Risk-Based Regulation Guidelines for Public Bodies in Zambia

BRRA

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Finance, Competitiveness & Innovation

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Acronyms

EMM	Enforcement Management Model
GoZ	Government of the Republic of Zambia
HC	Higher Committee
HSE	Health and Safety Executive
ICT	Information and Communication Technologies
ILIMS	Integrated Licensing and Inspection Management System
MoITS	Ministry of Investment, Trade, and Supply
OECD	Organisation for Economic Cooperation and Development
RBR	Risk-based Regulation
RIA	Regulatory Impact Assessment
WB	World Bank
WTO	World Trade Organisation

Glossary

Harm	It is any form of damage done to people (life, health, property, etc.), to the environment (natural and cultural), or to the other public interest (tax fraud harms state revenue). The magnitude of that harm will depend on the scope and nature of damage.
Hazard	It is any adverse event that may cause harm.
Probability of harm	It is the degree of likelihood that a hazard will occur that leads to potential harm.
Public body	The Government, any Ministry or Department of the Government, a local authority, parastatal, board, council, authority, commission, or other body appointed by the Government, or established by or under any written law, excluding a professional association or body.
Regulatory Impact Assessment (RIA)	It is a process of systematically identifying and assessing the expected effects of regulatory proposal using a consistent analytical method such as benefit cost analysis.
Risk	It combines the probability that a hazard will cause harm and the magnitude and severity of the harm caused if the hazard materializes.
Risk likelihood	The possibility of a potential risk occurring, interpreted using qualitative values, such as low, medium, or high.
Risk management	It is the identification, assessment, and understanding and treatment of risks through a coordinated and economical application of resources to minimize, monitor, and control the probability and/or impact of unintended events or to maximize opportunities.
Risk tolerance	This is the threshold to go beyond which is unacceptable to the regulatory agency or public body.

Introduction

Managing risk in an adequate and proportionate way in the regulatory process and for regulatory purposes is essential for regulatory agencies and public bodies in Zambia. In today´s world having capacities to identify and manage risks is a need for most institutions, which should also follow certain principles, so they adopt good practices as part of their regulatory design and enforcement procedures.

These Principles and Guidelines elaborate a vision for regulatory agencies and public bodies in Zambia to incorporate a risk-based approach to the way they regulate. They provide a set of Principles that public bodies should adhere to as part of their efforts to better regulate and ensure that their regulatory interventions are of high quality. The Guidelines then complement the Principles by providing additional detail on how public bodies could reach a stage where they put them in practice.

The Principles and Guidelines are not exhaustive, but they cover key states of the regulatory process. They offer an initial step to move towards a more cost-effective, proportionate, and targeted way to address risks. They set the ground for regulators to adopt innovative approaches, new tools and adequate practices, so they can be more effective in their decisions and ensure that the public and public goods are properly protected.

Nine Risk-based Regulation (RBR) Principles to be followed by Public Bodies in Zambia

In an evolving and challenging environment, where risks have had great impact on the way governments act and usually impose severe costs to the society, public bodies should consider the integration of a risk-based approach to ensure they handle them properly. Many countries are moving towards regulatory interventions that are supported by risk-based principles and tools, as risks are an integral part of doing business in the public sector and their management is critical to the achievement of government´s goals and government responsibilities.

The Government of the Republic of Zambia, in its efforts to improve regulatory outcomes and ease the doing of business, promotes the use of Risk-based Regulation (RBR) by public bodies to adapt the degree of control to the actual risks posed by industry sectors, economic activities and business establishments.

The following set of RBR principles should be promoted and applied by public bodies in Zambia. They are intended to support regulatory activity in a more effective and efficient way, to better use existing resources and to focus control activities in those activities and sectors where evidence shows it is necessary doing it. The benefits of embracing RBR principles will translate in more targeted interventions that result in better outcomes.

1) Integrate the use of Risk-based Regulation in your regulatory activities, from design, implementation, enforcement, and monitoring.

Regulators are responsible for realizing policy objectives. Such responsibility requires that they intervene when there is clear need to do it and to focus on sectors, activities and businesses that pose the highest risks to those objectives (e.g., environmental protection, food safety, occupational health & safety etc.).

The use of RBR is therefore important and necessary. Regulatory agencies and public bodies in Zambia should include a RBR approach from the initial stage of regulatory design and formulation to the implementation, enforcement, and monitoring of regulations. RBR should be promoted at all stages of the regulatory process, which requires a constant understanding of risks, their assessment, and innovative solutions to address them.

2) Train technical and legal staff on risk management to be used when regulating.

Having technical and managerial capacities to implement a RBR approach is important for a successful outcome. Regulators should encourage and support capacity-building activities that can expand the knowledge and expertise on RBR approaches and tools in their institutions. This will facilitate the incorporation of such an approach in the day-to-day activities of regulators.

Exchanging experiences among Zambian regulators can also be a way to develop capacities. Dissemination of good experiences and practices should be promoted within the Zambian administration.

3) Engage with stakeholders to identify and treat regulatory risks.

Risk analysis and risk management require the engagement and communication with stakeholders. This allows regulators to assess properly the impact of a new regulation and decide how to handle it. Any RBR approach should also be supported by evidence, which in most cases requires feedback from stakeholders, those that potentially may be affected by risks.

In the regulatory process, early engagement with different stakeholders is essential for a good regulatory outcome. Zambian regulatory agencies and public bodies should promote early participation of relevant groups (e.g., businesses, professional and industry associations, NGOs, consumers, etc.) when designing regulations and should encourage constant communication with stakeholders and to the public on the way risks should be treated.

4) Ensure transparency along the regulatory process that identifies and manages risks.

Transparency plays a key role for a successful implementation of a RBR approach. Any regulatory intervention needs to be designed in a participatory and open way. Solutions, mitigation efforts, obligations and requirements imposed to businesses and consumers should also be made public and communicated in a timely manner.

In Zambia, key documents and information about the regulatory process should be made available to stakeholders. They need information so they can also make decisions and better understand the way the public interest is defined, treated, and protected.

5) Promote inter-institutional coordination when dealing with risks in the regulatory process.

Risks do not occur in a vacuum. They generally create a variety of impacts that must be managed by different public bodies. It is therefore important to ensure coordination in the identification and assessment of risks, as well as to the measures that are put in place to address them. Inter-institutional coordination is essential to ensure that risks are treated properly, and positive societal outcomes are achieved.

The Government of the Republic of Zambia should commit to promote inter-institutional coordination to address regulatory risks and will promote such principle among public bodies to ensure they communicate, coordinate, and reach consensus on the best way to manage risks.

6) *When preparing a Regulatory Impact Assessment (RIA), reinforce the identification of risks and their treatment*.

RIA supports evidence-based decision making. RIA offers an important window to properly identify risks and assess their impacts at early stages of the regulatory process. The RIA requires also that the responsible regulator defines the best way to manage the identified risks, offering solutions that are tailored to the magnitude of the situation and respond in a proportionate manner to the complexity ahead.

Regulatory agencies and public bodies in Zambia should therefore improve the treatment of risks in the preparation of RIAs. They should use the RIA process as a starting point to identify, assess and manage risks when regulating, ensuring that a RBR approach is incorporated in the solutions proposed.

7) Strengthen analysis and management of risks when considering the best way to intervene and the use of alternatives to regulation.

One important outcome of using RIA in a systematic way is to ensure that regulators explore different solutions to a given problem. As part of the RIA process, regulators need to ask themselves whether preparing a regulation is the only way to solve a problem. Considering the different impacts that risks may have, it is important that regulators explore different options to solve the problem and consider the use of non-regulatory measures.

Dealing with risks requires capacities and innovation from regulators. Solutions may not always be legal interventions. Zambian regulatory agencies and public bodies could opt for alternative instruments to promote compliance and achieve regulatory outcomes. Treating businesses in a differentiated manner, for instance, depending on the level of risk they pose, can help in the design of more appropriate differential risk treatment strategies. RIA offers the possibility to explore these various options, and this is where a RBR approach may be extremely useful to support proposed solutions.

8) Improve data collection mechanisms and tools to support risk planning, profiling, monitoring, and enforcement when regulating businesses.

Data limitation is a serious problem faced by all regulators around the world. Complete and perfect data is also impossible to achieve. Regulators, therefore, need to balance that trade-off and, even if constant improvements should be sought, regulators need to take decisions with the existing information they may have. The Government of the Republic of Zambia should encourage regulators to improve their data collection mechanisms while at the same time prioritizing some foundation tools, such as the registry of objects and subjects, classified according to business activities, or a registry of regulations applicable to each regulatory domain.

All along the process to identify, assess, mitigate, and manage risks there are several tools that can be promoted, which require data and information to be fully operational. A gradual approach is necessary to make sustained progress over time.

9) Promote the use of risk management tools and Enforcement Management Models (EMM) in the regulatory process.

The ultimate purpose of enforcement is a) to ensure that businesses prevent harm by effectively managing the immediate and most serious sources of risk; b) to promote sustained compliance; and c) to hold businesses accountable in cases of sustained or severe non-compliance. Enforcement Management Models (EMM) refer to the decision-making frameworks regulatory agencies should follow to identify enforcement actions in the event of verified non-compliance.

The Government of the Republic of Zambia may promote the implementation of EMM in selected Zambian institutions with a view to improve enforcement decisions, increase transparency and fairness in enforcement procedures, promote accountability of regulators and ensure efficiency and impartiality in enforcement actions.

Guidelines to make use of Risk-based Regulation Principles

The purpose of these Guidelines is to provide the necessary, basic information to operationalize the principles that have been outlined in the previous chapter. They are not intended to offer exhaustive information on each topic, but to show the way a RBR approach can be adopted in public bodies in Zambia and the benefits of doing it.

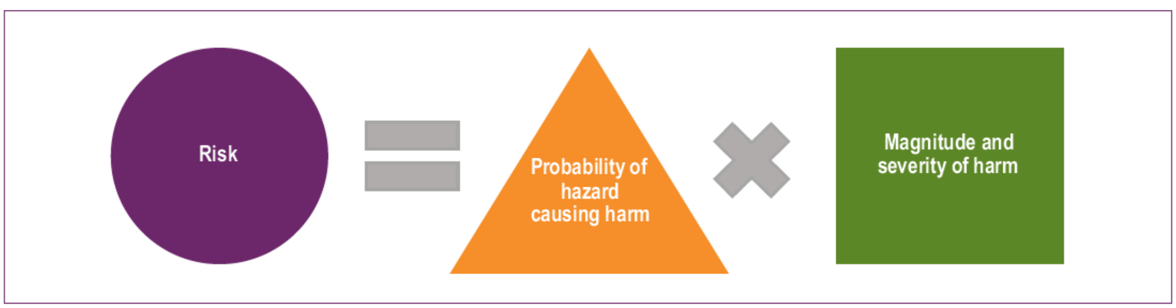
The Guidelines are developed following each one of the RBR Principles that regulatory agencies and public bodies in the Zambian administration should adopt and promote. They are preceded by a list of relevant concepts that will help regulators be familiarized with a RBR approach.

Key concepts

Several concepts are important to understand risk in the regulatory process. The most relevant are presented below:

Risk is the combination of the probability that a hazard will cause harm and the magnitude and severity of the harm caused if the hazard materializes. This can be illustrated as follows in Figure 1.

Figure 1. The concept of risk



Source: Molfetas, Aris & L. Grava (2020)

Hazard is any adverse event that may cause harm, and harm is any form of damage done to people (e.g., in terms of life, health, property, etc.), to the environment (e.g., natural and cultural), or to the public interest (e.g., tax fraud harms state revenue). The magnitude of that harm will depend on the scope and nature of damage. The probability of harm is the degree of likelihood that a hazard will occur, leading to potential harm.

Governments deal regularly with risks in many public policy domains (economic, financial, health, safety, environmental and national security, among others). Making decisions where future uncertainties are significant and unavoidable is part of the activities undertaken by regulators. Those decisions may have significant impacts, and it is therefore important they are proportionate, targeted and based on the assessment of the nature and magnitude of the risks and of the likelihood that regulation will be successful in achieving its aims. This means that "regulations should exist only when the risk is significant, that they should address the factors that can lead to harm, and that permit requirements, inspections and enforcement should be proportional to the level of a given product, business, activity, etc." (OECD, 2021).

In the regulatory sphere, looking at risks, and specifically at public risks, has been a concern for regulators, particularly in the last few years because of the complexity of issues and the magnitude of potential impacts. The Covid19 pandemics is an example of this situation, where governments had to take relevant decisions and address unprecedented risks.

It is in this framework where the concept of **Risk-based Regulation** (RBR) becomes relevant. RBR can be defined as a regulatory approach that helps governments realize policy objectives in a more efficient and effective way, as they deal with sectors, activities, and businesses by focusing on those that pose the highest risk to their objectives (e.g., environmental protection, food safety, occupational health & safety, etc.).

Benefits of introducing Risk-based Regulation

RBR helps governments adapt their degree of regulatory control to the actual risks posed by industry sectors, economic activities, and business establishments. In that sense, a well-functioning RBR system aims to protect public goods, such as safety, health, and the environment, while at the same time avoiding unnecessary burdens to businesses.

There are important benefits of introducing a RBR approach and system, which include the following elements:

- *Better realization of public policy objectives*. RBR helps achieve public policy objectives by targeting activities that pose the highest risks to the public wellbeing. This is particularly true where government is confronted with trade-offs and complex situations, and decisions have to be designed and taken to achieve public policy objectives. For instance, a way to handle the pandemics of COVID-19 implied serious restrictions to social mobility, which had impacts on economic activities. Governments had to make choices to protect human life, clearly prioritizing where the higher risks were.

- *Reduced regulatory burden for the private sector, especially for low-risk businesses*. RBR lowers burdens for a variety of lower-risk sectors and firms, whose control may require a lower level of resources by the government, and requirements on businesses may not be so stringent. In general, lowering burdens improves compliance and allows firms to benefit from a more level playing field.

- *Better use of scarce government resources*. Governments and regulators are generally lacking enough human and technical resources to perform control activities on every single sector and business. A RBR approach helps the government direct public resources towards the highest-risk areas, making the most of limited public resources.

- *Enhancing accountability, transparency, predictability, and consistency in decision-making*. Well-functioning RBR systems further improve accountability by enhancing transparency and predictability of requirements in given sectors and as applied to different firms. RBR means that the design of regulations should be based on a rational scientific assessment of the consequences of the risk to society that the regulation is intended to avert. An evidence-based approach helps governments target enforcement and inspection resources based on a transparent assessment of the risks posed by the regulated entity to the public.

A RBR approach explicitly acknowledges that governments cannot regulate to remove all risks and there is a need to manage them properly. Regulatory interventions need to be effective and efficient at addressing risks. Otherwise, regulatory failure may occur, leading to a situation where the vulnerability of the society can increase. Having adequate good governance arrangements to promote a successful design and implementation of effective regulation, where risk assessment and risk management are included, is also part of effective and efficient regulation.

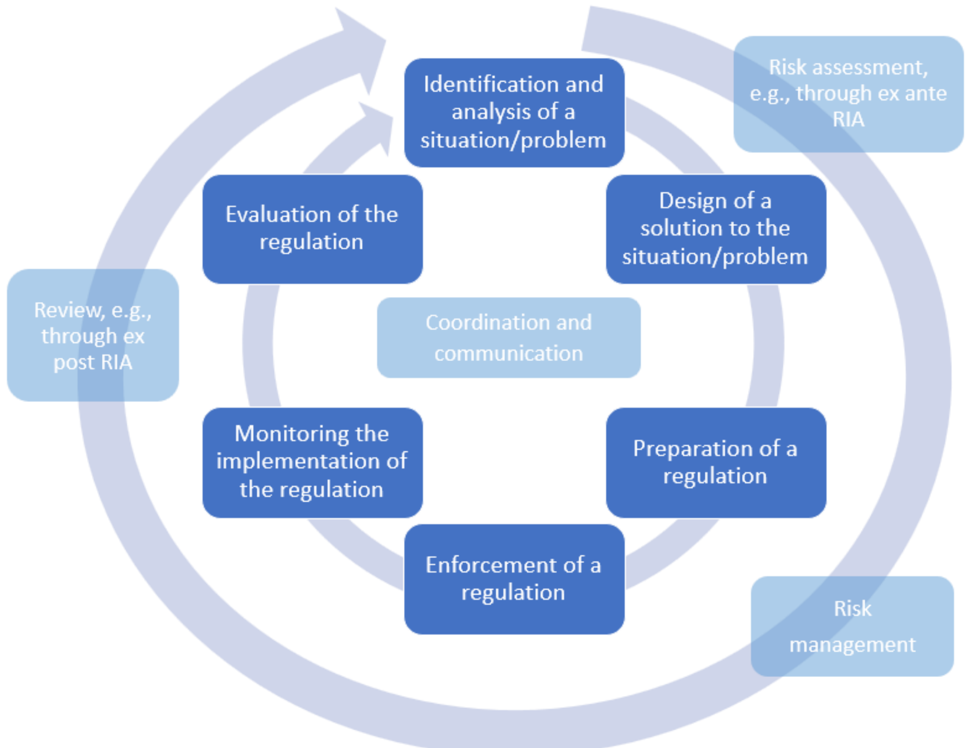
How to operationalize the Principles on Risk-based Regulation

This section of the Guidelines offers policy-makers concrete ideas on how to operationalize the RBR principles that the Government of the Republic of Zambia is promoted and should be followed by Zambian regulators. These suggestions are not exhaustive, they only outline the main actions that regulators should consider when building a RBR approach and strengthen particular tools required to make decisions based on a RBR approach.

1) Integrate the use of Risk-based Regulation in your regulatory activities, from design, implementation, enforcement, and monitoring.

The regulatory process is composed by different stages (see Figure 1). Regulators (i.e., any public body in Zambia that has some regulatory responsibilities) participate in the regulatory process in most of those stages. Their contribution can be either in identifying an issue or a problem, which may require a regulatory solution, and/or in deciding on the regulatory intervention, which may lead to the implementation of a regulation and to ensure its enforcement and monitoring.

Figure 2. Stages of the regulatory process and incorporation of a RBR approach



Source: Author's elaboration

Along that process, regulators may be confronted with risks of different nature. They may be the cause of the intervention, and therefore their proper identification and understanding is fundamental, or they must be treated when the regulation is being implemented. Regulators need to be able to identify those risks, assess and address them on a permanent basis.

At the same time, regulators are responsible for realizing policy objectives, which requires that they intervene when there is clear need to do it and to focus on sectors, activities and businesses that pose the highest risks to those objectives (e.g., environmental protection, food safety, occupational health & safety etc.).

The use of RBR is therefore important and necessary. Regulators should include a RBR approach from the initial stage of regulatory design and formulation to the implementation, enforcement, and monitoring of regulations. RBR should be promoted at all stages of the regulatory process, which requires a constant understanding of risks and innovative solutions to address them.

In the regulatory process, it is important that regulators integrate three main sequential phases to address risks: assessment, management, and review (see Table 1). All of them should be accompanied by risk communication and consultation to foster transparency and to ensure that stakeholders are adequately informed and engaged about proposed solutions.

Figure 3. Phases of risk policy

Risk assessment

- It involves framing and forecasting the probability and consequences of identified hazards. Framing involves constructing a conceptual model of the risk, and forecasting involves undertaking a scientific assessment of the likelihood of the risk and its impact of different nature.

Risk management

- It aims to design and implement actions and remedies to address risks through a consideration of potental risk treatments and the seelction of the most appropriate strategies and tools.

Review and evaluation

- Effective risk management requires a policy cycle based approach that has ex ante and ex psot features. Ex post evaluation of the effectiveness of policy solutions is necessary for the development of future responses and adaptive management within governments.

Source: Adapted from OECD (2010).

2) Train technical and legal staff on risk management to be used when regulating.

Capacity building is a precondition for a successful integration of a RBR approach in the regulatory process. Regulators need to create technical and managerial capacities to implement a RBR approach, particularly in complex policy areas and where trade-offs must be tackled effectively. Assessing, managing, and communicating risks requires knowledge, information, data, and expertise. Technical and legal staff in public bodies need to learn how to deal with this, particularly in conditions where technicity is essential to achieve public objectives and decisions should be made based on evidence and an adequate level of analysis.

Zambian regulators should encourage and support capacity-building activities that can expand the knowledge and expertise on RBR approaches and tools in their institutions. This will facilitate the incorporation of such an approach in the day-to-day activities of regulators. Designating a core group of technical staff that can be trained on RBR approach and tools can be the starting point, and then disseminate the knowledge inside the institution would be advisable.

Training can take different forms, from basic courses to understand risk management in the regulatory process, to more detailed capacity-building activities, depending on the sector the regulator operates (see some good international examples in Box 1). The preparation of guiding materials should also be encouraged in the Zambian administration to support regulators in the preparation of risk assessments and methodologies to assess costs and benefits related to the possible impacts created by risks.

Box 1. International examples of training and guidance on RBR to support regulators

Some countries have developed guidelines regarding RBR approaches to support the work of regulators in the public administration and create capacities to adopt a RBR approach when regulating. Israel, for instance, published in 2018 *A Guide to Risk Management in Regulation and Public Policy*, which has been created to assist government decision makers in the management of risks, as part of their decision-making process. The Guide incorporates the issue of risk management in the formulation of effective regulatory rules and public policy to have better protection of the public, more efficient actions and a reduction in the costs that may be imposed on individuals and businesses.

The Academy of Supervision in the Netherlands has introduced a training program for inspectors across different regulatory domains to harmonize practices. The program´s curriculum includes both theoretical and practical modules with hands-on information from inspectors in other inspectorates on how they conduct site inspections. These programs, taught in small groups, encourage peer-to-peer learning. Participants identified professionalism and risk-based enforcement as the most important topics the program covers.

In the United Kingdom the 2008 and 2014 Regulators Codes provided the legal basis for the so-called "Primary Authority" scheme, which enables businesses to receive advice from inspectorates on how to meet regulation through a single contact authority. The whole approach underlying Primary Authority relies on a high level of professionalism of inspectors, and in particular on them having fully internalized (and being fully proficient) in risk assessment and management. It also requires inspectors to know how to work with businesses in a co-operative way, how to explain and convince – but also how to investigate and spot hidden problems. The foundation of this approach is that inspectors (regulators) need a set of "core skills" (related to risk-based regulation and regulatory delivery) in addition to specific technical skills depending on their domain of activity. These core skills are organized in several groups, including "risk assessment", "understanding those you regulate", "planning activities", "checking compliance", "supporting compliance", "responding to non-compliance" and "evaluation".

Sources:
https://www.gov.il/BlobFolder/generalpage/risk_management/he/logo_Files_Management171018-6.pdf; World Bank (2021) and OECD (2021a).

Peer learning from other international experiences and solutions used by similar regulators can also be inspiring and offer a good starting point to see how other counterparts have dealt with similar problems in the specific sector where the public body operates.

Another way of creating capacities is to exchange experiences among Zambian regulators. There are currently some Zambian public bodies that are gaining expertise in addressing and managing risks from a regulatory point of view, and sharing those experiences with other institutions can constitute a motivating way to show improvement.

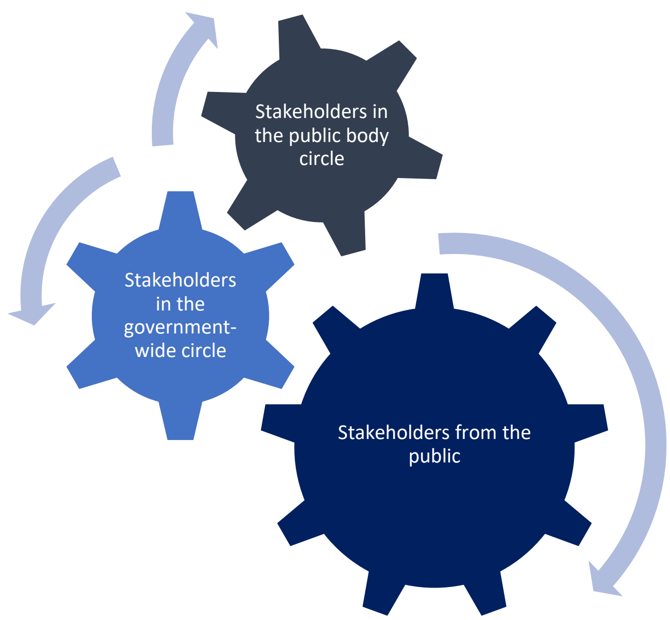
Dissemination of good experiences and practices should be promoted within the Zambian administration. It would be advisable to set up an inter-ministerial working group on risk management or promoting inter-ministerial working groups in certain policy areas as a way to ensure that institutions facing similar risks learn from experience. For instance, in the framework of the World Trade Organisation (WTO) Agreement on Trade Facilitation, border agencies should adopt and maintain a risk management system for customs control. Zambian Border Agencies are currently working on adopting such a system for trade facilitation, improve border processes and reduce clearance times. Exchange of experiences and capacity building is fundamental for a successful approach.

3) *Engage with stakeholders to identify and treat regulatory risks*

Risk analysis and risk management require the engagement and communication with stakeholders so regulators can assess properly their impacts and decide how to handle them. Missing information, or overlooking stakeholder concerns, or misunderstanding, can lead to failure to address those risks.

In this regard, it is important to correctly identify the relevant stakeholders and understand the possible impacts they may suffer from the materialization of risks. Because of this, good stakeholder mapping and analysis is a necessary and unavoidable step at the beginning of the regulatory process as it allows to identify and engage all the relevant stakeholders. Relevant stakeholders can be found not only in the inner circle of the public body (those with whom the public body normally deals with) but, depending on the risks to be treated, they can also be identified within other spheres of government (since risks may have broader effects or be linked to various policy areas, they might require the involvement of a wider set of government agencies) or of the public (see Figure 4).

Figure 4. Types of stakeholders to be considered in the mapping process



Source: Author's elaboration

Regulators should then elaborate a plan to define a) who to engage with and b) which tools can be more convenient to do it. Several techniques and tools help regulators to ensure stakeholders´ views are properly channeled in the regulatory process (e.g., technical working groups, expert panels, or through formal public consultation). Those tools should be promoted intensively, and regulators need to develop capacities to operationalize them in an effective and efficient manner.

A RBR approach should be supported by evidence, which in most cases requires feedback from stakeholders – i.e., those that potentially may be affected by risks. Stakeholders´ inputs are fundamental to analyze the costs and benefits related to any proposed solution and to determine the magnitude or the severity of the damage. They will also be fundamental part of enforcement and compliance solutions afterwards. This is why stakeholders' engagement should be a continuous process at all stages of the regulatory process.

In the regulatory process, early engagement with different stakeholders is essential for a good regulatory outcome. Regulators should promote early participation of relevant groups when designing regulations and should encourage constant communication with stakeholders and to the public on the way risks should be treated. For instance, in the United Kingdom, the Regulator´s Code, a framework that defines some principles on the way regulators must behave, emphasizes the interactions with stakeholders and the way regulators have to involve them at different stages of the regulatory process (see Box 2).

Box 2. The UK Regulator´s Code

The UK Regulators Code provides a flexible, principles-based framework for regulatory delivery that supports and enables regulators to design their service and enforcement policies in a manner that best suits the needs of businesses and other regulated entities. The Code seeks to promote proportionate, consistent, and targeted regulatory activity through the development of transparent and effective dialogue and understanding between regulators and those they regulate. The main principles of the Regulators Code are:

1. Regulators should carry out their activities in a way that supports those they regulate to comply and grow.
2. Regulators should provide simple and straightforward ways to engage with those they regulate and hear their views.
3. Regulators should base their regulatory activities on risk.
4. Regulators should share information about compliance and risk.
5. Regulators should ensure clear information, guidance and advice is available to help those they regulate meet their responsibilities to comply.
6. Regulators should ensure that their approach to their regulatory activities is transparent.

Source: https://www.gov.uk/government/publications/regulators-code

4) Ensure transparency along the regulatory process that identifies and manages risks.

Transparency plays a key role for a successful implementation of a RBR approach. Any regulatory intervention needs to be designed in a participatory and open way. Solutions, mitigation efforts, obligations and requirements imposed to businesses and consumers should also be public and informed to the society and relevant groups in a timely manner. Regulatory agencies and public bodies in Zambia should inform stakeholders about the risks they identify and the solutions they may find to treat them.

Key documents and information about the regulatory process should be made available to stakeholders. They need information so they can also make decisions and better understand the way the public interest is defined, treated, and protected. Businesses, consumers, and any other relevant stakeholder group need to trust the way government proposes the management of risk, and they need to feel they are part of the solution. In many cases, treating risks requires changes in behavior, which should be based on sound information.

Transparency also helps increasing the predictability of the business environment and promoting an effective investment climate. A robust RBR approach creates certitude in the way regulators address risks and it sets clear rules of the way risks are treated. Many regulators have become more effective in achieving their objectives once they have integrated the use of a RBR approach, also supported by ICT solutions, which have become helpful in organizing and collecting information, increasing transparency, and targeting business controls in a more efficient way (see Box 3).

Box 3. How transparency can help achieving regulatory objectives: international cases showing the use of a RBR approach

The government of Greece reformed its business licensing system between 2014 and 2017. Notably, Greece moved away from a regulatory system that was mostly based on burdensome ex-ante licensing requirements, which were ineffective in safeguarding the public interest, towards a regulatory delivery approach that leverages both ex ante and ex post tools and is based on risk proportionality. More than 300 business activities were reformed, including those in key economic sectors such as food and beverage manufacturing, tourism accommodation, extractive activities, logistics, waste management and retail service activities. Notably, the pre-2014 licensing system was based on overly prescriptive regulations and was plagued by overlap and duplications. Asking businesses to obtain numerous licenses and permits before they could operate. In 2016, a new risk-based system was introduced by law. It established the Integrated Licensing and Inspection Management System (ILIMS) and a framework for third-party conformity assessments as a possible tool for the licensing procedure for high-risk activities. As a result, the Government of Greece has classified economic activities into risk categories by conducting risk assessment of each economic activity based on its impact on health, safety and the environment, and by benchmarking against European best practice. For low-risk activities, the law replaced onerous licensing requirements with a registration. In other words, it required businesses owners only to notify the municipality through an online platform before commencing their business activity. This "notification" system required businesses operators to fill out a simple document providing the authorities with key data on their business so that inspectorates would be able to inform their risk assessments and prioritize inspections. This transparent system also allowed regulators and inspectors to focus their checks on those businesses that present higher risks to public safety and the environment.

Between 2007 and 2010, Italian Region of Campania undertook a reform of the food safety inspection system, moving from a regulatory delivery regime mostly focused on deterring non-compliant behaviours to a risk-based system based on the requirements set in the EU Hygiene Package. The reform initiative took place based on a specific regulatory demand, following some major accidents and a breakdown of trust of the private sector and the public (due to insufficient official communication on risks and to the lack of effectiveness of the control activities related to risk management). The underlying systemic problems that prompted the reform initiative were, among others, the lack of a planning system of controls based on risk categorisation. To address these problems, the initiative included a variety of elements supporting risk-based regulatory delivery, i.e., risk-based decision-making (including both risk-based enforcement and inspections planning), inspections processes and procedures, tools (checklists, IT system, etc.), Key Performance Indicators, human resources management, and vertical co-ordination. A main tool towards strengthening a risk-based approach introduced with the reform was the IT System. As a result, the reform has led to the following: i) classification of economic operators in risk categories and planning of inspection frequency commensurate with the risk level; ii) Improvement of quality and quantity of information provided to the Ministry of Health and the EU, in accordance with applicable rules; iii) Systematic distribution of inspection visits over the territory of the Region; iv) Identification of emerging risks; v) Number of activities performed as defined by relevant objectives; vi) Better human resources management.

In Mexico, the federal government introduced the Law for the Promotion of Citizen Trust in 2020, which is based on the development of a risk-based inspection system. Inspections at the federal level are determined by the National Regulatory Improvement Commission (CONAMER), which determines the purpose and frequency of inspections based on risk analysis. The law specifically foresees that risk analysis must consider both intrinsic risks and the business trajectory. The system is based on transparency and information for businesses. A portal has been set up, where businesses register and declare compliance with obligations. They receive all required information about future inspections through the portal, including relevant information about the process, requirements, and inspectors. Inspections are conducted only ex post, and businesses that comply with their obligations are rewarded. Those that fail to comply may receive stronger punishment measures.

Sources : Molfetas, Aris & L. Grava (2020); OECD (2021ª);
https://www.confianzaciudadana.gob.mx/

Regulatory agencies and public bodies in Zambia should increase transparency when dealing with regulated entities. An initial step, for instance, could be the improvement of inspections by publishing clear checklists and information about requirements imposed to businesses that are used by inspectors. Business would then be able to see what is expected from them, and the way inspectors make their assessments. This will reduce discretion and improvisation, concurrently increasing predictability. Reports prepared by inspectors should also be published, to make transparent the decisions made by inspectors and informing business what they need to improve.

5) Promote inter-institutional coordination when dealing with risks in the regulatory process.

Conducting risk assessment may require a coordinated effort across government. The interrelated nature of many risks calls for a whole-of-government risk scanning exercise that should be supported by some central co-ordination to set overall risk priorities. In many cases, it is important to identify where regulation and any other policy instrument can be useful to address and manage risks.

Risk assessment and risk management present significant coordination challenges. If risks have to be managed by more than one regulatory agency or public body, a whole-of-government perspective should be considered. Governments need to be careful in that sense, as some risk reduction strategies in one area may increase risks in another, or the treatment of risks may be only achieved with coordinated actions, implemented by various institutions. The way coordination is treated and ensured varies among countries (see Box 4), as this is related to administrative, legal and political considerations. There is, however, a clear trend at international level to look for solutions that strengthen coordination mechanisms.

Box 4. Improving coordination mechanisms: some international good practices

Countries try to establish coordination mechanisms to ensure that RBR approaches are properly implemented. In Jordan, a Higher Committee (HC), a stand-alone unit under the Ministry of Investment, Trade, and Supply (MoITS) was established to oversee reform. HC was first introduced as a temporary body through a Prime Minister´s decree, and subsequently became permanent through the Inspection Law. The Higher Committee includes four members of the private sector to ensure the private sector´s involvement in reform monitoring. MoITS established an operational arm, known as the Inspection Unit, to support the HC.

In Lithuania, the authorities established an Expert Committee consisting of representatives from the nine large inspectorates and a reform team. The committee met bi-weekly: it shared experiences, promoted and disseminated examples on best practices, built consensus on decision making, and coordinated reform implementation. The inspectors involved originally adopted the "declaration on the first year of business", under which signatory inspectorates committed to imposing sanctions only as a last resort if a business had been operating for less than a year, to allow sufficient time for new businesses to learn how to comply. By 2014, a total of 50 inspectorates (out of 60) had voluntarily signed the declaration. In addition, other reforms introduced risk-based approaches, checklist-based site inspections, and procedures to manage administrative violations.

Source: World Bank (2021).

As regulators and public bodies in Zambia start integrating a RBR approach in their regulatory activities, they should be able to identify risk priorities. The Business Regulatory Review Agency (BRRA) could also support regulators and public bodies in their efforts to identify those risk priorities that must be addressed. A list of priorities should be then prepared, openly discussed with stakeholders, and the center of the government could set up inter-institutional coordination mechanisms (e.g., specific working groups, task forces, etc.) to deal with those identified risks and with the goal to properly address them. The benefits of those interactions should be to have more effective and efficient interventions that results in better outcomes for the society as a whole.

The Government of the Republic of Zambia should commit to promote inter-institutional coordination to address regulatory risks and will promote such principle among public bodies to ensure they communicate, coordinate, and reach consensus on the best way to manage risks.

6) *When preparing a Regulatory Impact Assessment (RIA), reinforce the identification of risks and their treatment*.

Regulatory Impact Assessment (RIA) is a key tool to improve regulatory outcomes and achieve public policy objectives. RIA is "a detailed systematic appraisal of the potential impacts of a proposed regulation in order to assess whether the regulation is likely to achieve the desired objective and the costs of regulation are justified" (BRRA, 2018). Being a tool that supports evidence-based decision-making, RIA helps regulators better understand the likely consequences of their actions, by analyzing their impacts and the best way to intervene.

RIA is considered a key tool to integrate a RBR approach, as it should be conducted early enough in the regulatory process, so it allows for a deep understanding of the issue the regulator is confronted with. RIA requires regulators to properly identify risks and assess their impacts ahead of deciding the type of intervention that is more suitable to address the problem. The preparation of a RIA requires that the responsible regulator defines the best way to manage the identified risks, offering solutions that are tailored to the magnitude of the situation and respond in a proportionate manner to the complexity ahead.

The Business Regulatory Act, 2014, requires that regulatory agencies and public bodies that submit policies or proposed laws to regulate businesses perform an RIA. The preparation of that assessment includes the treatment of risk, and the *RIA Handbook for Regulatory Agencies and Public Bodies in Zambia* describes in detail how risks should be identified, analyzed, and treated as part of that process (see Box 5).

Box 5. Treatment of risk in the RIA Handbook for Regulatory Agencies and Public Bodies in Zambia

The RIA Handbook helps regulatory agencies and public bodies in Zambia to undertake a RIA and provides a step by step process on how the assessment is conducted. Risks have to be integrated in the preparation of the RIA, as part of relevant information to improve decision-making. Any regulatory proposal in Zambia, for instance, must be proportional to the risk being addressed, and full RIAs should identify potential impacts and risks of the proposed policy/regulation.

The RIA Handbook explicitly refers to how risks can be treated when problems are identified. At that stage, a risk assessment should be conducted, which involves evaluating the probability of detriment or harm as a result of existing policy/regulation or posed by the identified problem that requires intervention. Before initiating the risk assessment process, it is necessary to establish the risk criteria against which the risks will be measured. The Business Regulatory Act sets out that risk criteria in the regulatory making process relate to the governments´ mandate to regulate in the interest of: i) public health; ii) public safety or national security; iii) environmental protection; iv) consumer protection; and v) upholding of standards, food, drugs and services.

In the RIA process, risk assessment involves risk identification, risk analysis and risk evaluation. The RIA Handbook provides a risk assessment form as an annex to help government officials to support the assessment process.

Source: BRRA (2018).

Public bodies in Zambia should therefore improve the treatment of risks in the preparation of their RIAs. They should use the RIA process at early stages of the regulatory process, as that evidence-based assessment can inform decisions about the necessity and optimal degree of regulation needed to protect or promote public wellbeing, and it can also help determine whether regulation is needed for the economic sector or regulatory domain they are responsible for.

In case regulation is identified as the best solution, it would be important to determine what is the optimal degree of regulatory intervention needed to mitigate the identified risks. The following questions can guide regulators when considering risks and the reasons for regulation, how best to respond to changing circumstances, and what improvements are needed (see Figure 5).

Figure 5. Questions that help identify and manage risks in the RIA process

Risk treatment in the RIA process	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?

Source: Molfetas, Aris & L. Grava (2020)

The quality control established by the Business Regulatory Review Agency (BRRA) should also consider the way regulatory agencies and public bodies conduct the risk identification and proposed risk treatment as part of the RIA process. More detailed guidance on the way regulators consider risks in the framework of their RIAs could be elaborated, and BRRA could be engaged early enough in the regulatory process to ensure that risks are properly identified and managed in the preparation of the RIA.

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7) Strengthen analysis and management of risks when considering the best way to intervene and the use of alternatives to regulation.

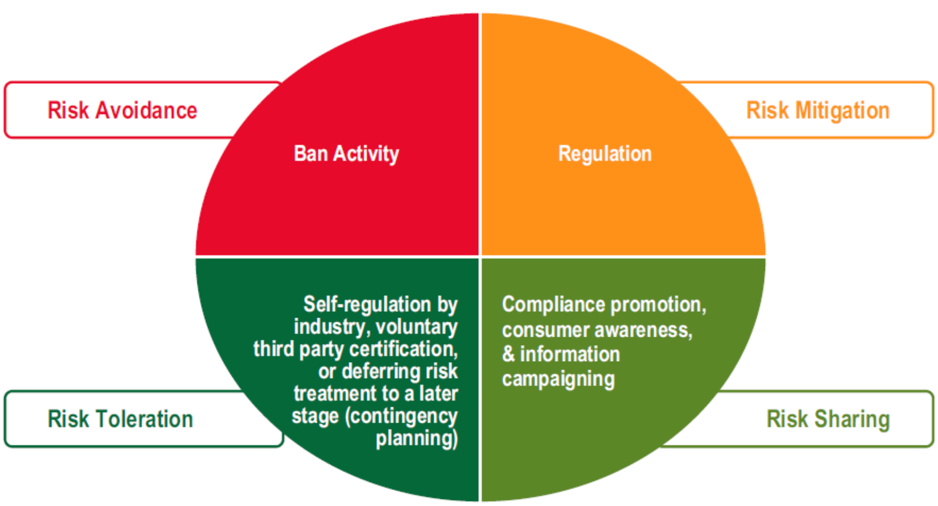
Dealing with risks implies a high degree of uncertainty. Regulators are always confronted with complex decisions to be made, and the selection of the most effective and efficient regulatory solution is not always clear cut. Using a RBR approach requires that the regulator integrates an informed analytical approach and to make explicit the choices made.

One important outcome of using RIA in a systematic way is to ensure that regulators explore different solutions to a given problem. As part of the RIA process, regulators need to ask themselves whether preparing a regulation is the only way to solve a problem. Considering the different impacts that risks may have, it is important that regulators explore different options to solve the problem and consider the use of non-regulatory measures. Risk becomes thus a key consideration in the selection among regulatory and non-regulatory approaches, as well as in the assessment of costs and benefits of the proposed solution and the development of models of enforcement and compliance.

Dealing with risks requires capacities and innovation from regulators. Solutions may not always be legal interventions. Regulators can opt for alternative instruments to promote compliance and achieve regulatory outcomes. Treating businesses in a differentiated manner, for instance, depending on the level of risk they pose, can help in the design of more appropriate differential risk treatment strategies. RIA offers the possibility to explore these various options, and this is where a RBR approach may be extremely useful to support proposed solutions.

Figure 6 illustrates the way regulators may treat risks, and based on that, the various solutions that regulators may have to deal with them. In a RBR approach, the regulatory agency or public body will need to first explore the risks arising from the activity or sector and then consider risk-treatment strategies in addition to regulation. One or a combination of risk-treatment strategies may be selected.

Figure 6. Regulation is One of Several Risk Treatment Strategies



Source: Molfetas, Aris & L. Grava (2020)

In the integration of the RBR approach, regulatory agencies and public bodies in Zambia should consider the use of alternatives to regulation. Today various Zambian institutions are going beyond the "command-and-control" approach. They are using more flexible solutions, providing information to relevant stakeholders, and engaging with them to look for solutions. In addition to the traditional licenses, regulators can explore other tools, such as information campaigns, consumer awareness, voluntary certification, self-regulation by businesses, self-declaration of compliance, mandatory third-party certification, compliance promotion, etc.

8) Improve data collection mechanisms and tools to support risk planning, profiling, monitoring and enforcement when regulating businesses.

A strong RBR approach requires that risk should be assessed in an objective, data-driven way.. In this context, necessary data may include the database of regulated objects (establishments) and subjects (legal entities), as well as information on the risk criteria – intrinsic (static, such as the type, size, or location of the entity) or acquired (dynamic, such as measures and compliance history) data for each business.

Data limitation is a serious problem faced by all regulators around the world. Complete and perfect data is often impossible to achieve. Regulators, therefore, need to balance that trade-off between data availability and their regulatory needs. Even if constant improvements should be sought, regulators need to take decisions with the existing information they may have. Over time, however, regulators need to improve data collection strategies and mechanisms, and invest in gathering and collecting relevant information that may help them put in place a sound RBR approach (see Box 6).

Box 6. Some instruments that help collecting data and information

The implementation of a RBR approach requires that regulators generate data that is useful to improve decision-making. In a context where data may be limited, it is important that regulators conceive instruments that gradually allow them to create the required datasets for the RBR approach to properly function. Over time, as data and information build up, the implementation of the RBR approach may require lower amounts of effort. This, however, is not the case at the beginning, when the effort is the greatest

Among the instruments that can be useful to generate data are the following:

- *Questionnaires and surveys*. These instruments require limited inputs and enable to reach many people or businesses. They are useful when seeking to gather well defined information. Good questionnaires are based on the following key principles: they should be short and be formulated with clear-cut questions – simple sentences, one topic per question; answers should support the risk management process, so the questions should be structured to get the required information.
- *Existing databases*, such as the business registry or the agency´s own registries. Many regulators may have good quality information that could be relevant for other regulatory agencies or public bodies. Tax authorities or business registries, for instance, can be an initial entry point to get relevant data to create business profiles,

which are essential for the RBR approach. In addition, business associations can also be relevant as data sources.

- *Checklists* are a common tool used when implementing a RBR approach because they can be extremely helpful when dealing with issues of compliance. For instance, as part of inspections, checklists help frontline staff to control relevant issues in a consistent and standardized way. At the same time, checklists help businesses understand what objects will be inspected and how, thus supporting their efforts to increase compliance.
- *Risk-based complaint management system*. Complaints are a vital source of information for regulators. A solid RBR complaint management system can help understand and manage different kind of complaints. Some complaints may require a case specific response while others may concern larger or systemic issues requiring a more comprehensive approach. In the latter case, complaints are rather a source of intelligence and planning for the future.

High quality data should be shared between regulators. This approach will facilitate the regulators' activities but also reduce the burden on businesses, which would be otherwise required to spend their time providing information to the regulators. Signing protocols or memoranda of understanding can be a good way to ensure there is data sharing, also protecting data information and confidentiality.

Sources: Source: Molfetas, Aris & L. Grava (2020); Prime Minister´s Office (2018)

In the case of Zambia, data collection and data processing need to be strengthened. Several regulatory authorities and public bodies are aware of the need to improve the use of technological solutions to support data collection and analysis, as well as the challenges they face to get reliable data and information from regulated entities. These elements are essential to consolidate robust RBR systems and they deserve particular attention and resources so they can be developed. Consolidating databases may take years to be built, so it is important to start soon and build over time.

The Government of the Republic of Zambia should encourage regulators to improve their data collection mechanisms while at the same time prioritizing some foundation tools, such as the registry of objects and subjects, classified according to business activities, or a registry of regulations applicable to each regulatory domain. Creating risk-based checklists for inspections can also be an initial step to identify who should be prioritized when inspected.

All along the process to identify, assess, mitigate, and manage risks there are several tools that can be promoted, which require data and information to be fully operational. A gradual approach is necessary to make sustained progress over time.

9) Promote the use of risk management tools and Enforcement Management Models (EMM) in the regulatory process.

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. Deciding on an enforcement action (e.g., a financial penalty) may require considering several factors, such as the violator´s compliance history, previous enforcement actions imposed on the business, the severity of the violations, etc. An Enforcement Management Model (EMM) can help in achieving consistency in these cases, where decisions need to be made over non-compliance.

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. A robust EMM can support consistent, transparent, proportionate decision making through standardized criteria and enforcement procedures (see Figure 7 for the main EMM principles).

Figure 7. Principles of a robust Enforcement Management Model

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 but as the agency´s use of a similar approach in similar circumstances.

Source: Molfetas, Aris & L. Grava (2020)

The setup of an EMM requires two basic steps:

- Step 1: Set out the principles for enforcement decisions and the available enforcement actions. The basic move is to get away from a highly prescriptive sanction system. This can be achieved by introducing general categories of enforcement actions through regulation, using the accepted general categories of enforcement actions (see Figure 8).

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Figure 8. Broad categories of enforcement actions (from more common to less common)

Source: Molfetas, Aris & L. Grava (2020)

- Step 2. Develop the EMM. This can be operationalized through decision-making frameworks (for example, decision trees - see the figure in Box 7 as an example) that guide the enforcement process. The enforcement process should combine the information collected during the monitoring process (e.g., through a site inspection to determine the seriousness of the non-compliance and the associated degree of risk) with contextual factors (e.g., business´s relevant incident history).

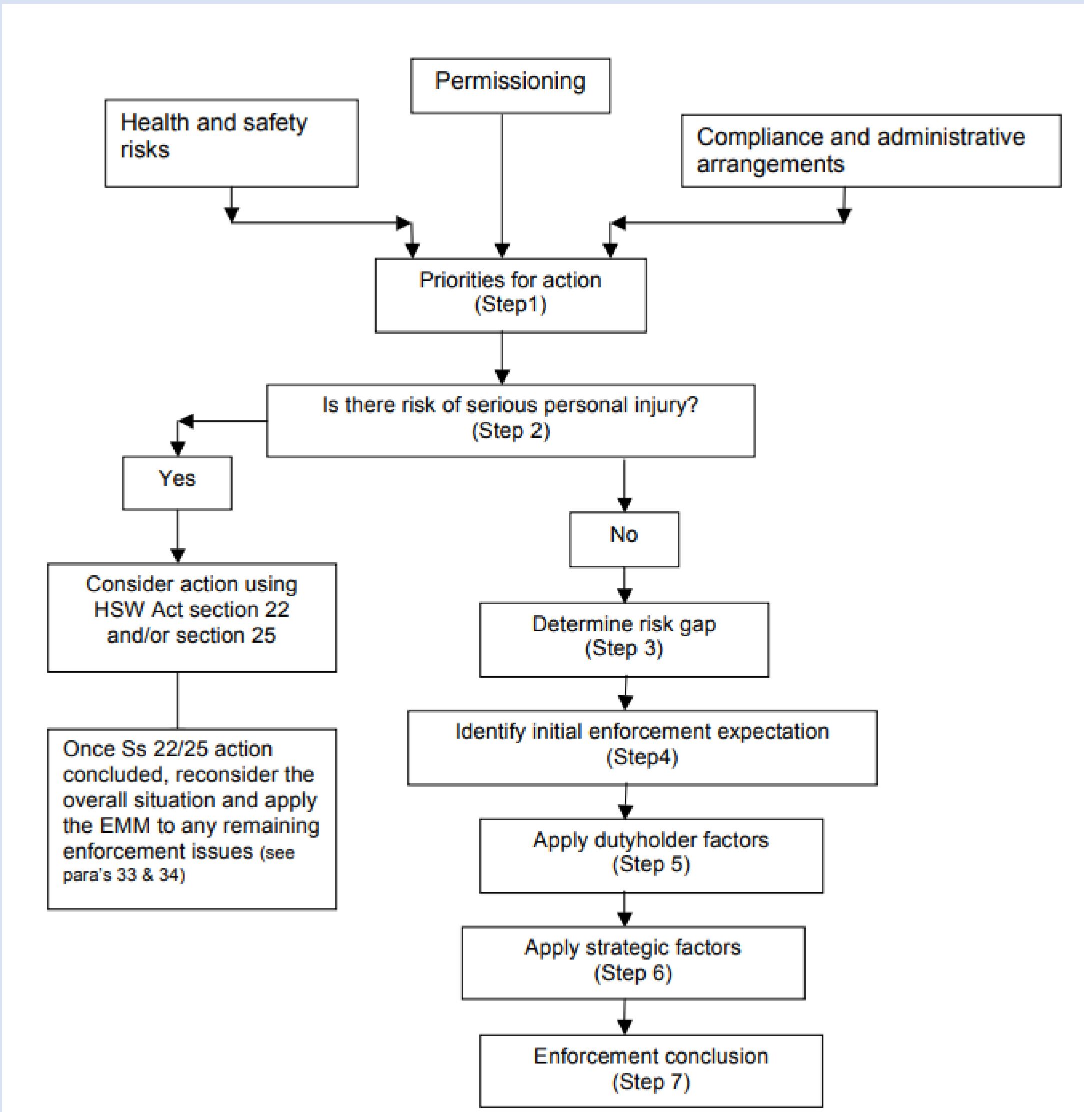
Box 7. The Enforcement Management Model of the UK Health and Safety Executive

The Health and Safety Executive (HSE) is Britain´s national regulator for workplace health and safety. As a regulator, its main goal is to prevent workplace death, injury, or ill health. HSE works with duty holders to help them understand the risks they create and how to manage them.

The Enforcement Management Model (EMM) is a logical system that helps HSE inspectors to make enforcement decisions in line with the HSE´s Enforcement Policy Statement, which sets out the principles inspectors should apply when determining what enforcement action to take in response to breaches of health and safety legislation. A fundamental principle indicates that enforcement action should be proportional to the health and safety risks and the seriousness of the breach.

The EMM provides inspectors with a framework for making consistent enforcement decisions. It also assists less experienced inspectors in making enforcement decisions and it helps managers monitor the fairness and consistency of inspector´s enforcement decisions in line with HSE´s policy. The review process of the EMM tries to reduce the inspectors' levels of discretion. While some levels of discretion are unavoidable because of the complexities and nuances of specific situations, EMM is there to support that enforcement decisions are impartial, justified and procedurally correct. In this regard, EMM promotes enforcement consistency by confirming the parameters, and the relationships between the many variables, in the enforcement decision-making, and promotes proportionality and targeting by confirming the risk-based criteria against which decisions are made. Furthermore, it offers a transparent framework for decisions and ensures that those making decisions are accountable for them.

The following figure provides an overview of the different elements of the EMM used by HSE. Detailed guidance is available for each one of the elements (https://www.hse.gov.uk/enforce/emm.pdf).



Source: www.hse.gov.uk

The Government of the Republic of Zambia may promote the implementation of EMM in selected Zambian institutions with a view to improve enforcement decisions, increase transparency and fairness in enforcement procedures, promote accountability of regulators and ensure efficiency and impartiality in enforcement actions.

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