Guidance on
Risk-Based Inspection

Guidance on
RISK-BASED INSPECTION

CONTENTS

01. Introduction

The regulatory tool of inspection is going through a transformation. This is a global trend, across both developed and developing economies, and across six continents. The main reason is that the new model is both more efficient and more effective in delivering public benefits. The traditional model is known as the Command and Control model, or sometimes called the "Policing" model. The new model is Risk-Based Inspection (RBI).

Figure 1. The Command and Control Model

Command and Control Model

Laws and Rules

Inspections

Sanctions

Result?   Safety!?

Command

Control

Figure 2. The Risk-Based Model

Real World, Values and Dangers

Hazard Analysis / Identifying Risks

Risks to be Managed

Entity's Risk Profile

Checklists

Prioritised Inspections

Inspection Record / Learning

The chances of the Command-and-Control approach actually leading to significant safety results are low, which is a major reason for dropping it. The model that is replacing it is focused on delivering results. It is still based on implementing laws and rules, but that part of the model is just one way of delivering the results

needed in the real world. The laws may not work very well. In a sense, the "law" that matters is the "Law of Cause and Effect", not The Law on Agriculture, or any other sectoral laws. It is about delivering real world results and what connects it to the real world is risk.
This model moves on from the concept of

"enforcement", where use of force underpins the approach, to a range of ways of implementing the laws and the rules – although still including enforcement when necessary. These other ways use engaging, motivating and enabling the businesses, and often the consumers, in order to bring about change on a far greater scale than can be done by the traditional model.

This Guidance is in two Parts. The first explains the technical system of Risk-Based Inspection and how to develop it. The second explains how to achieve better results through having that system as the foundation for a new approach to implementing laws.

The diagram in Figure 2 will be unpacked later, but first it should help to explain more about risk and how it can be applied.
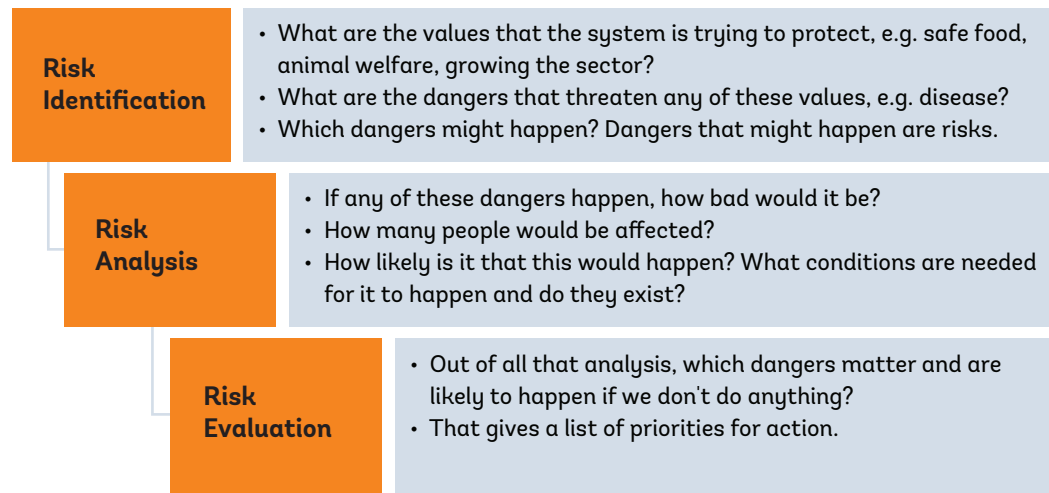
Part 1

THE TECHNICAL SYSTEM

02. The Basics of Risk-Based Inspection – Risk Assessment

Figure 3 describes the risk assessment process that lies behind any risk-based inspection system. It has to start with analysis of the particular sector that will operate the risk-based system. That is, the risks driving the risk-based inspection system have to be the risks of that sector.

Figure 3. The Risk Assessment Sequence

Risk Identification
- What are the values that the system is trying to protect, e.g. safe food, animal welfare, growing the sector?
- What are the dangers that threaten any of these values, e.g. disease?
- Which dangers might happen? Dangers that might happen are risks.

Risk Analysis
- If any of these dangers happen, how bad would it be?
- How many people would be affected?
- How likely is it that this would happen? What conditions are needed for it to happen and do they exist?

Risk Evaluation
- Out of all that analysis, which dangers matter and are likely to happen if we don't do anything?
- That gives a list of priorities for action.

Source: Author's diagram

This work is essential to a risk-based system. Some countries try to simplify it by taking only one risk – the risk of non-compliance with the regulations. They still see their job as just checking technical compliance. Therefore all they need to identify is the likelihood of non-compliance. This is also further simplified by basing their assessment on the historical data they have of non-compliance. If a business has been non-compliant, they argue that it is likely to continue to be non-compliant. This ignores the external factors affecting compliance.

Instead, a range of risks needs to be identified, arising from the real dangers in the sector that threaten what the sector is trying to protect. The analysis of the sector can become a very complex and sophisticated exercise, but it can also start fairly simply.

Applying risk is always a matter of common sense. The questions asked are always simple. It is finding the answers that is challenging. Therefore, there needs to be a Risk Assessment Unit somewhere in the organisation with the skills, data and functional responsibility to build and maintain a full analysis of sectoral hazards,

Simple Risk Assessment Example
Identification of value – worker safety
Hazard / Threat – working at height.
Risks – lack of safety harnesses, lack of hard hat, badly set up ladder, badly designed scaffolding, lack of training, poor light, weather conditions, noise preventing communication with the ground.

emerging risks and identification of risk criteria. This needs data. A risk-based inspection system is also one way of gathering valuable data from across the sector, and inspections should be designed in a way that also takes advantage of that aspect, i.e. being a survey of businesses.
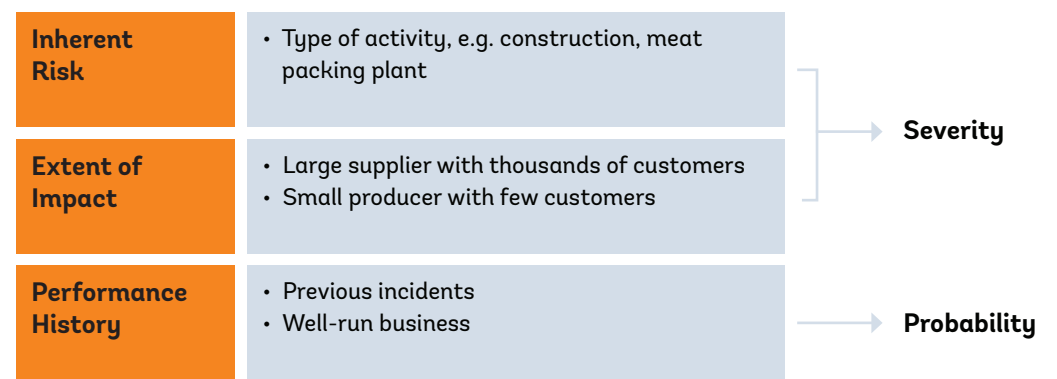
03. The Basics of Risk-Based Inspection – Risk Profile

> Another tool that the inspector needs under the risk-based inspection system is a map that shows where the main problems are likely to be, so that inspections are carried out there first. This comes from each business having its own "Risk Profile".

The realities of all the activities that go into operating the sector go into assessing the sectoral risks and identifying key risk criteria. But the other major factor is the business itself. Some risks come from external factors but central to everything is the way that the business manages the risks. Additional risk can come simply from bad management. The business both creates and manages risks. The essence of a successful sector depends on how well the businesses do that. The identification of risk criteria is a start for building a profile of each business. Risk criteria come from the evaluation stage of the risk assessment when some risks are judged to be important enough and likely enough to happen that they need to be dealt with. They will often be particular activities, such as demolition of buildings. Knowing that a specific business specialises in demolition immediately starts to build

a risk profile of that business. It is engaging in an inherently high-risk activity. If it is then found that it has ten teams operating across the country every day, it is likely to be classified as a high-risk business. As this simple example shows, some basic information about a business can quickly build into a picture that reflects the level of risk presented by that business. But the level of risk is a combination of the severity of the potential damage and the probability that the damage will occur. So that demolition business will definitely be high-risk if it has a history of accidents. However, if it is a well-resourced business with specialised and well-maintained equipment, well-trained operators and has a reputation for safety, it may not be high-risk. It is unlikely ever to be low-risk but it need not be high-risk. This is summarised in Figure 4 below.

Figure 4. Assigning a Risk Profile to a Business

Inherent Risk	• Type of activity, e.g. construction, meat packing plant	
Extent of Impact	• Large supplier with thousands of customers • Small producer with few customers	**Severity**
Performance History	• Previous incidents • Well-run business	**Probability**

Source: Author's diagram

The factors that are used to assign a Risk Profile can be given scores, e.g. a demolition business will score higher than a plumbing business and a large operator higher than a small one. A bad history will score higher than a good one. Adding these up provides an overall score which can then be classified as High, Medium or Low Risk. (A business with no known history is usually given a middle score for history, until the first inspection.) If the scoring system is highly developed, businesses can be quite extensively rated in terms of their level of risk, e.g. you can identify the top 50. In that way, inspectors can be allocated to go where the risk is highest and ignore the ones with low risk. How often in a year they need to go will also depend on the level of risk in the business.

Once again, the basics of risk-based inspection are not complicated and will already be second nature to many inspectors or Inspectorates. What risk-based inspection as a system does is develop these basic ideas into something more systematic that will also increase both efficiency and effectiveness through better targeting. It takes years to improve all the tools, even if they are quite basic at the start. The key factor of the performance history of the business necessarily takes time. Its performance can vary over time, with different market conditions or changes in management. It should be repeated that what is being assessed is not simply the number of technical non-compliances but the management capacity of the business. To repeat another point, the success of the sector depends on how well the businesses manage the risks they have to control.

It also takes time to develop the scoring systems for risk assessment and risk profiling. A business that has a hundred customers has a higher risk level than a business that has ten but how much higher is the risk if it has a thousand customers? Is there more risk in managing biosecurity on a breeder farm than in transporting day-old chicks? It is usually easy to identify the top five high-risk businesses, but it takes a sophisticated system of scoring and assessment to rank the

top 500. But there will be a point beyond which greater levels of detail produce diminishing returns. It should not be forgotten, however, how important it is also to identify and stop wasting resources on the bottom end, on the low-risk businesses that can do very limited damage but still provide some socio-economic benefit. But risk must also be applied to all the activities of the Inspectorate. Pre-registration inspections should also depend on how much it matters whether an inspection is needed. A change of management at an established business doesn't need a re-inspection of the building. Having ex ante inspections should only be done when there is justification for using the scarce inspection resources needed. Generally, ex ante controls are not as effective as ex post controls and should be reduced as much as possible. Post-market controls may not even need people with the training and skills of inspectors. The more skill and accuracy that goes into establishing a targeted inspection function, it should not be wasted by sending inspectors to follow up a complaint from an individual or to go to see whether there is a building in a field, for a registration application.

04. The Basics of Risk-Based Inspection – Checklists

The third key tool for risk-based inspection is the checklist that is to be the basis of the inspection. This is the agenda for the inspection, setting out the points to be checked. They are based on the rules in the regulations but they do not simply check compliance with each rule. Each question is scored and the weight of the scores reflect the importance of the rule in managing the risks involved. Unimportant details will have a low score or may even not be on the checklist. The checklist should be shared with the business prior to the inspection so that the business knows what the inspector will be looking for. Various points flow from this:

- The checklist re-connects the regulatory operation with the underlying reality being managed, rather than just checking each point in the rules. It is a key element in risk-based regulation, allowing the specific situation facing the inspector to be assessed as a matter of risk management rather than legal compliance.

- Despite that emphasis, it will still be backed by the full powers conferred in the regulations so that sanctions can be imposed if appropriate. Sanctions can only be imposed in the case of violations of the regulations and not just on the inspector's assessment of the risks.

- There have been cases in other countries where the checklist convinces businesses of the value of the rules and they see the benefit of compliance. The rules make sense to them in a practical context, rather than being an abstract obligation.

- The checklist prevents a corrupt inspector from inventing violations to punish or threaten to punish.

- Some countries have tried to require businesses to carry out a self-assessment of the checklist prior to the inspection, in order to increase their awareness of the issues and start to challenge themselves.

However, checklists take time to develop and tend to be main factor in how long it takes to develop a fully working risk-based inspection system. The initial interpretation of the regulations and guidelines into checklists has to be done by the same skilled people as the risk assessment, i.e. a Risk Assessment Unit, because it is prioritising risk issues. That prioritisation is also reflected in the scoring system for the various points being checked. This requires skilled risk analysis. But the form also has to be practical and capable of being used as an operational tool. This is often a matter of trial and error, with feedback from the inspectors being crucial. One of the earliest problems was the simple one of yes/no questions on the form when the situation facing the inspector didn't fit either. But the issues that arise will be more varied and perhaps sector-based. They are resolved by feedback from the inspectors and discussions between inspectors and analysts.

An example of a checklist is at Figure 5. (The original goes on for another four sections.) It is from Mongolia and is a check on hygiene conditions for a food business. It lists the regulatory requirements, but it is not simply a Yes / No. Non-compliance for each provision has a score. At the end, a table converts the total scores to a rating of High, Medium or Low Risk. Points to note are these:

- The answers are weighted throughout, recognising that some issues are more important than others.

- There is a further column to re-score the business on a follow-up, allowing a clear comparison.

- It goes into great detail over one Article in the Law because of the importance of these factors.

- It is a fairly early example from a country that has developed more sophisticated checklists over a few years. The scoring allows only 3, 5 or 10 whereas a wider range is not unusual in checklists.

- The assessment table has a low threshold for High Risk of only 50% of the overall score. This also indicates that it is an early example of their development of checklists. A few years' results across a range of businesses would allow them to review their scoring.

05. Planning Inspections

Risk-based Inspections allows work to be pri-oritised, by scoring all the businesses according to the level of risk they present. Each business will have an overall risk profile that allows it to be placed in a list of importance. The earlier section on risk profile showed how the profile is a combination of external risk factors and the performance of the business. The next section on checklists then added another score. It fits within the assessment of the business's performance under the risk profile.

How the scoring converts to a work plan can be flexible. It could be done on an absolute basis, i.e. anything over, say, 75 is High Risk, anything between 30 and 75 is Medium Risk and the rest are Low Risk. Alternatively, if there is enough differentiation in the scores, all businesses will be listed in order, so the risk level can be percent-ages, i.e. the top 25% High Risk, etc. It should work through to a pyramid, as in the classic idea of the Risk-Based Inspection Pyramid, illustrated in Figure 6 below.
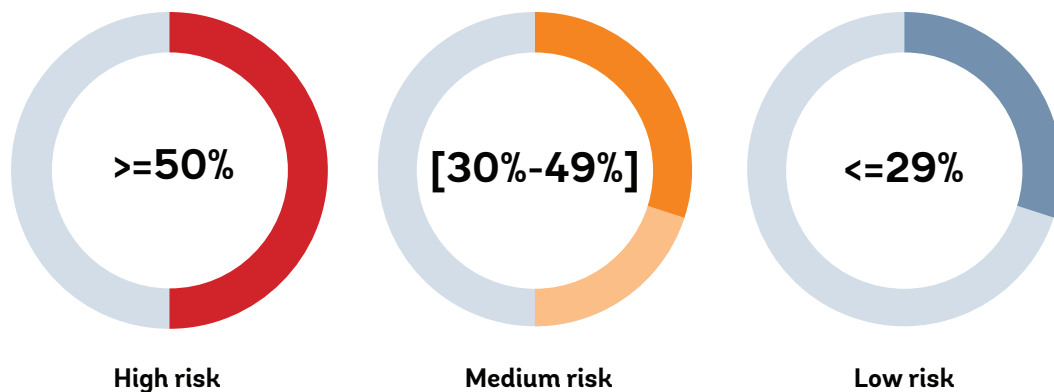
Figure 6. The Risk-Based Inspection Pyramid

Source: Author's diagram
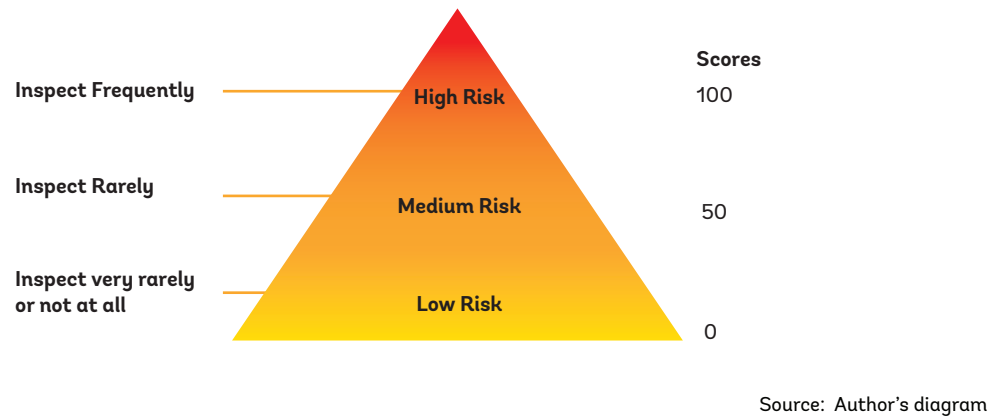
Figure 5. Example of a Checklist

No	Names, articles and provisions of corresponding legislation, rules, procedures and standards	Questions	Approved scores		Scores taken	
			Compliant	Non-compliant	During inspection	During follow-up inspection
	I. Surroundings, buildings and facilities		0	69	0	0
1	Food Law, Article 10.1.3	Buildings and facilities are constructed, expanded or renovated according to a drawing of a professional organization	0	10		
2	Trade centre and its service. General requirements MNS 5021:2007 standard, Article 6.1	Planning, design of building of trade facilities and practices conform to the service technological flow	0	10		
3	Construction norms and rules 31-03-03	Outer area has pavement, and commodity unloading area and parking lots are paved and has lawns	0	3		
4	Food Law, Article 10.1.2	Connected to the central or local/sectional water supply system	0	5		
5	Food Law, Article 10.1.2	Connected to the central sewage system	0	5		
6	Food Law, Article 10.1.2	Ventilation system works properly and is adequate (physical measurements)	0	10		
7		Ventilation pipes have insect screens	0	3		
8	Food Law, Article 10.1.2	Walls are made of materials suitable for cleaning and are clean	0	3		
9	Food Law, Article 10.1.2, Construction norms and rules 31-03-03	The ceilings are free from unpainted parts and fallen panels, free from dust accumulation and no visible presence of mould growth	0	3		

No	Names, articles and provisions of corresponding legislation, rules, procedures and standards	Questions	Approved scores		Scores taken	
			Compliant	Non-compliant	During inspection	During follow-up inspection
10	Food Law, Article 10.1.2, Construction norms and rules 31-03-03	The windows are made of easy-to-clean materials and are clean	0	3		
11		The windows have insect screens on the opening parts and do not allow accumulation of dust	0	3		
12	Food Law, Article 10.1.2, Construction norms and rules 31-03-03	The doors have smooth and even surface, and are made of waterproof and non-corrosive materials	0	3		
13		Doors can be fully closed or are self-closing and are kept closed when not in use	0	3		
14	Food Law, Articles 10.1.2 and 10.1.4	Has adequate natural and artificial lighting (physical measurement)	0	5		
	TOTAL SCORE		0	69		
	ASSESSMENT				……… Risk	……… Risk

>=50%

High risk

[30%-49%]

Medium risk

<=29%

Low risk

In theory, that is straightforward, and it has been successfully applied around the world. But establishing such a system takes time, resources and organization. It will usually take at least three years before enough data is gathered to have a reliable overview of where the main problems are in the sector and it will need a specialized team to lead that work. But it is a challenge that has to be faced sooner or later.

risk. Scoring will give at least a first spread of the businesses but there are limits to how far this should be taken. If there are three High Risk businesses within an easy distance of each other, it is better to inspect all three at around the same time, rather than criss-cross the country according to the actual scores. The system is supposed to be efficient as well as effective.

Using the results

The centralised inspectorate in Mongolia built a Risk-Based Inspection system with very modest resources. Data from all inspections was gathered and analysed in Excel spreadsheets on a laptop by one inspector. After three years' worth of data was collected, she went around all the inspection teams, both in the main city and in all the rural areas, sharing the results.
She could show clear patterns of results and trends but also identify anomalies which needed explaining. When visiting a team with anomalous results, the discussion usually deepened the understanding of what the team was doing. Trends could be seen according to location or size of business, or market effects or gradual development of the system itself.
These discussions convinced the inspectors of the value of the system and increased their professional satisfaction by a new awareness of the difference they were making as the "risk landscape" came to life.

The first problem usually encountered is that the pyramid is upside down, i.e. the great majority of businesses have been assessed as High Risk. This is usually inexperience, with inspectors being reluctant to accept any business as Low Risk. It is also a natural tendency in people starting to talk in terms of risk that risk identification is easier than risk assessment. Risk assessment involves judgement and knowledge whereas risk identification requires a bit of imagination. However, everyone is capable of crossing a busy road, where their lives can depend on the assessment, which is done without thinking. Collecting the factors involved in the risk profile and making the assessment takes experience in developing judgement, just as a child is much less able than an adult cross a road safely.

But the pyramid has to be the right way up, otherwise risk is no longer useful as a criterion for prioritization. It is also the case that there will always be a progressive scale of the level of risk presented by various businesses. Even if they are identical, a business supplying one more customer than the other is theoretically higher

Although a fully developed system takes years, a start can be made on a more methodical way of approaching planning by using the experience and knowledge of the inspectors. In any country, an experienced inspector will be able immediately to identify the worst five businesses in his area but he may take longer to identify the top 50. The other factors of the type of activity and the potential impact (which is usually derived from the size of the customer base) are capable of being identified and a list made up. This will only be in the formal sector but that is the starting point. The risk profile is made up partly from objective factors such as activity and size that can be obtained from data already held in some parts of government. That is a large part of the justification for the registration and licensing process. The historical record of performance is what takes time to develop and gather but in some ways that is the least important factor. If a business has the potential to cause serious damage, it probably needs some level of supervision regardless of its performance record. Conversely, a small street vendor is unlikely to be worth inspecting no matter how badly run.

Special or investigating inspections will be needed and, by their nature, are not planned. However, they should still be risk-based. Complaints can cause problems when trying to follow a risk-based approach because they will rarely be other than low-risk incidents. They will matter to the person complaining but that should not be a criterion for allocating public resources. An experienced inspector's time spent investigating a complaint is the same as that spent inspecting a high-risk business. There needs to be a system for handling complaints that minimizes the use of experienced inspectors.

The ratio of planned to unplanned inspections is a key performance indicator of an inspection agency. The target should be 85/15 or even 90/10 of planned/unplanned.

06. Following the Data

Given that the essence of the inspection is a reality check on the business (and, to some extent, on the system itself), reporting findings is a vital stage. A digital system is essential because the data needs to be not only stored but capable of searching and analysis. This does not need an expensive IT project. Remarkable results have been achieved elsewhere with basic spreadsheets in Excel on a laptop, although anything more sophisticated could still be beneficial. The World Bank has supported a specialized inspection IT system in over eight countries which has shown good results.

The updated or confirmed risk profile for that business is the primary data. This is the centre of the risk-based approach. That data builds the "risk landscape" of the sector and allows not only better deployment of inspectors but analysis of what is happening in the sector. The data should be dynamic, as each inspection of the same business updates the picture. Changes in risk levels can show progress in delivering the regulatory objectives but may also show different changes in different parts of the sector, inviting investigation into what might be happening. Figures 7 and 8 below (from Mongolia) also show how checklists can provide data on changing risks within various activities.

Figure 7. Construction risks according to activity

Carcass construction installation work inspection checklist: Low 75, Medium 8, High 8

Brick construction installation work inspection checklist: Low 20, Medium 5, High 12

Assembled construction installation work inspection checklist: Low 0, Medium 0, High 0

Building usage inspection checklist: Low 26, Medium 57, High 148

Low   Medium   High
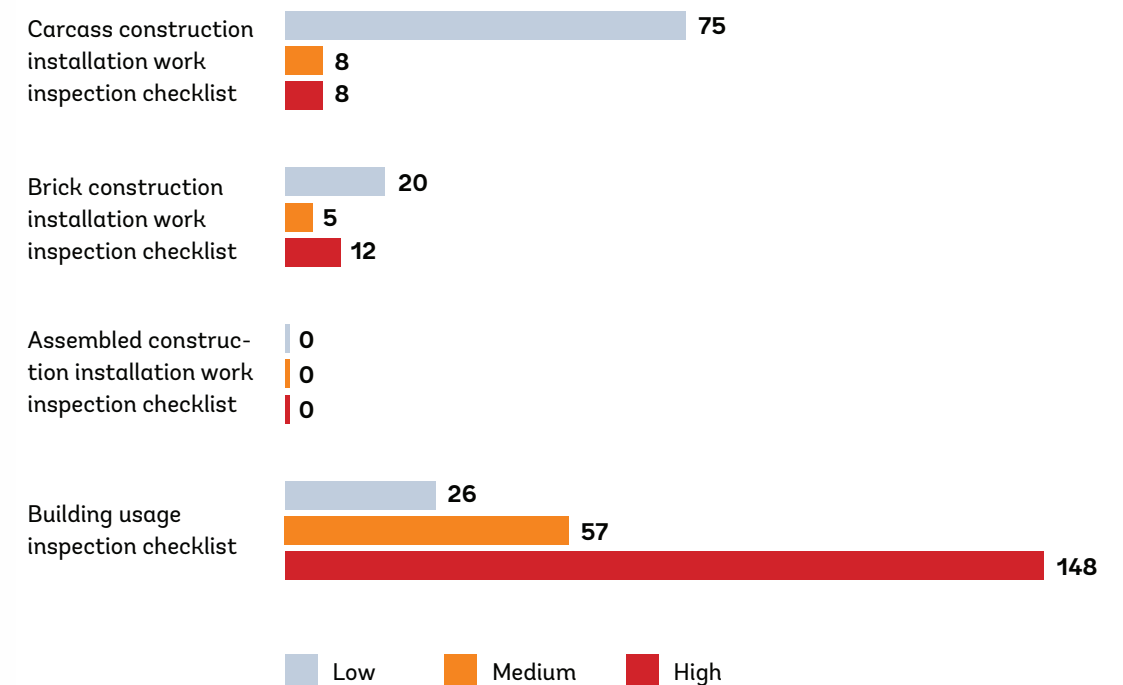
Other data can be updated or confirmed, such as management changes or changes in activities carried out. There should be even less justification for a renewal process for registration. Inspections do not collect commercial data on profitability but production figures are relevant to the "impact" element in assigning a risk profile. Profitability, however, can be a very important factor in business compliance, with bigger risks being taken the closer the business is to closing down. The inspection report should have space for observations by the inspector which could legitimately include such concerns.

Checklists take a few years to settle into an optimal form, through experience in use. Some questions may turn out to be inappropriate and other issues may keep coming up without a clear place in the checklist to record them. There has to be feedback from inspectors on the usefulness of the checklist and regular review.

Figure 8. Environmental Risks
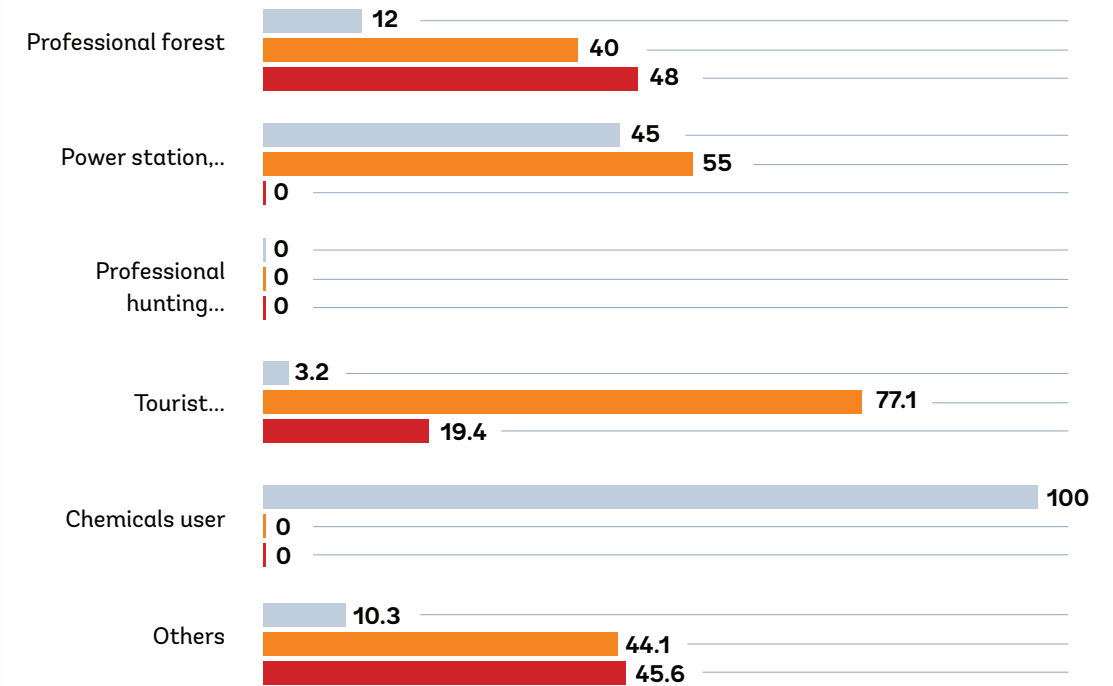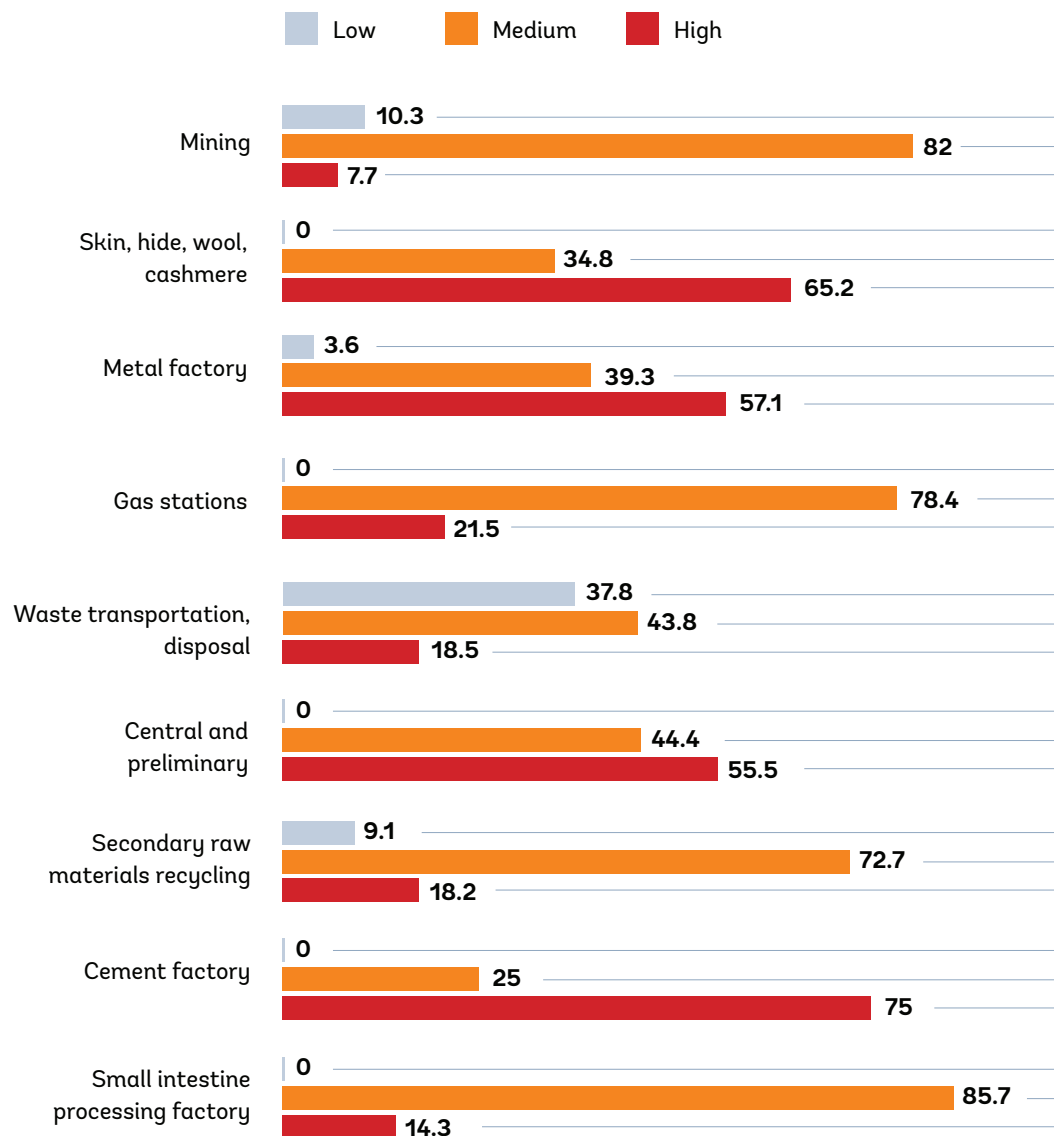
There also need to be occasional discussion sessions amongst the inspectors. All inspection systems have a need for some use of discretion but this is extremely difficult to build in. It is essentially subjective and usually arises in unforeseen situations. What has been found useful in managing this is having inspectors share their experiences and have their decisions peer-reviewed by colleagues.

The inspection may not be complete at the end of the visit. Some improvements may be needed to be carried out by the business and need to be checked that they have been done and done correctly. Even with a supportive ethos towards the business, inspectors still have power to impose sanctions and situations may arise where this has to be considered. Such situations are rarely resolved within one visit. Sanctions should be used to ensure improvement in the future, not as punishment for the past, therefore there is usually a need for follow-up. When things go badly, follow-up can be significant. It can involve appeals or court procedure or even legal action against the inspector or the Inspectorate for alleged misuse of powers.

07. Performance Management

Changing from a focus on process to a focus on results has implications for performance indicators, both for individual inspectors and also for the management they are under. When what matters is process, performance indicators are usually outputs from the process. These tend to be:

- **Number of inspections;**
- **Number of non-conformities found;**
- **Amount of fines imposed.**

The number of inspections is of doubtful value without a risk-based system. Many could have been of low-risk or well-run businesses that should not have been inspected anyway. The number of non-conformities may be useful data in a wider context but as a performance indicator it tends to reward a greater number found just as a large amount of fines would also be rewarded. But these last two are indicators of failure of the regulatory system, not success. These indicators therefore drive negative approaches to inspections, looking for failure and imposing sanctions.

The Mongolian example in Figure 9 below shows positive results, even if it took four years to achieve. It really took off in 2014, after three years.
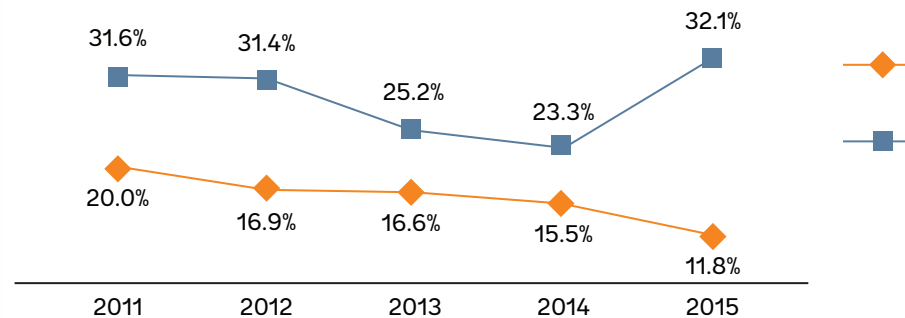
Figure 9 – Achieving results over time.

Over a four year period, the Mongolian central inspectorate could show that the number of High Risk entities (in red) had been reduced and the degree of compliance (green) had increased in 23 sectors – with four examples given here.
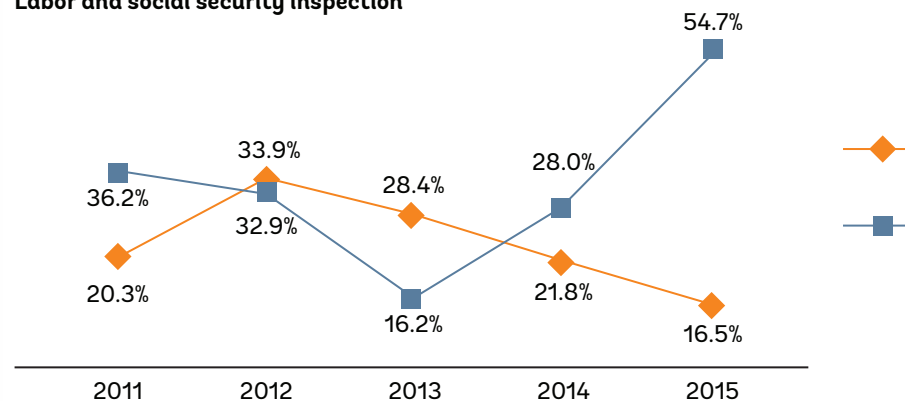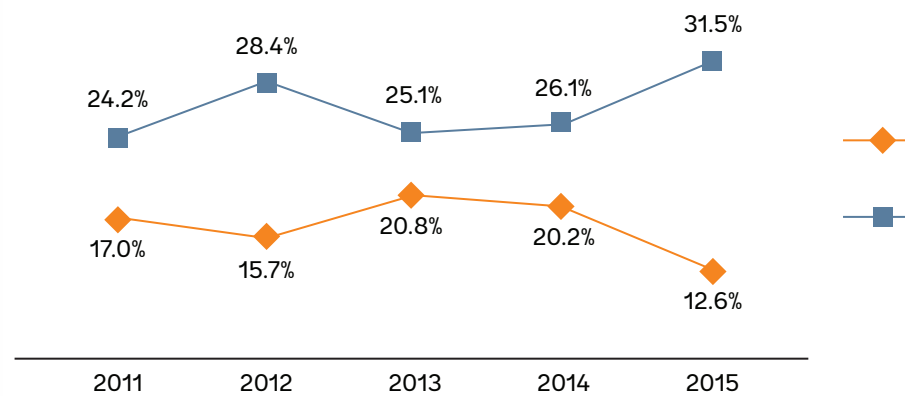
Environment, geology and mining inspection
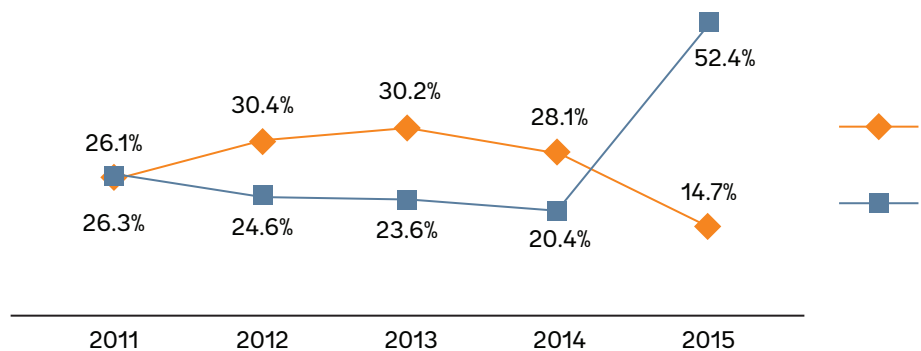
Health inspection

Labor and social security inspection

Infrastructure inspection

Performance indicators should reflect successful delivery of the system indicators, such as:
- Reduction in the number of risk profiles that are High Risk;
- Reduction in the number of non-conformities found;
- Increase in number of businesses self-regulating;
- Number of informal businesses migrating to the formal sector.

But the performance indicators most needed relate to the original objectives of the sectoral regulatory framework, such as:
- Reduction in animal disease outbreaks;
- Reduction in workplace accidents;
- Preventing import of invasive species;
- Reduction in outbreaks of food-borne illness;
- Improve consumers' awareness of dangerous products.

These indicators are real-world results, which is what the Risk-Based Approach is designed to deliver. That takes us back to the original diagram about the Risk-Based Approach in Figure 2: What is being managed by the regulatory system is the impact of the business entities on the real world. The regulatory system imposes rules on the businesses as a way of making that impact beneficial. The diagram at Figure 2 is therefore framed within what happens in the real world, at the top, and actions by the business entities at the bottom. The green connectors trace the risk-based process, and the blue connectors are the feedback loops. This is a visual representation of how the risk-based system works.

- The starting point is the situation in the real world, with the values to be protected by the regulatory system and the dangers that threaten these values.

- These dangers are analysed in hazard analysis of the sector which examines what is happening across the whole sector, in both economic and technical terms. It can also take a strategic view of future, such as the impact of new technologies. It identifies the main threats and those that are likely to occur are identified as risks.

- Having identified risks that may damage the sector, the next step is to identify those that the regulatory system can do something about. There will be socio-economic trends that the regulatory system can't do much about but the Inspectorate can work with partners to explore where it may be able to make a difference.

- Checklists need to be written to combine the rules from the regulatory framework with the impact they will have on the risks to be managed. The risk analysis allows a weighted score to be given to each of the regulatory requirements so that the inspection is a worthwhile check on how well or badly the business entity is doing in managing the risks it has to control.

- In parallel, the risk analysis also identifies the factors to take into account for each business entity in order to assess what level of risk that entity presents. This is built into the risk profile for that business. Part of the risk level is the activity itself, e.g. a food-processing plant, part is the extent of the possible damage it could cause e.g. whether it supplies many other businesses, and the other part is the management capacity of the business, i.e. whether it can control its risks.

- The Risk Profile allows inspections to be prioritised, with the High-Risk businesses being inspected before Medium Risk (and with Low Risk rarely inspected at all). The risk-based process up to this point delivers the focus for the use of resources where it is likely to be most effective (and to avoid resources being spent where it is not worth it). But the risk-based process at this point has also delivered the checklist which ensures that the inspection will be practical and effective.

- Each inspection also generates data and learning. This feeds back into refining both the checklist and the risk profile. It takes experience to refine a really effective checklist and inspectors need to feed back on how it has worked in the range of situations they cover. The management capacity of the business is the third element in the risk profile and that comes largely from its inspection record. The inspector will see at first-hand how well or badly it is controlling its risks. The inspection data can also be seen as a survey of the businesses in the sector and analysis of that data can identify trends, patterns, outliers and perhaps even performance data for the sector as a whole.

- There is no clear connector between the process to this point and the actions of the business entity. There should be some effect arising from the inspection, but it can be difficult to attribute the business's actions to that. At one level, the inspection is passive and reactive, noting what is happening, but it can also be dynamic and proactive. The extent of a causal link between the inspection function and the actions of the entity is complex but that does not mean it is ineffective. It is one factor amongst many.

- The risk-based inspection cycle has concentric cycles. There is the inner cycle where the inspection itself feeds back into the risk profiles and checklists, as explained above. But the main, outer one is the impact of the actions of the business entities on the real-world situation. That is the whole point of the regulatory system. But that can also start the cycle over again, depending on what impact it has had. It can show whether the system is delivering or not, but it may also show how well or badly it is working. The real-world situation should be regularly updated anyway, quite apart from the feedback from the business entities, in order to identify emerging risks from other factors. That feeds through the risk analysis process to the risk profiles and checklists again.

Part 2

DELIVERING RESULTS

08. Compliance

The Risk-Based Approach is designed to provide both efficiency and effectiveness. Efficiency comes from prioritising where to apply resources and effectiveness comes from focusing on results. This second Part now looks at how to use the technical system in better, proactive ways to deliver better results. This is the new discipline of "Regulatory Delivery" – how to make regulatory systems work.

Responsive Regulation

One of the main tools of regulatory delivery is called "responsive regulation" and builds on the attitudes of the people being regulated. The traditional view is that they are all much the same, are primarily reluctant to comply and will find whatever ways they can to avoid complying. Some policymakers go further and assume that all businessmen are crooks. Experience across widely different countries has applied the "responsive regulation" model that segments the people subject to regulation into four categories – already compliant, willing to comply but not fully compliant, opportunists and criminals. Very broadly, these categories also break down proportionately by number and volume of output into the distribution shown in Figure 10 below.

Figure 10. Responsive Regulation – Categories, Distribution and Responses

Different techniques are needed for different attitudes to compliance.

But the main aim should be to raise overall levels of compliance.

| Criminal | ← | Robust enforcement |
Opportunist	←	Persuasion or sanctioning
Compliant	←	Monitoring
Willing to Comply	←	Support and advice

Source: Author's diagram

Most businesses are either already compliant or willing to comply. Very few are actually criminal. The point of all this, however, is that each category requires a different response from the Inspectorate. Robust enforcement, with strong sanctions and wide publicity, is needed if there are criminals who are causing damage or danger, with no concern for the impact on others. So, the policing model is not entirely invalid, but these should be very exceptional cases, rather than a basic approach to the whole exercise. It may even be that the activities should be dealt with by the police insofar as they may come under the criminal law anyway.

The most important category is those willing to comply but not yet compliant. That is the key to effective delivery of the regulatory objectives. Insofar as they are not compliant, the reason for non-compliance is key. If they don't know what to do, fining them will not change that but instead reduce the resources they have to invest in compliance. With this group, sanctions are usually counter productive.

The finding that most businesses are either willing to comply or compliant is not as unusual as is sometimes thought. These are businesses and they have enough problems managing their core business activities that any external pressures need to be minimized with the least possible hassle, including compliance with externally imposed regulations. There is rarely any point in fighting against the system, so it becomes another overhead to be managed as economically as possible. And if they can be shown that the actions that constitute compliance actually benefit the business, they will be motivated to comply. Figure 11 below shows the "responsive regulation" distribution in one country where the World Bank surveyed inspectors in five parts of the country for their assessment of the attitude of the businesses to compliance. These inspectors worked regularly with the businesses so had no difficulty in making the assessment. Some additional questions in the survey further supported the findings.
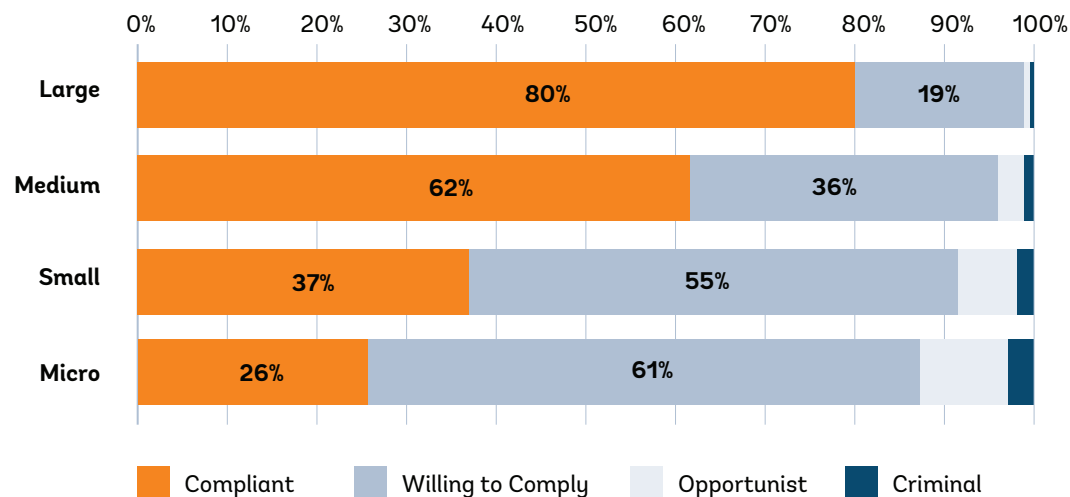
**Figure 11.** Actual distribution in one country survey

Opportunist 5%
Criminal 1%
Compliant 51%
Willing to Comply 43%
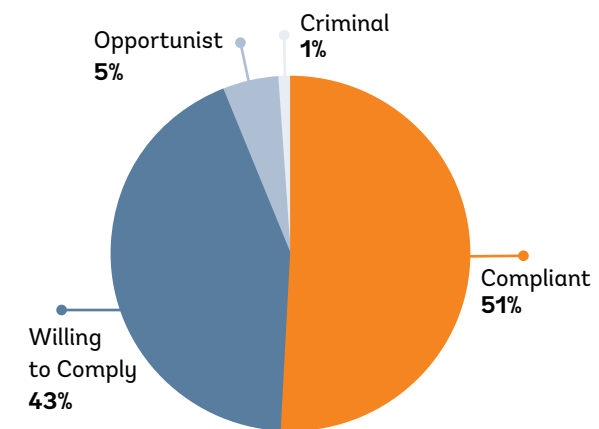
Source: Unpublished World Bank survey

Figure 12. Distribution according to size

Legend: Compliant | Willing to Comply | Opportunist | Criminal

In this survey, 94% of businesses were assessed as either already compliant or willing to comply. This was then broken down according to the size of the business, as shown in Figure 13 below. It is not surprising that the larger businesses were more compliant. They have the resources to manage compliance and will often be competing at a level where compliance comes as standard. Multinational companies need to meet global standards that often go beyond any individual country's standards or regulations, simply because it is inefficient to have different operations in different countries. The smaller the company, the greater the non-compliance. Again, that is to be expected. With the smallest, there was the highest incidence of opportunist or criminal activity but another question in the survey looked at the extent to which non-compliance was deliberate or unintended – see Figure 13.

Figure 13. Deliberate and unintended non-compliance


Legend: Deliberate | Unintented
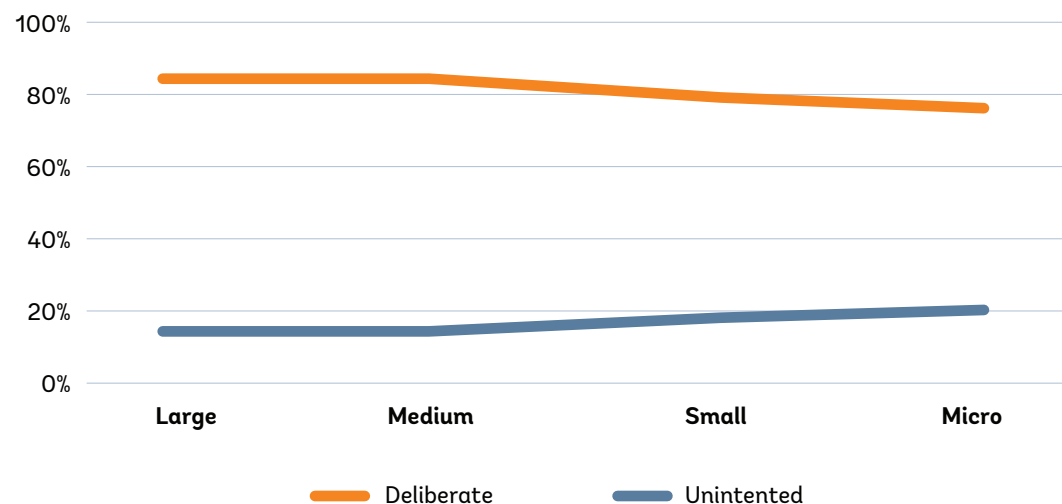
There are two points to take from this diagram. First, that the overwhelming number of non-compliances are unintended. This bears out what the inspectors in that country told us in open questions – most businesses are just trying to get it right. Second, the deliberate cases increase with how small the business is. The inspectors explained this in terms of these small businesses not having the resources to comply, rather than not caring about compliance. They knew some things were wrong but couldn't see how to avoid it.

Managing compliance

What this shows us is a very encouraging message that the great majority of businesses – including the small ones – are willing to work with inspectors to comply with whatever rules are set. The challenge of this message is working out what the Inspectorate needs to do to build on this and convert those willing to comply into complaint businesses. In Figure 13, the area circled in green shows the main challenge for successful delivery – work with the smaller end of the sector to find out the barriers to compliance and then tackle these barriers.

Figure 14. Drivers of compliance
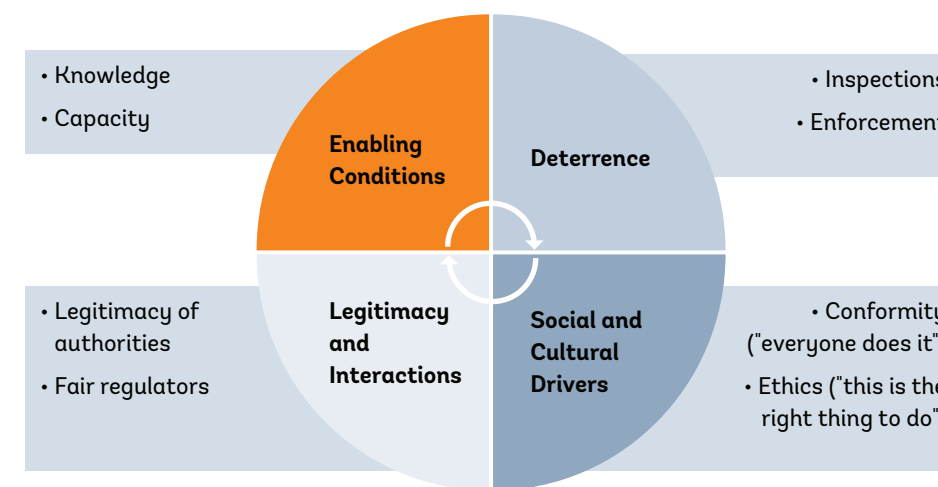
Source: "From Chasing Violations to Managing Risks", Florentin Blanc 2018 Elgar

Figure 14 above gives a model of drivers of compliance, based on extensive research in many countries. Cost of compliance matters, of course, but is not the key factor. Deterrence matters but much less than we thought before. The main factors are usually:

Ignorance – of the regulatory requirements or even of how to operate efficiently in that sector;

Capacity – they know what to do but don't have the skills, staff, premises or equipment;

Costs – they can't afford the full compliance costs;

Legitimacy – they are being treated badly and don't respect those enforcing the rules;

Competition – their competitors aren't complying (and getting away with it) so why should they? (This one also works the other way if compliance is seen as good – "this is how we do it round here")

The complexity of these factors again shows how a simplistic model of deterrence, sanction and inspection is not going to be effective in most cases.

A final factor to add to this consideration of the overall approach to regulatory delivery is the difference between increasing compliance and reducing non-compliance. Closing down a bad business doesn't create a good business. So, how much does the policy depend on stopping the wrong things or increasing the right things? If the objective of the policy is to create positive outcomes, it will probably depend on encouraging positive actions by businesses. A simple example is the regulatory system for food safety in Shanghai, a city of around 26 million people. The objective is to provide safe food for 26 million people. Closing down 100 restaurants will be statistically insignificant in tackling that problem. What the regulatory system needs to do is to appropriately support perhaps a quarter of a million small food businesses to improve their practices. Reducing the proportion of criminals does not increase the number of compliant businesses.

How much compliance do you need?

The objectives of the policy must always determine the approach to delivery. The discussion above looked at regulatory objectives that are positive, such as increasing safety, but some regulatory systems are about reducing undesirable outcomes, such as anti-monopoly rules. Most regulatory objectives, however, are about positive outcomes. The theory is that if enough businesses do the right things, then the regulatory objectives will be delivered. But what constitutes "enough"?

This varies from one system to another but 100% compliance per business across 100% of the businesses is only a dream. Even the best multinationals will have a minor issue somewhere, but does it matter? The smallest businesses may never achieve even 50% compliance but if many of them move from 30% compliance to 40% compliance, that will raise the overall outcomes across the country. In 2007, the UK's Food Standards Agency set a target of 75% of inspected food businesses being "broadly compliant". If that was met, the FSA considered that its policy would be delivered. (In the last few years, over 90% of food businesses have been broadly compliant.) But note also the use of "broadly compliant". Just as it would be enough for 75% of the business to be good enough, each business didn't need to be 100% compliant either. The measure of "broadly compliant" was scoring 3 to 5 (out of a maximum of 5) on the hygiene rating scheme.

Not all rules are equally important in terms of delivering results. Also, the more specific the rule, the greater the chance of a technical non-compliance that makes no difference at all

to the policy. If a doorway is 5 centimetres less than the prescribed width, it is the detail of the rule that is the problem, not the performance in practice. The rules should specify the results to be achieved and leave it to the business to deal with the realities of life and work out the best way to achieve it.

So, an inspection system that fines businesses for technical non-compliances that have little impact on the regulatory objectives is more about providing work for inspectors than delivering a regulatory system. What matters is whether the business is aware of the issues, is trying to get it right and is not doing anything that is genuinely dangerous. Minor issues should be dealt with by explaining what is wrong and how to remedy it. An inspector is too valuable a resource to waste on turning a good enough business into an exemplary business. Enforcing a pointless rule raises the real danger of alienating the business and turning it from being willing to comply to trying to subvert or game the system.
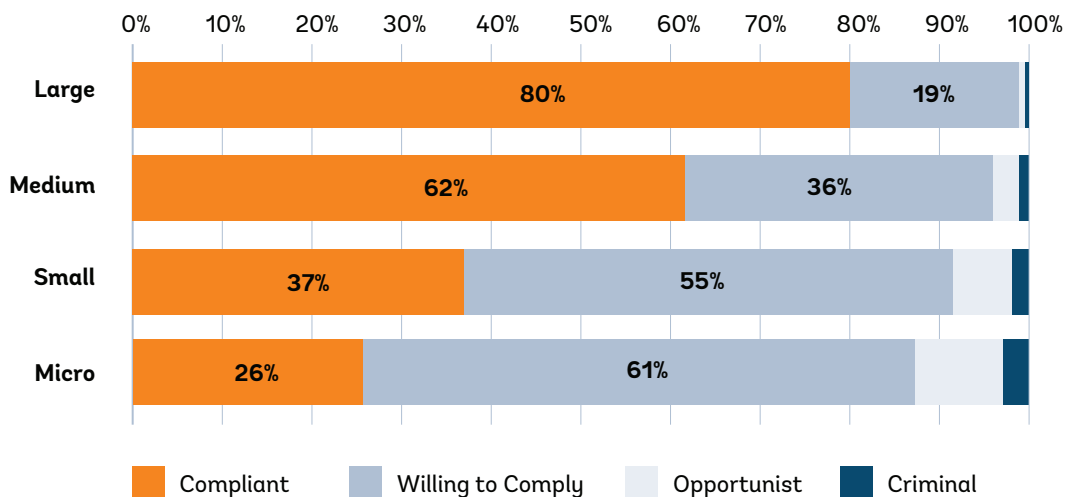
How many inspectors do you need?

Inspectors are useful for more than just inspections. They are the "eyes and ears" of the regulatory system. But they need to be used that way to get the benefit, and this is not often done. They gather a lot of incidental knowledge about the sector and about business practices so potentially can be valuable advisers to businesses. They may also have significant technical expertise in the issues of that regulatory system, both in terms of the rules and the science. Again, this can make them valuable to businesses in advising them on better ways of operating. Or they may be overloaded, under-trained and under-paid, in which case they are likely to extort money from businesses and do more damage than good. One-on-one inspection is expensive and may not be worth it in many cases. Inspections are paid for by the taxpayers and it should be possible to

estimate what benefit the taxpayer gets from that investment. The truth is that many inspection teams exist for historical or legacy reasons or a general assumption that a rule-based system has to have some element of checking by government officials. When trying to tie down a causal connection between inspection activities and regulatory outcomes, it usually proves extremely difficult. There is nothing automatic about it. When Armenia introduced risk-based inspection, it placed a moratorium on inspections of SMEs until the inspection body had a full set of checklists. It took three years, during which time nobody noticed any difference in regulatory outcomes. The inspections had been delivering no public value at all. It was the same in Georgia after the "Rose Revolution", when most inspection bodies were disbanded, and no public harm was subsequently identified. This is not to say that inspection is a waste of time but rather that establishing what public value results from having inspections can be difficult and contentious.

The better question to ask is how to optimize the inspection resource available. First, of course, apply the Risk-Based Approach. But this is not just a matter of inspecting the very High Risk businesses. It is a matter of assessing the optimal outcomes for the sector. This goes back to the choice between reducing non-compliance and increasing compliance. It is useful to look again at Figure 12.

Figure 12 Distribution of compliance by size.

	Compliant	Willing to Comply	Opportunist	Criminal
Large	80%	19%		
Medium	62%	36%		
Small	37%	55%		
Micro	26%	61%		

This shows that working with the businesses that are willing to comply but not yet compliant should be a major focus. But many of them will be Low Risk because they are small or micro. Individually, they are Low Risk but collectively they may be High Risk. The individually High

Risk businesses are more likely to be large, simply because of the potential impact. As a matter of assessing the risk to the sector, the Inspectorate should cover both. The way to do that is to look beyond just inspections.

09. Beyond Inspections – Engaging and Influencing

The move away from the policing model of inspections has been a positive one of developing new ways of working, not just a rejection of a model that was failing. Coercion is needed when the business refuses to stop dangerous practices but that is not often the case. If a business is trying to be compliant, coercion is not only not needed but will alienate the business. What matters is building on the willingness of the business to comply. But that requires a new approach, new methods and new skills.

The key to increasing compliance is to understand the barriers to compliance and to deal with them. This means genuine engagement with the businesses. Experienced inspectors will already have some understanding of some of the issues, but this needs systematic gathering of data, preferably by a survey of businesses by an independent third party, to encourage businesses to be open. If the data begins to show common themes and issues, there no longer needs to be a one-on-one transactional level that is necessary for conventional inspections. The same remedy to a problem may work with hundreds of businesses.

Figure 15. Example of a Modern Regulatory Infographic
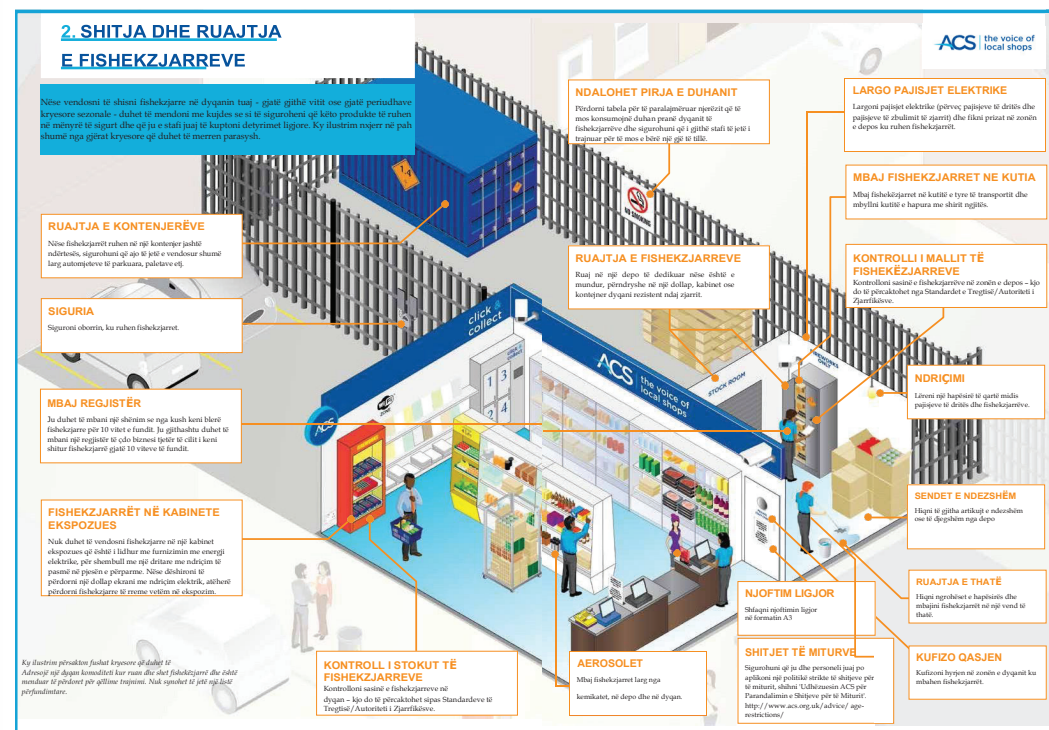
Source: Association of Convenience Stores - https://www.acs.org.uk/advice

A common barrier is not knowing or not understanding the rules. Better ways of announcing and explaining the rules is part of engagement and can make a significant difference at relatively little cost. This can be seen in Figure 15 which is an example of using infographics to socialise and explain a set of rules for a small business. This is the way that modern regulatory delivery is moving. Small businesses don't read laws or regulations or even guidelines or standards, but they shouldn't have to.

Infographics can be disseminated online and don't even need to be printed centrally and distributed. The business can print them locally and pin them to their walls. They can also be produced in different languages, at little extra cost.

The real potential for engagement, however, is with the informal sector. A single online infographic or a YouTube video can reach thousands of small and micro businesses. For them, improvement is more important than compliance. Even if they wouldn't pass a proper inspection, if they can improve their practice levels then that is progress. Improvement across thousands of small businesses is significant progress. The food control authority in India is tasked with delivering safe and wholesome food to 1.5 billion people every day and it is now trying to raise practice levels across the enormous informal sector. It has produced 350 YouTube videos and very few secondary regulations.

This is a new way of implementing regulations but it is based on the same fundamental approach as the traditional method – influencing the actions and decisions of businesses in a way that will deliver the intended outcomes. We now have different ways of doing this that weren't available before. Ten years ago, it was radical to suggest that a regulatory agency should have a Facebook page but now social media skills are becoming necessary to being an effective regulatory agency.

Another way for an Inspectorate to extend its effectiveness is to work with partners that are looking at the same problem, perhaps from a different angle. A classic case is Customs, which can be a very useful partner to various Inspectorates because of the control available at borders and the systems that Customs will have already devised for managing data on imports. The voluntary sector may also be concerned with some of the socio-economic issues underpinning some Inspectorates' regulatory objectives and may already have well developed networks across the country. Trade Associations may be useful, if they are well run, but developing a good quality website for the Inspectorate may begin to provide a better platform for engagement with businesses. For some sectors, consumers can be a very powerful ally because their buying choices can influence businesses more convincingly than an inspection. Inspectors can impose fines but consumers can make or break businesses. There may also be opportunities to share problems with the Inspectorate's counterparts in other countries.

10. Institutional Requirements

All this has implications for the Inspectorates. This Guidance is presenting what is happening across the world in the development and implementation of regulatory delivery. To illustrate how far this model has grown, a recent conference on regulatory delivery had 400 delegates from 60 countries across six continents (including a delegation from Kosovo, whose General Inspector made a presentation of the current challenges in the Kosovo reforms). What is outlined in this paper is a mixture of settled learning on the application of Risk-Based Inspection and also highlights from good international practice. The Inspectorates have an opportunity to build on this collective global experience but they first have to decide on their level of ambition. The Law on Inspections is, in some respects, state of the art. The Inspectorates' level of ambition could extend to leapfrogging other countries and aiming for a state-of-the-art system.

RBI can't really be applied piecemeal by individual inspectors. It requires a systems approach from the Inspectorate. It may be that the Inspectorate already has a well-resourced inspection system that is not risk-based but it has a good management team and some data analysis. That will make it much easier to make the transition. Where the system has been based on checking technical compliance and imposing fines for all violations, there will be a significant cultural challenge in adapting to RBI, in addition to a management challenge. If an inspector has been rewarded for imposing fines and finding many violations, it will be a big adjustment to become supportive to businesses that are trying to improve.

To fully apply Risk-Based Inspection requires a framework as set out in Figure 16.

Figure 16 – The New Inspection Framework
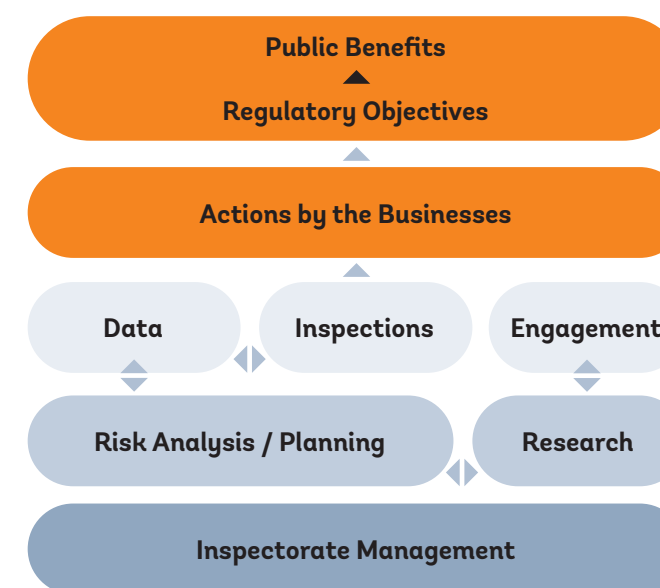
Inspections are in the centre but it is clear that there is a lot more to the Framework than inspections:
- The overall purpose is delivering the intended public benefits, through delivering the objectives of the regulatory system being applied.
- But these objectives are delivered by what the businesses do, not directly by the inspectors or any other part of the government: the government's challenge is to find ways of influencing what businesses do, and inspection is only one tool. Other forms of engagement with businesses, through advice and education or pressure from consumers, can also affect their actions. This can also have an impact on the informal sector.
- Central to the change in inspection operations is the application of risk tools. They increase both the efficiency and effectiveness of inspections by targeting them where they will have more impact. A risk-based approach needs analysis and analysis needs evidence and research.
- Data are fundamental to evidence and analysis. They are what ground the analysis in reality. They show what needs to be done and later show whether that worked. Inspections are both based on data and also themselves generate data on how the sector is working.
- Underpinning all that is the management team for the organization. There is much more to this than dispatching inspectors to carry out inspections.

These functions may require recruitment of new skills which some current Inspectorates don't have. Some are currently hiring many new inspectors and that may be an opportunity to bring in some of the new skills. New inspectors don't necessarily have to take up traditional inspection roles but could be deployed in engagement and research as well as inspection, to create a wider role. Others are lacking sufficient inspectors for the conventional system of inspection and may need to develop the wider approach to supporting compliance in order to increase their reach.

Ideally, each Inspectorate will have the following range of skills and staff, in addition to Inspectors:

Table 1 – Staffing Requirements in addition to Inspectors

Function	Skills	Number
Risk Analysis and Assessment	Risk management, economics, statistics	4
Engagement	Comms., social media, graphic design	3
IT services	IT skills, statistics	2
Legal services	Enforcement, advising on inspection issues	3
Planning and strategy	Sectoral experience, economics, legal	3
Senior Management	Director and Deputy Director	3
		18

The relationship with the relevant Ministry is extremely important. The focus on regulatory objectives should bring both institutions closer and also may allow support for the Inspectorate with some of the new skills they need, especially on risk analysis and perhaps on Communications. It may take time for the Ministry to understand more about delivery but the partnership should strengthen them both. They also need to find a way of making all the relevant laws more suitable for modern regulatory delivery. An insistence on enforcement of detailed laws will reinforce the Policing model and make reform more difficult, whereas agreement between the Inspectorate and policymakers on delivery objectives should override any purist lawyers until the relevant laws are amended.

11. Conclusions

This Guidance paper gives an overview of how to build a Risk-Based Inspection system and how to use it to greatly increase the value of a modern Inspectorate, focused on real-world results. The paper often repeats that it will take around three years to develop, but there is a lot of learning from other countries to build on. But Kosovo starts with other advantages as well:

• It is a small country that has already shown an ability to leapfrog development paths and achieve remarkable results in international league tables;

• The Law on Inspections is as good as they get and provides a strong legislative base for both institutional and operational effectiveness;

• The Office of the General Inspector coordinating a small number of Central Inspectorates is a cutting-edge model for strong development of effective practice;

• The relationship with the relevant Ministry through being an Executive Agency follows some of the leading countries in this field, e.g. the United Kingdom, combining policy and delivery.

All this is generic, as is this Guidance. Each Inspectorate will have its own journey and needs to apply the learning and the frameworks to its own requirements. Risks are sector-specific, and each sector will also have its own Kosovar characteristics. This is where partnership working with the Ministry is vital, but the Law on Inspections recognises this and gives the General Inspector a role to support the Ministry in its supervision of its Central Inspectorate. Different regulatory regimes adapt to RBI in different ways. Market Surveillance will apply it in a different way to Labour, whose system will look more like Agriculture, Food Safety, Veterinary and Forestry, whereas Environment, Water, Nature, Spatial Planning and Construction will be different from both. There will also be significant challenges with the terms of the laws to be implemented, where some may have such a prescriptive approach that RBI will be vulnerable to challenge by conservative lawyers. Some smaller, specialist Inspectorates may have been set up with an extremely narrow remit to supervise specific processes.

Beyond all these challenges lie the cultural issues and vested interests in maintaining the current systems, but that is the case with most reforms. What is proposed here is a paradigm shift in how governments operate to deliver benefit to their people, economy and environment. The traditional approach to delivery of regulatory systems goes back many generations and has left many legacy systems whose origins we have all forgotten but we still apply. But the Risk-Based Approach is based on current realities and has proved itself across many other countries.