks and achieve the risk reduction goal. Gaps in information sources must be identified, and ways must be found to mitigate them. Reliable mechanisms for data collection are also needed to ensure that the database is regularly updated.

Step 3: Assess the Risks

The third step, assessment of risks, is composed of a number of sub-steps:

- **Risk identification:** The regulatory agency must identify potential types of hazard as well as the subjects that can be adversely affected by that potential hazard and the resulting harm they may suffer (see figure 5 for examples). A “risk” is the probability of harm occurring, so it is necessary to first identify the hazard to be mitigated. In turn, a hazard must relate to the intent behind the government’s public policy objective, otherwise the harm may be real but unimportant. The starting point is to identify the objective, then the potential hazards to it, and finally the harms that may occur due to those hazards. This identification task can be accomplished using a combination of desk research and operational experience.

Figure 5. Examples of Workplace Hazard Identification and Related Harm Caused

Regulatory Demmain: Occupational Safety		
Workplace hazard	Example of hazard	Example of harm caused
Object	Knife	Cuts
Substance	Benzene	Leukemia
Material	Mycobacterium tuberculosis	Tuberculosis
Source of energy	Electricity	Shock, electrocution
Condition	Wet floor	Slips, falls
Process	Welding	Metal, fume, fever
Practice	hard rock mining	Silicosis
Behavior	Bullying	Anxiety, fear, depression

Source: https://www.ccohs.ca/oshanswers/hsprograms/hazard_risk.html.

- **Risk analysis:** The regulatory agency must match the hazards identified with potential negative consequences and analyze the elements of risk involved. One common approach is to describe the levels of harm for each regulatory domain (e.g., workplace safety, environmental protection, consumer safety) and then to analyze them in terms of the various elements of risk:

- nature of the possible harm
- extent of the possible harm
- probability of harm occurring

In some cases, the elements of risk may be obvious, while in other cases they may require extensive research (e.g., determining the impact of salt on cardiovascular diseases).

- **Develop risk criteria:** The risk analysis will help identify the risks to regulators’ objectives and set the basis for developing criteria relevant to assessing the overall risk posed by the regulated

entities. These criteria can then be used to develop a risk profile for each object. Risk criteria include the intrinsic (or static) characteristics of the regulated entities and acquired (or dynamic) risk criteria (figure 6 provides an example from the tourism industry).

- **Intrinsic (or static) risk criteria** can be used to classify inspection objects into risk groups. These characteristics usually remain unchanged over time, are easily identifiable and known, and can be assigned scores before any inspection is conducted. These include:

- type of activity/processes/equipment
- size of the activity or scope/volume of operations
- characteristics of people and number of people in or near the establishment that may be exposed to risk
- location of the establishment/specific aspects of the building (i.e., basement, high rise, etc.)

Figure 6. Example: A Possible Approach to Tourism Entity Risk Criteria

Intrinsic Criteria			
Facilities within the Establishment <ul style="list-style-type: none"> • Swimming pool • Waterpark • Sports facilities • Bars • Night club • Events • Restaurants 	Public Safety <ul style="list-style-type: none"> • Number of occupants • Indoor smoking • Mechanical hazards • Electrical hazards • Gas storage • LPG tank • Number of floors • Floor area • Building height • Active fire safety systems • Number of fire exits • Pests control 	Food Safety <ul style="list-style-type: none"> • Restaurants selling and preparing food from animal origin • Restaurants selling and preparing food from non-animal origin • Raw foods • Perishable foods • Scale of food management activities • Water sourcing • Alcohol service • Cold storage • Disposable gloves use 	Occupational safety <ul style="list-style-type: none"> • Working conditions • Number of workers • Staff working in heights (e.g. cleaning windows)
Security <ul style="list-style-type: none"> • Checks • Safety measures for occupants 			Location <ul style="list-style-type: none"> • Adjacent to other residential or commercial buildings • Adjacent to a school, Kindergarten, hospital, nursing home
Acquired Criteria			
Record of Compliance <ul style="list-style-type: none"> • Complaints against the operator • Willingness to comply • Ability to comply within the timeframe • Number of violations • Number or value of fines • Frequency of violations 		Other Considerations <ul style="list-style-type: none"> • ISO 22000 • Status of implementation of HACCP or GHP rules • Golden list • Recognition awards • Grade 	

- **Acquired (or dynamic) risk criteria** include those that may change over time and cannot be easily assessed without a site inspection. These include:

- *Availability and adequacy of internal risk management systems/measures.* This can be disaggregated into additional criteria by separately assessing management (e.g., such as competence, technical knowledge, commitment to compliance), and management systems. (Relevant questions for the latter include: Is there an adequate system for managing relevant risks?

Does it include allocation of key responsibilities to staff? Is the system being implemented and monitored? Has the organization adopted management system standards? Has the system been audited by a certified third party?)

- *Compliance profile,* including the object’s compliance history, its attitude toward compliance, and barriers to non-compliance (e.g., awareness, capacity to comply, informal competition, objection to regulations).

Box 2. Tips on Some “Don’ts” in Designing Risk Criteria

- **Avoid lengthy, complicated risk criteria.**
- **Avoid automatically using legal requirements that don’t target the root problem; start with risks, not rules.**
- **Avoid overweighting the size of activity/scope/volume of operations and underweighting the type of the activity.** For example, a very large rewrapping and repackaging establishment will pose lower risks to food and occupational safety than a small slaughterhouse, since inadequate facilities and hygiene at slaughterhouses can result in contamination of meat and occupational hazards to workers.
- **Avoid formulating ambiguous criteria that may be subject to interpretation.** For example, in the context of occupational safety, working at height is a well-established source of hazard. At the same time, since “working at height” is subject to interpretation, it is advisable to define a measurable threshold for this criterion.
- **Avoid classifying too many objects in the high-risk category.** Since finite resources must be prioritized on the high-risk objects, classifying too many objects as high-risk will undermine prioritization.
- **Avoid using criteria where evidence is not robust.** For example, the damage arising from some genetically modified organisms (GMOs) remains a matter of scientific debate. Therefore, using the presence of GMOs as a proxy for risk may be premature.
- **Do not assume that low-risk objects will remain low risk perpetually; risks are dynamic.**

Box 3. Risk-Based Regulation in Jordan

The World Bank Group supported the Government of Jordan in reforming its inspection system based on an RBR approach. The reform connected 14 inspection directorates in the regulatory domains of labor rights, environmental protection, public health and safety, occupational safety and health, food and drugs safety, fire safety and municipal inspections through an Integrated Inspection Management System (IIMS). The objective of the IIMS was to establish a shared registry of objects and subjects, automate inspection procedures, and enable data exchange between the directorates. The RBR reform in Jordan also included developing risk assessments to inform the inspectorates’ inspection planning by identifying intrinsic and acquired criteria. Each criterion was broken down into weights with a clear scoring scheme. This was initially designed using a simple Excel file with formulas that calculated the combined risk score, assigned a risk category (high, medium, low), and frequency of visits for each category. The tools were tested by the inspectorates to ensure they were relevant and yielded realistic outputs. The profile risk criteria were incorporated in the inspection checklist so that inspectors could collect and update this information at each visit. The risk tools were later automated through the IIMS.

- **Risk evaluation:** The last sub-step of risk assessment requires using the risk criteria:
 - To identify the risks that matter in a specific economic sector or regulatory domain, and
 - within a range of risks, to rank them in importance.

Determining the relative importance of each risk criterion is achieved by assigning higher weights to risk criteria that may have greater significance vis-à-vis the severity, magnitude, and probability of harm to the regulator’s objectives. For example, in the environmental protection regulatory domain, industrial use of dangerous chemicals is a source of harm; therefore, raw materials and refined products used in industry can be a risk criterion. At the same time, within the dangerous materials category, some will be more dangerous than others. For example, boiling water can be dangerous since it can result in serious burns or even death, but it is comparatively less dangerous than radioactive material due to the different nature and extent of potential harm posed by the two substances. The purpose of risk evaluation is to assign different scores to each criterion (in this example, radioactive materials and boiling water) and to rank them relative to each other risk criterion. For example, a regulator may determine that the risk criterion “location” is more important than the risk criterion “materials.” A chemical factory operating in a remote rural area poses the same hazards as a chemical factory operating in a peri-urban area, but the latter can potentially cause far more harm because of its proximity to neighboring people and buildings. Weighting thus reveals what is important to the regulator and the regulator’s risk tolerance. These determinations can be supported by a risk

matrix (see figure 4), a simple tool used to increase the visibility and understanding of risk criteria and to assist in decision making.

Step 4: Classify objects into risk categories based on each object’s risk profile

The final step of the risk assessment process is to classify the regulated population into risk categories by building a risk profile using the risk criteria developed earlier. This requires assessing each object on each of the selected criteria to determine the nature of harms posed by each regulated entity and the extent of the harm posed in terms of the number of people affected, the vulnerability of some groups of people or the environment, and so on. These assessments are used by the agency to assign scores to each regulated entity. These scores must then be combined with a score reflecting the probability that the risk will materialize, based on the regulated entity’s compliance profile. The intersection of the potential severity and magnitude of the hazard with the record of the entity’s (non) compliance will determine the estimated risk level for each object. The purpose behind the risk profile is not to see how “hazardous” a business is but how important it is to inspect the business. For example, an oil and gas operation must always be inspected even though it may be extremely well run and have an excellent compliance record. By contrast, a small business, such as a convenience store, may have a poor compliance record but it may not be worth using significant resources to inspect it since the nature of the business may not pose serious risks to the regulators’ objectives. Typically, regulatory agencies use tools such as risk matrices or pyramids to stratify and communicate risk profiling into low-, medium-, and high-risk categories.

Box 4. RBR in the Age of COVID-19

At the time of writing this note the COVID-19 pandemic is sweeping across the globe, posing new challenges to policymakers, regulators and businesses. Although it is still early to predict how the unfolding crisis will play out and what its impact will be on businesses and societies around the world, the need for frameworks that will help regulators prioritize mitigating the threat and reopening the economy becomes even more pertinent. Since regulators must now strike a new balance between the compliance burden on the private sector and the heightened risks to public health and occupational safety, RBR can help assess those risks as science offers more insights on how the virus spreads and how businesses must adapt their operations. RBR can help regulators strike a better balance when shaping new health and safety regulations, when planning their monitoring and enforcement activities, and when reopening their economies. Inspecting each business establishment to ensure compliance with new health regulations and protocols can drain even the most well-resourced institutions. RBR can help regulators prioritize their activities, as well as develop guidance tools for businesses. **During the pandemic**, use of RBR has helped regulators determine which businesses pose the highest risks to public health and consequently issue prohibitions and other restrictions on their operations (this is related to Levels 1 and 2 of RBR described in this paper). **During the reopening**, for example, Ho Chi Minh City, Vietnam has introduced a Scoring System for self-assessment of Covid-19 infection risk by businesses. The self-assessment helps businesses assess the Infection Risk Index (IRI). The IRI will determine whether they can re-open, if adjustments are necessary, or if they need to suspend operations. **After economies have reopened**, the intrinsic (static) and acquired (dynamic) risk criteria of businesses can be monitored to determine whether businesses are in compliance with Covid-19 public health requirements (Level 3 of RBR) and the regulator can take appropriate enforcement action.

Risk-based Planning

“Risk-based planning” builds on the risk assessment phase described above to determine the tools, resources, and level of regulatory control most appropriate to accomplishing the strategic goal for risk reduction.

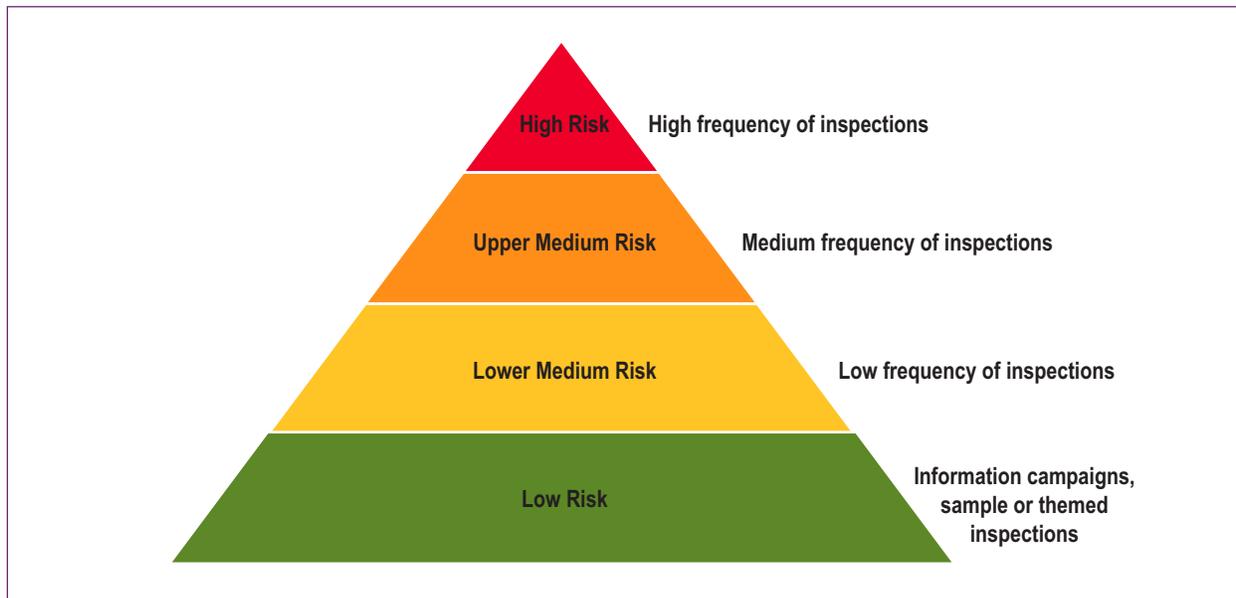
A “risk pyramid” can be a useful classification tool for gaining the high-level perspective needed for risk planning. Regulators can create profiles using any shape they choose; however, the most useful shape is often a pyramid, because it guides the regulator toward targeting a smaller number of the most high-risk entities. The base of the pyramid represents the largest number: the low-risk objects requiring less frequent site-inspections, which can typically be carried out on an audit basis. In some jurisdictions, self-reporting, information provision, and voluntary certification could suffice. The middle levels of the pyramid represent medium-

risk objects that require moderate monitoring, as compared to the low-risk objects. This level may require compliance audits, third-party certification, and a reasonable number of site inspections. The top of the pyramid represents high-risk objects that may require more frequent and thorough monitoring (see figure 7 for an example).

Step 1: Match the number and type of objects of each risk category with available resources

Step 1 requires regulatory agencies to take stock of their resources in terms of number and skills of personnel, equipment, infrastructure, and funding. Doing so will indicate how resources can best be deployed to attain the regulator’s risk reduction goals while limiting the frequency and duration of monitoring activities (e.g., site inspections, complaints management, desk research, archiving, and information sharing).

Figure 7. A Risk Pyramid Stratifying the Regulated Population and Matching Risks to Available Resources



Source: Adapted from Ian Ayres and John Braithwaite, *Responsive Regulation* (Oxford University Press, 1992), p. 3.

Step 2: Develop tools for monitoring and data collection to inform risk profiling and risk-based planning

Regulatory agencies should aim to design an initial risk-based system in such a way as to generate as much data as possible. Gathering additional data will enable the regulator to further refine the framework. Once enough data has been collected, subsequent versions of the risk-based system can require less information from low-risk firms. Some of the main channels for collecting this additional information include (1) existing databases, such as the business registry or an agency’s own registries; (2) proactive strategies, such as checklists that can be used during site inspections; and (3) reactive strategies in the form of a risk-based complaint management system.

- **Existing databases:** Agencies tasked with planning, profiling, monitoring and enforcement can leverage existing databases from other regulatory agencies to improve their intelligence and avoid duplicating efforts. For example, they can use data from existing business registries,

the tax authorities, or other regulators that may have good-quality data on the private sector. This can include data from commercial chambers and professional associations. This type of information can help an inspectorate comprehensively map all objects and subjects in their jurisdiction rather than exclusively relying on site-inspections and complaints. Moreover, if or when other inspectorates develop good-quality databases, these should be shared with other relevant inspectorates and regulatory agencies. The ultimate objective should be to build comprehensive business profiles that integrate information from the business registry, the licensing authorities, and the inspectorates.

- **Risk-based checklists:** Checklists are compliance-assessment tools that guide frontline staff during site inspections, ensuring standardization and consistency in their activities in the regulatory domain; they also help regulatory agencies determine the most appropriate response to mitigate those risks. Checklists help simplify and strengthen the inspection procedure by ensuring that frontline staff focus on the key elements

of compliance and on what are likely to be the main risk areas. In addition, checklists can help raise private sector awareness and compliance regarding the areas on which the objects will be inspected. Finally, checklists can be a useful tool to collect, process, and analyze information in an efficient, reliable, and standardized manner that will inform risk assessments and risk-based planning. By ensuring consistency, checklists serve as especially important tools for less developed systems as well as for mature systems trying to implement RBR.

- **Risk-based complaints management systems:** A common challenge in non-risk-based regulatory systems is that regulatory agencies tend to become reactive and to respond to every complaint received. The solution is to create a system that distinguishes serious complaints that require a response from ones that require no response but are still useful for intelligence and planning purposes.

Box 5. Checklists and Other RBR-Based Reforms in Moldova

The World Bank Group supported the Government of Moldova in implementing a 2011 law that introduced RBR for inspections. This entailed institutional reform that resulted in merger, liquidation and reorganization of the existing 58 inspectorates into 13 inspectorates and 5 regulators, implementation of an Inspections Management System and adoption of risk tools such as risk profiling of industries and firms, inspections planning, risk criteria ranking, complaints management systems and checklists to be used during site inspections. A typical checklist consists of information about the inspector and business subject to inspection, information about the business to determine if the earlier assigned criteria is still valid, a list of questions with assigned weighting, reference to the legal basis for each criterion, a scaling table to assign rating, and a list of relevant normative acts. Each inspectorate developed separate checklists for inspecting businesses operating in different areas within a sub-sector. For example, the Ministry of Agriculture, Regional Development and Environment developed checklists of businesses that fall under the supervision of the Food Safety Agency, such as separate checklists for vet chemists, vet warehouses, alcohol production, wine production, poultry production, cattle farming, pig breeding, production, import, sales and storage of plant protection products and fertilizers. The use of checklists reduced the duration of inspections since both inspectors and businesses understood what the inspector needed to check. Checklists also brought discipline and structure in place of discretionary decision-making.

Benefits from the implementation of RBR were the following:

- Average frequency of inspections per company was reduced by 55% - from 5.15 to 2.3.
- Average duration of an inspection was reduced by 41% - from 1.35 to 0.79 days.
- Annual number of days for all inspections per business was reduced by 70% - from 6.05 to 1.81 days

Ultimately, it was calculated that private sector firms were saving USD 5.4 million per year in compliance costs savings and 41,883 firms have benefited from the inspections reform, of which an intrinsic and critical part was the RBR component.

Step 3: Revise the risk criteria and risk planning when/if necessary

Risk assessments should not be treated as static X-rays but rather as dynamic tools that must be constantly updated and refined. The regulatory agency must prioritize data collection and embed

intelligence gathering in all its operations, from site inspections to desk research to complaints management. In good-practice RBR systems, the regulatory agency will access data from other agencies, including where relevant, information on public good outcomes.

Enforcement Management Models in Risk-Based Frameworks

The ultimate purpose of enforcement is to ensure that businesses prevent harm by effectively managing the immediate and most serious sources of risk; to promote sustained compliance; and to hold businesses accountable in cases of sustained or severe non-compliance. Frontline staff must consider several factors before deciding on an enforcement action (e.g., a financial penalty), such as the violator’s compliance history, previous enforcement actions imposed on the business, the severity of the violation, and the associated degree

of risk, among others. Consequently, consistency is important in enforcement action decisions. This can be achieved through an Enforcement Management Model (EMM). EMM refers to the decision-making frameworks regulatory agencies should follow to identify enforcement actions in the event of verified non-compliance. EMM can help management monitor the fairness, transparency, and consistency of enforcement decisions; support experienced inspectors in making decisions in complex cases; and guide less experienced frontline staff. Overall, a robust EMM can support consistent, transparent, proportionate decision making through standardized criteria and enforcement procedures. In turn, this

Box 6. Principles of a Robust Enforcement Management Model²

- Enforcement actions must be effective in achieving compliance and risk control.
- Enforcement actions must be proportionate to the risks posed to the regulator’s objectives by the non-compliance event.
- Decisions on enforcement actions must be transparent and justified. Businesses subject to an enforcement action must be informed why the regulator reached that decision.
- Enforcement actions must be consistent in their approach. Consistency must not be interpreted as uniformity, however, but as the agency’s use of a similar approach in similar circumstances.

promotes accountability for frontline staff as well as efficiency, impartiality, and fairness in enforcement decisions.

Step 1: Set out the principles for enforcement decisions and the available enforcement actions

Implementation of a risk based EMM requires moving away from a highly prescriptive sanction system. This can be achieved by introducing general categories of enforcement actions through regulation, such as a framework law on inspections,

or by amending existing regulations on sanctions. The five broad categories of enforcement actions, ranging from less to more severe and from more common to less common, are captured in figure 8.

Step 2: Develop the EMM

The EMM can be operationalized through decision-making frameworks (for example, decision trees) that guide the enforcement process. These decision trees should aim to combine information collected during the monitoring process — for example, through a

² According to the U.K. Health and Safety Executive’s Enforcement Policy Statement, “Proportionality means relating enforcement action to the risks. Those whom the law protects and those on whom it places duties (dutyholders) expect that action taken by enforcing authorities to achieve compliance or bring businesses to account for non-compliance should be proportionate to any risks to health and safety, or to the seriousness of any breach, which includes any actual or potential harm arising from a breach of the law. In practice, applying the principle of proportionality means that enforcing authorities should take particular account of how far the business has fallen short of what the law requires and the extent of the risks to people arising from the breach.”

Figure 8. A Robust Enforcement Management Model Supports Inspectors through a Variety of Enforcement Actions and Standardized Decision-Making Frameworks



Note: This is a simplified model; e.g. repeated medium violations may justify a financial penalty.

site inspection to determine the seriousness of the non-compliance and the associated degree of risk — with contextual factors. These may include the business’s relevant incident history, if any. In cases where the business has had a previous enforcement action for the same violation, regulators should determine if the operator has the capacity to comply but purposefully circumvents the requirements for economic gain or if it demonstrates the willingness and ability to cooperate and takes concrete steps to mitigate the non-compliance.

Risk-Based Regulation Maturity Model

Risk-based regulation can be implemented by governments at various stages of development and to varying degrees. As mentioned above, risk-based regulation is typically linked to licensing and inspections systems and therefore the implementation of licensing and inspections reforms often determines the stage of maturity of the RBR reform. A Maturity Model (see table 1) presents the stages for reform to assist reformers in sequencing and prioritizing reforms for levels 2 (operational) and 3 (planning, profiling, monitoring and enforcement). The Model will not always be

the same even in the same country as different regulatory agencies will be at different development stages.

The framework in table 1 below presents four generations of RBR:

- **Initial (“zero”) level:** no risk-based approach. These exhibit overlap and duplication, prescriptive regulation, no systematic data collection, low capacity, and lack of information.
- **First generation of reforms:** foundations for RBR. This generation exhibits some clarified mandates, basic strategy, data-collection system, classification according to business objectives, some technical expertise, basic risk-assessment methodology, basic checklists, and publicly available information.
- **Second generation of reforms:** applying RBR in some sectors/domains. RBR principles and risk models have been piloted or implemented in a number of regulatory agencies; long-term strategy, clear mandates, information sharing, and collaboration exist among regulatory agencies; standardized tools are deployed for risk assessments, checklists, and so on; information communications technology (ICT) is in widespread

use; and performance management, complaints management, and enforcement management are developed.

- **Third generation of reforms: implementing a comprehensive RBR system.** Related domains to apply RBR are integrated; risk assessments have been designed based on numerous sources

of data; business profiles are comprehensive, with static and dynamic characteristics; key performance indicators are based on outcomes; risk models are used, including application of new technologies; risk-based enforcement management modules have been adopted; and ICT is extensively used to support all monitoring and enforcement functions.

Box 7. Some Caveats to Applying RBR

Implementation of risk-based systems requires developing the overall maturity of a licensing and inspections system over time (see section below on the maturity model for RBR). Reformers who attempt to introduce elements of RBR without first ensuring their reforms' solid foundations risk failing to reap the benefits the approach offers. For example, the starting point for improving an inspections system plagued by overlap and duplication is NOT to introduce risk assessments and risk-based checklists. Rather, the starting point should be to address those overlaps through institutional reform, legal reform, or governance tools (e.g., cooperation agreements) to clarify the mandates and mission of the various inspectorates, align their mission with risks, consolidate inspectorates where necessary to improve efficiency and effectiveness, and ensure integration of the new institutions at the operational level. Using the maturity model described in table 1, it is possible to assess the current licensing and inspections system and sequence reforms to implement an RBR system.

Nevertheless, RBR has a role even in the most challenging environments, including fragile and conflict-affected countries. For example, RBR can introduce a systematic methodology for ensuring public health and safety while reducing burdens on low-risk businesses; guide decisions on what data is necessary for evidence-based decision making at all levels of government; reduce discretionary decision making by requiring justification for inspection targeting and regulatory enforcement; and provide a framework for prioritizing regulatory enforcement decisions.

Note: All previous generations of reforms are assumed to be incorporated into the next more advanced level.

Table 1. Risk-based Regulation Maturity Model

Text in purple relates to level 2: selection of regulatory instruments and licenses.

Text in green relates to level 3: inspections, monitoring & enforcement.

	Weak Regulatory Compliance System	First Generation Reforms: Introducing Foundations for RBR	Second Generation Reforms: Applying RBR in Some Sectors/Domains	Third Generation Reforms: Implementing a Comprehensive RBR System
Institutional Framework	<p>Overlap & duplication are prevalent between the regulatory authorities.</p> <p>Inspectorates' missions are overlapping, and there is no coordination.</p>	<p>Mandates between some regulatory authorities are clarified in some regulatory domains and/or economic sectors.</p> <p>Institutional framework for inspection functions is coordinated and consolidated to remove overlaps and duplications.</p>	<p>Mandates between most regulatory authorities are clarified in most regulatory domains and/or economic sectors.</p> <p>Conformity assessments by certified third parties are introduced as a possible tool as part of the licensing procedure (e.g. for high risk activities).</p> <p>Information sharing between some inspectorates and planning of joint inspections.</p> <p>Agreements between regulatory agencies to regulate information sharing and collaboration (e.g., Memoranda of Understanding or Standard Operating Procedures).</p>	<p>Mandates between all regulatory authorities clarified based on regulatory domains and/or sectors.</p> <p>Integration, consolidation, or merger of food, environmental protection, occupational safety, public health, and border inspection management (for phytosanitary, veterinary, and sanitary inspections).</p>
Legal Framework	<p>Legal framework is fragmented and overly prescriptive.</p> <p>All or most business activities require ex ante authorizations.</p> <p>There is no standardized classification of business activities.</p> <p>The legal framework on inspections is unclear; overlaps and duplication are prevalent.</p>	<p>A framework policy or law on licensing or a consolidated law on licensing and inspections is available and has introduced principles for RBR. And/or a legal act on RBR may have been adopted by an agency.</p> <p>A classification of business activities is being used by some regulatory authorities.</p> <p>A framework policy or law on inspections or a consolidated law on licensing and inspections is available and has introduced RBR principles.</p>	<p>Implementing regulations for regulatory domains or economic sectors are reformed consistent with RBR principles and guidelines.</p> <p>A classification of business activities is being used by all regulatory authorities and is based on an international standard (ISIC, NACE, NAICS, SIC, etc.).</p> <p>Legal framework on all aspects of enforcement (i.e., sanctions) is reformed consistent with RBR principles.</p>	<p>New regulations are designed based on scientific evidence, technical experts' opinions, inspectors' inputs, and data.</p> <p>Continuous improvement of sector regulations by involving the inspectors through a consultative process.</p>

Strategy	A long-term strategy for achieving the objectives of the regulatory agency does not exist.	Long-term strategy for achieving the objectives of the regulatory agency is available, but it is not well articulated, with specific mission, goals, and key performance indicators (KPIs).	Long-term strategy includes a specific mission and goals. KPIs are not well developed or they are based on outputs instead of outcomes.	Long-term strategy includes a specific mission, goals, outcomes, and objectives. KPIs are based on outcomes.
Data Collection & Reporting on Inspections	There is no systematic collection and analysis of data on businesses.	There is a recording and reporting mechanism to systematically collect data on inspections and generate statistical reports for analysis. Registry of inspection subjects (business entity/ entrepreneur) and objects (location/facility) classified according to business activities.	Improved reporting available on inspections and tracking of KPIs. ICT module that allows recording of inspection outcomes in a systematic manner has been developed.	A comprehensive business profile that integrates information from the business registry, the authorities issuing licenses, and the inspectorates has been adopted. Document and workflow systems are fully automated.
Human Resources	Regulatory agencies are not familiar with risk-based principles. Inspectorates have limited capacity, and staff are not assessed on their competence.	Inspectors receive training and acquire technical expertise on the regulatory domain and/or economic sector they are tasked with supervising.	Inspectors receive advanced training and have technical expertise in the regulatory domain and/or economic sector they are tasked with supervising as well as in risk-based approaches. Inspectors are audited to contribute to Continuous Professional Development in core competencies. ICT module on management of inspectors' competencies to map which inspector is more appropriate to inspect each subject/object.	KPIs are developed to measure the inspectors' performance in achieving compliance objectives based on core skills, such as risk assessment, understanding of regulated subjects, compliance promotion, proportionality, and adequacy of inspection measures.

<p>Risk Assessments & Inspections Planning</p>	<p>Regulations are not being designed based on risk.</p> <p>There is no registry of regulations, and there is no risk assessment or inspections planning.</p>	<p>Risk assessments are being used to determine the most appropriate approach to regulating business activities (registration, licensing, technical requirements).</p> <p>A basic inspection planning functionality allows inspectorates to use simple criteria to generate lists of businesses and locations for inspections.</p> <p>A registry of up-to-date regulations applicable to each regulatory domain is available.</p> <p>Basic checklists for compliance have been developed.</p>	<p>Risk models are developed for each regulatory domain (identifying risk categories, risk indicators, and weights).</p> <p>An ICT module to simulate risk-models has been developed.</p> <p>Risk-based inspection checklists have been developed.</p> <p>The registry of inspection subjects/objects and inspection history and complaints were used to develop a basic risk-based inspection planning functionality.</p>	<p>Risk-based inspection planning is based on risk models.</p> <p>Risk models experiment with predictive elements by leveraging new technologies such as AI (artificial intelligence).</p>
<p>Complaints Management & Enforcement Management</p>	<p>No complaints or enforcement management takes place.</p>	<p>A complaints management system has been implemented to efficiently manage inspections and prioritize complaints.</p>	<p>Enforcement management has been reformed based on RBR principles. Operational manuals are available to support inspectors in decision making on enforcement actions.</p>	<p>An ICT module for decision support on enforcement management is available.</p>
<p>Transparency</p>	<p>Information on ex ante authorizations and technical requirements to operate a business is not publicly available.</p> <p>Information on inspectorates' mission, goals, and performance is not publicly available. Information on compliance promotion is not publicly available.</p>	<p>All issuing authorities publish basic information on ex ante authorizations and technical requirements related to their regulatory domain/mandate, but this information may be fragmented and/or uneven.</p> <p>A public inspection portal is available to publish summary inspection reports and to receive feedback from the private sector.</p>	<p>All issuing authorities publish detailed information on ex ante authorizations and technical requirements related to their regulatory domain/mandate, but this information may be fragmented and/or uneven and not client-centered.</p> <p>Inspection checklists are published online.</p> <p>Grievance and redress/appeals management is available.</p>	<p>All relevant information on ex ante authorizations and technical requirements is available online through an authoritative resource. This information is standardized, and the database can provide entrepreneurs with tailored information.</p> <p>Client-facing checklist and guidance modules are available that allow businesses to carry out risk self-assessments.</p>

Other Key Considerations

ICT Solutions

Information communications technology (ICT) solutions are critical to implementing RBR systems, especially at the planning, profiling, monitoring and enforcement level. ICT solutions range from simple Excel lists with static criteria to simple websites that allow low-risk businesses to notify authorities and automatically register their activity to comprehensive technology solutions that support the entire life cycle of inspection activities. The latter type of solution is known as an Inspection Management System (IMS).

Basic IMS includes a registry of inspection subjects (legal entities) and objects (physical locations) classified according to business activities; a registry of regulations applicable to each regulatory domain; and modules to support systematic reporting and recording mechanisms for inspections findings. Intermediate solutions include modules that support risk-based inspections planning, complaints management, and risk model simulations. IMS may also include front-end capabilities, such as public inspection portals for publishing summary inspection reports to improve transparency, online channels to submit complaints and appeal enforcement decisions, and basic mobile inspection capabilities. Advanced systems can integrate inspection practices across multiple inspectorates and risk-based inspection planning and risk modeling; some modules support decision making on enforcement management, fully fledged document and workflow systems, automated or real time integration with other information sources such as registries, and performance management capabilities enabled through business analytics. Lastly, comprehensive ICT solutions such as IMS can also include procedures for licensing and registration, to offer the entire lifecycle of regulatory compliance, through Integrated Licensing Management and Inspection Systems.

The key benefits of ICT for RBR include (i) the ability to create registries of regulations and regulated entities; (ii) improved targeting through

a better identification and follow up of risks; (iii) lower administrative burdens for businesses and entrepreneurs to comply with regulations; (iv) increased quality and effectiveness of inspections leading to higher compliance; (v) improved internal efficiency and reduced administrative costs for governments; and (vi) increased transparency of inspection operations for businesses, leading to fewer opportunities for corruption. Implementation of ICT solutions, however, may incur significant expenses, require training, and pose challenges for retaining expertise.

In addition to the benefits of ICT, research shows that introducing an inspection management system, especially one shared across various inspectorates, can help institutionalize many of the good practices required for effective business inspections.

Implementing an RBR Project

Reformers can take several broad, sequential steps to successfully implement RBR projects.

1. Diagnose the licensing and inspections system; assess whether the system is mature enough to implement an RBR approach.
2. Communicate the RBR concept and the merits of the approach to key stakeholders.
3. Identify a champion who can spearhead an RBR approach and raise awareness and obtain buy-in from other agencies relevant to making it work.
4. Introduce RBR in a framework law or regulation.
5. Introduce ICT solutions to support implementation of RBR tools.
6. Support the client with guidelines on how to implement the law in operations, from developing risk assessments and risk classification systems to enforcing rules.
7. In an inspections project, it is possible to go more deeply into sectors and develop vertical modules for risk assessments.

