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INVESTMENT CLIMATE

Food Safety Toolkit
Risk Assessment, Enforcement and Inspections

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About the Investment Climate Department of the World Bank Group

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Risk responsibilities at national and international levels

As previously discussed in the Module entitled "Legislative Reform," the architecture of the food safety regulatory system needs to be built upon several key elements, three of which are risk focused.

A food safety regulatory system needs to provide for the following:

- **Risk assessment.** This is the process of identifying food safety hazards, assessing likelihood of occurrence and severity, and evaluating the significance.

- **Risk management.** This is the coordinated and economical application of resources to minimize, monitor, and control the probability and/or impact of food-borne incidents and to maximize the realization of opportunities to prosper throughout the food sector.

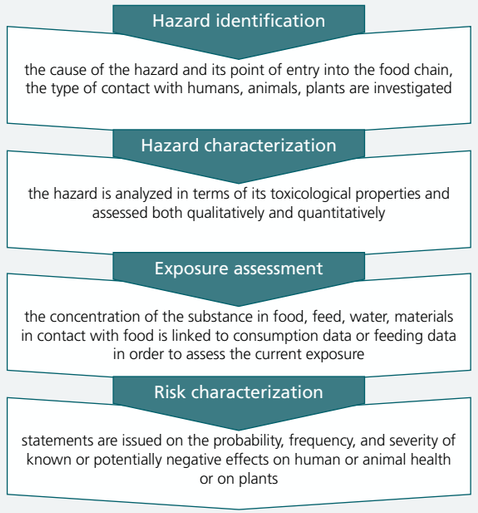
- **Risk communication.** This is the process of ensuring that the logic, outcomes, significance, and limitations of the risk assessment are clearly understood by all stakeholders.

Risk assessment

Regulations and inspection should be based on scientifically sound estimation of hazard risk and an assessment of its management. A risk-based approach considers hazards and likelihood of compliance. This chapter focuses on ensuring a sound underpinning for analyzing hazard risk, informed by good scientific data and evidence backed up by a risk-based approach to regulatory delivery.

Risk assessment of hazards consists of:

Figure 5.1 Process of Risk Assessment



Risk assessment is done according to a defined methodology in an open and transparent manner. In order to secure the independence of the scientific work, a body in charge of risk management should be separated from that performing risk assessment.

[1] Hazard Characterization for Pathogens in Food and Water Microbiological Risk Assessment Series 3, WHO/FAO 2003; Exposure Assessment of Microbiological Hazards in Food, Microbiological Risk Assessment Series 7, WHO/FAO 2008; Risk characterization of Microbiological Hazards in Food, Microbiological Risk Assessment Series 17, WHO/FAO 2009

Risk assessment at international level

Results of risk assessment can be used for the development of new or revision of existing regulations, adoption of new measures, and development of policies. The results provide decision makers with advice in the areas of food and feed safety, nutrition, animal health and welfare, plant protection and plant health, and environmental safety. Information on contaminants (biological, chemical, physical), but also on food consumption and emerging risks can be analyzed. Correlating this data estimates the severity and probability of risks for particular hazards. The EFSA is one example of an international organization that carries out this type of risk assessment role.

Risk assessment at national level

Risk assessment requires specific capacities to be in place and can be very expensive. It is, therefore, advisable to use scientific information provided by EFSA, the FAO, WHO, the OIE, and IPPC and to perform risk assessment only for hazards that are specific for a certain country or in case when special circumstances in a country enhance the probability of a hazard.

In order to help countries perform risk assessment in a standardized and comparable manner, WHO and FAO publish a series of guidelines for risk assessors.[1]

At the national level, a food safety agency or a specialized scientific panel could:

- organize expert risk assessment and organize experts in scientific groups that will investigate risks associated with groups of commodities (or one sector). Agencies or panels frequently copy the model of the Codex Alimentarius committees;
- coordinate and/or manage a network of organizations that assesses health risks (public health services and especially their epidemiological units);
- coordinate and/or manage a network of organizations that assesses the impact of risk management, according to areas of their competence (in developing countries impact of measures is rarely followed, while in developed countries this question is high on the agenda when deciding on new regulations or measures);
- communicate risk to the public – scientists should provide unbiased information and help increase public trust in measures taken by government agencies;
- provide government agencies with expertise in scientific and technical support for policy and decision making;
- collaborate with other national and supranational food safety agencies (like EFSA) in research and shaping of national policies; and
- perform nutritional studies (on nutritional status of the population, nutritional toxicity) in order to have the necessary information for risk assessment of hazards at the national level.

Snapshot 5.1
European Union Practice

In EU countries, national food safety agencies use information developed by EFSA and perform their own risk assessment only for some specific contaminants, usually those that are subject to specific national programs of eradication and monitoring. In Sweden, for example, the food safety agency conducts investigation on Salmonella in food in its own laboratory, which is also the reference laboratory for the EU, and uses these results when assessing the risk and proposing measures. In the United Kingdom, the Food Standard Agency performs independent research on risks and issues guidance on enforcement of food safety legislation, as well as overseeing whether local authorities perform enforcement according to the guidance. In Croatia, the food safety agency performs risk assessment mainly according to data gathered from the national food safety system and only compares that data with the existing ones published in the international scientific literature and EFSA.

Risk management

"Risk management is the process of weighing policy alternatives in the light of results of a risk assessment and, if required, selecting the appropriate actions necessary to prevent, reduce or eliminate the risk in order to ensure the high level of health protection determined as appropriate."[2]

In the risk management phase, the decision makers need to consider a range of information in addition to the scientific risk assessment. These include, for example: the feasibility of controlling a risk; the most effective risk reduction actions depending on the part of the food supply chain where the problem occurs; the practical arrangements needed; the socio-economic effects; and the environmental impact. It is important to stress that all these issues need to be taken into consideration when assessing the risk of a particular hazard. Both national and international bodies are involved in risk management.

Risk management at national level

National risk management bodies, which are official regulatory and control bodies (inspections and testing laboratories), exist in most countries. While in some countries a risk-based approach is taken, in others the approach can have no basis in hazard identification and risk. If this is the case, it is recommended that reforms of the national food safety management system should be prioritized. Examples from EU member states, Canada, or some fast developing countries where functional management system exist may be used as models.

It is important to emphasize that when there is no reliable information available from recognized international sources on specific hazards, national bodies are allowed to implement their own standards. This implementation may also be accompanied by precautionary measures on imported goods, and these measures can require meeting higher standards than may be in place within the importing or exporting country. The burden of proof will be on countries implementing these new higher standards. The standards should not be implemented to limit trade and should only be rigorous enough to prevent the hazard.[3]

[2] Article 3, point 12, Reg Ec 178/2002.

[3] Section 2, Article 7, Reg EC 178/2002, Articles 5, points 6,7,8 of the WTO-SPS Agreement

In order to increase the capacity of the national management bodies, international standard setting bodies organize training for officials worldwide. Also, a practice of setting up contact points for such organizations within the structure of national agencies is facilitated by the CAC, OIE, and IPPC. Through contact points information can be exchanged on best international knowledge and on national results of implementation of measures based on risk management. If this "two way communication" exists, it will increase the local capacity, secure understanding of international standards, and prevent requirements from being issued on the basis of unnecessary protectionism.

On the other hand, if such contact points are placed within bodies that have no responsibility for implementing measures aimed to reduce or eliminate potential hazards (for example, a case when contact points are placed in the standardization offices), then the information flow might be jeopardized and the body responsible for issuing regulations and measures in the food safety area could be deprived from access to the international knowledge. Also, in case when the contact point for one international organization (or sometimes even for several of them) is only one person – usually a director (general manager) of one governmental body, the information flow to all participants in the national risk assessment/management area is often obstructed and when such a person leaves the service, no historical memory remains on how to use the international standards and why they are recommended. This sets a ground for risk management based only on nationally available data and limits the quantity and quality of information used when assessing risks and planning regulations and measures.

Risk Management at International Level

The EU Directorate General on Health and Consumers (also known as DG SANCO) monitors how risk management is being performed by individual member states. One of the ways in which it does this is by overseeing how rules and measures are applied, and inspecting how these measures function in EU member states as well as third countries. It organizes inspection visits to countries, provides reports with recommendations for improvement and according to data from its own inspections keeps an updated list of facilities permitted to place products on the EU market. It also supports national and regional authorities when preparing particular risk management measures.

According to DG SANCO and EFSA findings and recommendations, the European Commission, European Parliament, and member states issue policy, legislative documents, and relevant measures.

Risk communication

Both national and international bodies should be involved in the process of risk communication to ensure that all stakeholders (regulators, businesses, and citizens) are fully aware of outcomes, limitations, and implications of the risk assessment process.

Mechanisms for doing this may vary depending on the nature of the risk and the threat to public health. Newspapers, television, and the Internet – websites and social media – are the most common vehicles used to facilitate communication. Strategic formulation of risk communication mechanisms should form an integral part of risk management for both national and international bodies. Information on risk should be provided by credible sources and based on real hazards. Both level of risk and outcome of risk management have to be communicated.

Enforcement and inspections approach – risk focus

The first principle of an effective approach to enforcement of food safety is that regulatory interventions, such as inspections, cannot ensure food safety. The responsibility for ensuring food safety belongs to the business. This is also central to the introduction of a risk-based approach to inspections and enforcement, as it is not possible to control or eradicate all risk.

It is often through enforcement that businesses experience regulation on a day-to- day basis and this is where burdens can be most acutely felt. Even well designed food safety regulations cannot address food safety if enforcement is not targeted, risk based and focused on the outcomes of protecting safety. Food safety inspections can be some of the most burdensome state interventions in many developing countries, affecting a huge number of businesses, and in many cases carried out with a strong "rent seeking" bias.

While enforcement of food safety regulations is usually carried out using an inspections based approach, it is crucial that regulators understand the importance of selecting the right type of intervention to control the risk and meet the needs of the business in achieving compliance. This could mean taking samples, providing information to consumers, delivering advice or carrying out an inspection. Selecting the right intervention should be guided by a clear sense of the purpose of regulation and the outcome to be achieved – namely protecting public safety rather than simply checking compliance with a technical set of standards.

Inspections should never be designed to cover all establishments because this is not an effective use of public money. Experience shows that agencies that try to inspect all food business operators are not effective in controlling risk or improving food safety and incur high costs. Agencies have a choice between a "random focus" (by trying to check all premises and failing) and "risk-based focus" (choosing to focus efforts on those businesses that present a higher risk, the better choice).

Risk-focused approach

So what is meant by a risk-focused approach? The term "risk assessment" can mean many different things according to the different contexts within which it is used. Here a risk-focused approach means thinking about:

- the key regulatory risks that the legislation and food safety authority is designed to control, and definition of objectives to address those risks;
- the design of risk-based interventions by deciding the best type of intervention to achieve the outcome, taking into account the business environment and wider market conditions; (the intervention may be education, provision of information, inspection);
- risk assessment of individual businesses and premises; and
- sanctioning according to risk, taking a proportionate response to non-compliance.

Risk assessment involves a number of commonly used terms. However, it is important that these terms are correctly understood by inspectors in order to adopt a risk-based approach. The key terms are given alongside definitions in Box 5.1

Box 5.1 Glossary of Key Terms in Risk Assessment[4]

Glossary of Key Terms in Risk Assessment[4]
Hazard This is anything with the potential to cause harm. This includes objects, substances, conditions, processes, premises, and activities. The level of a hazard will be determined by the potential severity of the harm it can cause.
Harm Adverse impact on individuals, the environment, or on other businesses. This is a wide definition that includes physical, mental, social, and economic adverse impacts.
Risk A function of the level of a hazard and the likelihood that the hazard will cause harm. The likelihood of a hazard causing harm is represented by the likelihood of compliance.
Likelihood of compliance The likelihood that a business will achieve compliance. Assessing the likelihood of compliance involves consideration of a range of factors that allow a business to be compared with others for the purpose of conducting a risk assessment. It is largely a reflection of the inspector's confidence in management's ability to achieve compliance and so control the risks presented by the hazard in the foreseeable future.
Risk assessment The process by which the risk associated with a particular hazard is identified and categorized. The categorization process normally allows comparisons to be made between businesses.

Risk-based enforcement requires a methodology and set of criteria to assess businesses. The level of risk posed by a particular business can be calculated using the simple formula:

hazard x likelihood of non compliance

The accuracy of this formula is dependent on the availability of information on hazards (which is a fact-based assessment) and the ability of inspectors to assess the likelihood of non-compliance in a business (which is a judgment-based assessment).

In assessing hazards, most criteria involve consideration of:

- the sector of activity;
- specific processes used;
- scope of operations;
- the number of people affected (or potentially affected) by its operations; and
- where relevant, geographical locations (for example, close to sources of pollution, or likely to cause pollution to other critical sources such as drinking water).

In assessing the likelihood of non-compliance, relevant factors include:

- assessing the attitude of the management;
- implementation of compliance systems; and
- data from previous inspections and responses to previous advice given.

Scores for hazard and scores for likelihood of non-compliance can be given and then translated into a risk-assessment matrix, such as the one shown at Table 5.1. This allows the categorization of businesses into high, medium, and low-risk categories.

[4] http://www.bis.gov.uk/assets/brdo/docs/resources/risk-assessment-paper.pdf

Table 5.1 Example of Risk Assessment Categorization from the United Kingdom[5]

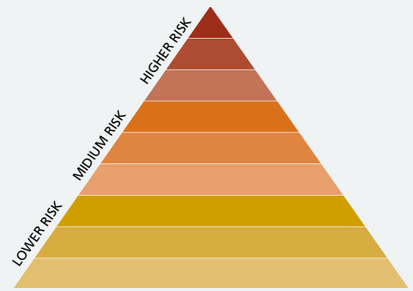
Level of hazard	Risk categories: Likelihood of non-compiance				
	VERY LOW	LOW	MEDIUM	HIGH	VERY HIGH
HIGH	LOWER MEDIUM	UPPER MEDIUM	UPPER MEDIUM	HIGH	HIGH
UPPER MEDIUM	LOWER MEDIUM	LOWER MEDIUM	UPPER MEDIUM	UPPER MEDIUM	HIGH
LOWER MEDIUM	LOW	LOWER MEDIUM	LOWER MEDIUM	UPPER MEDIUM	UPPER MEDIUM
LOW	LOW	LOW	LOWER MEDIUM	LOWER MEDIUM	UPPER MEDIUM

Table 5.2 Estimation of Risk Associated With Individual Food Business Operator[6]

Establishment	Compliance profile	Product risk profile Inspection priority
Low	High	1
Low	Low	2
High	High	2
High	Low	3

*1 1= top priority; 2 = medium priority; 3 = low priority

Figure 5.2 Business Profiling Following Risk Assessment



Robust risk assessment should lead to the following type of business profile (Figure 5.2), where there are few high-risk businesses premises. When implementing a risk-based approach, care should be taken to avoid an overly cautious approach where low risk becomes medium risk and many businesses are rated as high risk. This is a significant problem if inspectors are not rigorous in applying risk assessment, based on available data.

Risk assessments (or risk "ratings") of businesses should be based not only on what is found at the time of an inspection or other intervention, but should also take account of other relevant available information, to inform the decision. Risk assessment plays a crucial part in improving targeting of resources, consistency for business, and transparency to business. Risk assessments based on good intelligence (for example, information shared with other regulators) support effective risk-based targeting, which reduces duplication of regulatory activity and reduces burdens on compliant businesses.

It is important for businesses to receive meaningful feedback from regulators on their compliance performance and how to improve it. A business should be able to understand the risk assessment systems they are subject to, and particularly, what criteria is used to assess their performance, what the trigger points are for changes in assessment ratings, how easy is it to move between ratings, and what that means for the frequency and nature of the response from inspectors.

[5] Proposals for Developing a common approach to risk assessment, BRDO http://www.bis.gov.uk/assets/brdo/docs/resources/risk-assessment-paper.pdf

[6] FAO Food and Nutrition Paper 89

Planning and data

Risk-based inspections can only be achieved if time and resources are spent on strategic planning and analyzing. Strategic planning includes collating information, identifying trends, and making evidence-based decisions on where to focus resources and the efforts of inspectors. It is desirable to have dedicated planning and analytical teams based in food safety organizations. The key functions of these teams should be prioritization, risk planning, and evaluation. This includes identifying what type of food safety issues agencies should focus on, categorizing businesses according to risk levels, and monitoring improvements in rates of business compliance and public safety.

Risk-based planning requires data in order to identify priorities and categorize businesses according to risk. Types of data required include complaints about products, complaints about food businesses, records of previous inspections, sampling and testing, and data on major incidents and outbreaks of foodborne disease. This data needs to be held on a database to allow information on businesses to be collected and stored for future risk profiling and evaluation.

The FAO Risk Based Food Inspection Manual[7] recommends the following necessary data to inform risk assessment:

- Information on existing food operators (updated Register of Facilities).
- Categorization of food operators (according to the type of food they produce, process, number of expected consumers).
- Prioritization of inspection based on high- or low-risk food operator's profiles- occurrence of foodborne diseases and type of safety and quality management system they have. Priorities are reviewed after each inspection according to new data (changes in establishments, type of products, market).

Effective sharing of data between agencies is central to the success of the "farm to table" approach to food safety. If electronic databases are interconnected, or allow easy data sharing with other agencies, all potential sources of hazards can be better identified and results of their control visibly displayed. It also helps, for auditors coming from the side of buyers (EU, United States) to perform inspection of one particular segment or the whole food safety system, since it displays effects of measures undertaken and provides insight into functioning of the food safety system in whole.

Where possible, a common food safety database is desirable. This database should cover all steps in food production, transportation, sale, services, and results of all laboratory analysis of samples taken at all steps, kept and updated by the central national responsible agency for food safety. If a central database is not possible, different databases should be either interconnected or allow easy exchange of information. The introduction on electronic databases and effective system design can be a major undertaking, and our assistance on this point often focuses only on "how" and "what" rather than on supporting the setup of the whole system.

[7] FAO Food and Nutrition Paper 89, ISSN 0254-4725 ftp://ftp.fao.org/docrep/fao/010/i0096e/i0096e00.pdf

Prior registration and approval

Prior registration of food businesses helps to support decision making on risk-based interventions by providing enforcing authorities with information they can retain on a database that can be used to assess frequency of inspection and interventions. In many intervention countries the requirement for food business operators to be subject to wide range of prior permits, licenses, approvals, certifications, and examinations for staff, is very common.

This requirement is reflected in the food safety legislation of many developed as well as developing countries. For example, the U.K. Food Safety Act 1990 required that all food businesses underwent formal registration not less than 28 days prior to commencing trade. This allowed for enforcement agencies to create a database of existing and emerging food businesses that required inspection prior to them being allowed to trade.

The usual position is that registration of food businesses is undertaken once the business has begun trading for the purpose of ensuring that the necessary enforcement interventions are undertaken at the appropriate intervals determined by risk. The process of food business registration provides a framework for regulators to use so that they can identify the FBOs that require inspection as well as creating a database of FBOs for the purposes of communication, advice, and guidance. This serves the additional purpose of giving regulatory agencies an understanding of the complexity and diversity of FBO activity is useful in informing the regulatory delivery resource agenda in terms of understanding the numbers of enforcement and inspection personnel that may be required as well as establishing any specialist sectors which may need additional enforcement expertise.

The principles of FBO registration and approval are sound and sit favorably alongside the wider objectives and guiding principles of regulatory delivery. However, in many intervention countries the notion of FBO approval and/or registration can pave the way for onerous and complex requirements for permits and certifications that may or may not be risk based and proportionate.

Reform in this area should follow the guiding principles that premises registration should be simple and inclusive, and designed to ensure that FBOs are known to enforcing authorities for the purposes of inspection, guidance, and advice. Any wider requirements for premises registration and approval should be based on risk, proportionate and linked to measurable parameters, such as:

- products of animal origin – meat, fish and dairy products;
- high-volume operations implicating the above product groups; and
- high-risk process sectors such as canning.

In the EU, additional approval is sought by enforcing authorities for food handlers dealing with high risk products (products of animal origin). Further information on the EU regulations for products of animal origin can be found in Annex 1.

Choosing appropriate risk-based interventions

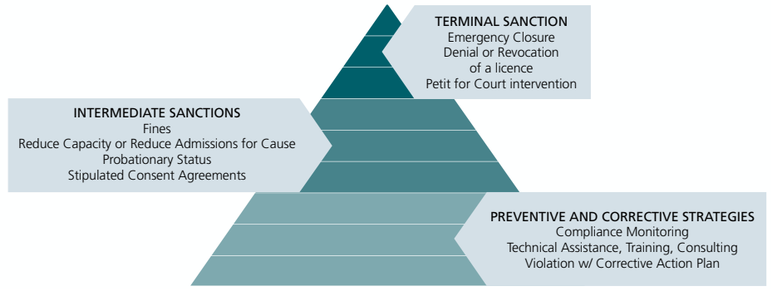
Currently, much of enforcement activity is focused on inspections. One way of thinking about inspections and enforcement is that they provide information and reassurance to the majority of businesses that want to comply. If provided with the information on "how to," inspection can also be an effective means to encourage more businesses to improve, but cannot eradicate deliberate non-compliance or criminality. A well-targeted inspection system can, however, help to reduce the numbers of businesses that are deliberately non-compliant, and to limit their negative impact.

However, in addition to using inspection, it is important that regulators develop an approach that delivers the best intervention for the circumstances, and here agencies should develop an approach inspired by the "enforcement pyramid," shown in Figure 5.3. Effective approaches to securing compliance require inspectors with a range of softer skills, in addition to technical knowledge, including understanding business, assessing risks, investigation, and effective communication.

As shown in the pyramid, the main response to non-compliance should normally be explanation and information, combined with an enforcement notice (particularly for first relatively minor issues), with sanctions being used with graded severity. Inspectors have different mechanisms of warning or penalizing food business operators, depending on the level of food safety risk caused, or potentially caused:

- Advice is an informal action through which inspectors assist food handlers in achieving compliance to safety practices and rules.
- Written notice – This is a formal letter usually containing a list of non-conformities and detailed instructions how these should be corrected and a time given for improvements.
- Official recall of food – This occurs when food contains hazards that can endanger public health.
- Warnings – These are issued when a violation of a legal provision has been determined and the food handler has admitted to breaching the law.
- (Administrative) court procedure – When food business operator does not comply with a written letter or when after a warning was issued, fails to correct the problem in question.
- Closing down facilities – This action should be ordered when there is a reasonable doubt that an outbreak is associated with food produced in a particular facility, or when a facility fails to comply with hygiene and safety requirements in such a manner that food produced may pose an immediate threat to health.

Figure 5.3 Enforcement Pyramid



Inspectors should look at how food handlers have secured food safety, whether their systems provide enough protection and whether they are satisfied that procedures are in place to correct hazards if they remained in products.

If inspection is identified as the most effective tool, a number of different types of inspection visits may be used:

- Scheduled visit (according to the annual plan and based on risk).
- Follow-up visit (in case when non-conformities were identified at the scheduled visit and in order to check how recommendations given by inspector were followed).
- Surveillance visit – inspection of one homogenous group of food operators (control of hazards in production of one type of commodity, for example: ice cream producers; egg farms; green houses).
- Monitoring of contaminants/pests/animal or plant health according to the national monitoring plan (for example: the monitoring plan on eradication of Trichinella, Brucellosis, Tuberculosis, certain plant pests, or pesticide residues in certain food).
- Audit of food safety systems in place (are all necessary elements of a mandatory system in place, for example, HACCP).

Regarding the nature of the inspection, developing checklists (and guidelines for implementation and control of preventive programs) that lay out clearly the main requirements can support greater transparency. Checklists should be based on risk criteria, focusing on the highest hazards. Checklists should follow the natural course of operations starting from purchase of inputs, production and ending with the release of final products. To provide transparency to businesses, checklists should be publically available and easily accessible, for example, through publication on inspection agencies' websites. This enables food operators to use them when performing self-inspection, prepare for the official inspection, and follow on a continuous basis the recommendations for their type of operation.

Training and education

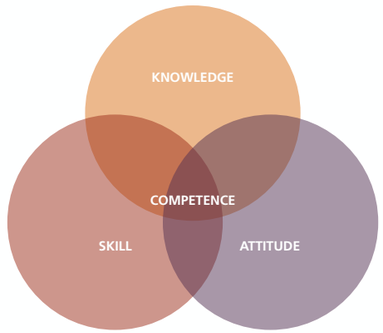
Even though this toolkit covers the legal and institutional aspects in detail, often the most important challenge to the success of food safety reform is the change in attitudes in relation to food safety needed by regulators, food business operators, and citizens.

Competency of inspectors

Moving to a risk-based approach to enforcement and inspections is usually a considerable change compared with the existing situation in many developing countries "prior situations," so, risk-based planning requires considerable retraining of inspections staff. In the past, inspection was mainly product-based, relying on visual inspection and sampling of final products. Safety and quality parameters of food were equally important. While food safety problems endanger health, lower quality products need not to be unsafe. Visual inspection and sampling of final products, without a clear plan, didn't improve the food safety situation and repeatedly, year after year, the huge numbers of samples were tested, without reducing the number of foodborne diseases. Scientific knowledge gathered in the meantime indicated that, control of hazards (biological, chemical, physical) at the place they emerged or at the place where a specific technological operation is conducted, dramatically improve safety of food.

Regulators and particularly enforcement staff very often will need thorough retraining in a number of areas. The three aspects that make up a competent inspector are shown in Figure 5.4.

Figure 5.4 Elements of Inspector Competency



Knowledge – technical scientific knowledge of food safety issues needs to be up to date and in line with the reformed food safety system. For example inspectors will often need to move from checking purely formal requirements ("is the floor in the prescribed material?") and look at the production process as a whole, and at its critical aspects (the HACCP approach in practice, regardless of the presence or absence of a formal "HACCP certification requirement").

Skills – generic skills needed to be an effective inspector include the ability to assess risk in terms of hazard and likeliness; planning/prioritization skills; ability to advise and influence businesses as part of securing compliance; ability to communicate with food business operators and other stakeholders as well as the ability to conduct inspections, interviews, and other interventions appropriately.[8]

Attitude – the attitude and culture of inspectors needs to be appropriate to the aims of the regulator. "Rent-seeking" behaviors often need to be eliminated and inspectors need to understand better how to promote compliance rather than just punish infringements. Inspectors need to be able to take on more "integrated" roles, with fewer specific inspectors focusing only on small parts of the food chain, and more "multi-purpose" ones that can handle different types of establishments, depending on changing priorities based on risk analysis. Changing the culture of regulators is difficult and needs strong leadership.

Food business operators[9]

Outreach to food business operators is essential to ensure that they understand their role and responsibilities in relation to food safety. The focus of education or information for food business operators will depend on the types of changes implemented as part of the reform project but could include the way modern requirements work (in particular the focus on process), what liability entails for them, and advice on how to comply with the law.

Part of the inspectors' role should be to provide the food business operator with information and advice to help them to comply with the law. Regulatory agencies will often design campaigns and literature designed to support businesses by providing information about new requirements.

As part of the reform process, it is important to gather the views of businesses on the current situation, and consult on proposed changes to food safety rules. It can be difficult for policy makers or regulators to see how particular changes will affect businesses without asking them.

Businesses should be able to understand what regulatory requirements apply to them, and how they should act in order to comply with food safety law. Businesses should also understand how inspectors will behave and should feel able to complain about the behavior of inspectors if they are unhappy.

[8] For an example of UK competency framework for regulators see http://www.bis.gov.uk/assets/brdo/docs/competency/sms-core-regulatory.pdf and http://www.bis.gov.uk/brdo/resources/competency

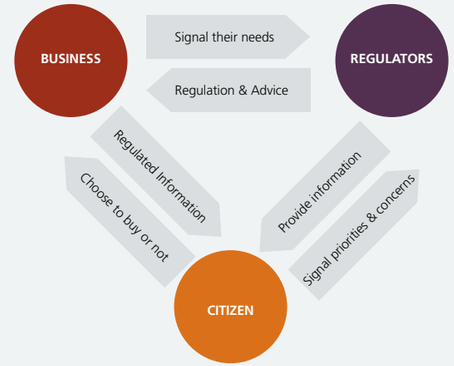
[9] There is considerable detail in this area contained in the already existing firm specific Food Safety Toolkit designed by IFC Sustainable Business Advisory. see https://spark.worldbank.org/docs/DOC-36707

Educated citizens

Education and information for citizens is a key way to influence attitudes about food safety, which in turn can drive food businesses to produce and sell safe food. Citizens should understand that food safety regulations are there to ensure that the food they buy is safe to eat and should be able to quickly report any deficiencies to food business operators or regulators.

In countries where there is a market economy or a developing market, making information publicly available about the safety of food sold to consumers can act as a mechanism to drive food businesses to comply with food safety regulations. For an example see Snapshot 5.2 below.

Figure 5.5 Relationship Between Business, Regulators, and Citizens in the Regulatory System



[10] Information taken from Impact of Restaurant Hygiene Grade Cards on Foodborne-Disease Hospitalizations in Los Angeles County, Journal Of Environmental Health, March 2005, Volume 67, Number 7 and Effectiveness of Altered Incentives in a Food Safety Inspection Program, Preventative Medicine 32, 239-244 (2001)

Snapshot 5.2 Using Consumer Information to Improve Food Safety[10]

Inspection of retail food premises is a key component of efforts to prevent food-borne illness and improve food safety.

In 1998, Los Angeles County Department of Health Services implemented a new inspection program that required inspection scores of restaurants and commercial food establishments to be publicly displayed. To further increase transparency and availability of this data, a searchable internet-based database was established providing information on inspection scores, non-compliances found, and restaurant closures. The program was also accompanied by improved inspection targeting of high-risk premises, additional training of inspection staff, and increased efforts in providing education and training materials for restaurant owners and staff.

Results show that this new approach was associated with a 13.1 percent decrease in the number of foodborne disease hospitalizations in Los Angeles County in the year after introduction, a decrease that was sustained in following years. Data also suggests that the program increased compliance, improved inspection scores, and influenced consumers' choices. Published inspection scores allow consumers to include information on food safety practices when they choose where to eat, therefore creating an economic incentive for restaurants to maintain good hygiene, which should ultimately lead to fewer foodborne illnesses.

The concept of decreasing the number of outbreaks of food-related illness through improved information to consumers is an increasingly popular one, with similar schemes in operation in the United Kingdom and Denmark. By introducing economic incentives to businesses, regulators can drive business compliance and improve food safety outcomes.

Snapshot 5.3
U.K. Primary Authority Scheme: Providing Reliable Advice to Business

The United Kingdom is widely recognized for its innovative work on inspection reform, including the development of the Primary Authority scheme which was launched by the government in April 2009. Primary Authority was originally established to address a historical problem of inconsistency of enforcement among regulators. It has since grown to become a highly successful scheme that enables businesses to receive professional, tailored compliance advice that is respected by all other inspection agencies, providing businesses with confidence to invest and grow.

Primary Authority is based on the concept of a new, more positive relationship between regulators and business that delivers benefits for business and is more efficient for regulators.

As part of the scheme, a regulator acts as a "primary authority" for a named business, and is responsible for providing the business with detailed compliance advice and support. This advice should be specific to the business needs and mode of operation, and based on high levels of technical knowledge and understanding of the business environment. By forming a good relationship, the regulator is more able to influence compliance and improve performance, and the business is able to get the advice it needs to get things right first time.

As an added means to give business confidence, the scheme contains protections for businesses that if they have followed the advice given by the primary authority, their actions cannot be challenged by another local regulator and enforcement action cannot be taken against them. This assurance gives businesses confidence to invest in their compliance with the knowledge that another inspector will not impose a different set of requirements, which often results in both unnecessary time and cost burdens.

In the United Kingdom, the scheme has proved successful, with over 700 businesses participating, including many large, multi-national companies and with strong representation from businesses within the food sector. The U.K. government intends to extend the scheme to enable more businesses to participate and allow trade associations to gain assurance from primary authorities for the compliance advice they produce for member businesses.

For more information on Primary Authority, see http://www.bis.gov.uk/brdo/primary-authority

Snapshot 5.4
Use of Private Veterinarians in Croatia

In Croatia, the number of veterinary inspectors at the local level employed by the government is not sufficient to cover all food business operators dealing with food of animal origin. According to the Croatia Law on Veterinary, licensed veterinarians perform control over animal health, transportation of animals, slaughtering, milking, production of dairy products, fishing and fish farming, processing of fish, and production of honey, eggs, poultry. Therefore, due to lack of state-employed veterinary inspectors, the State Veterinary Inspection Directorate hires private veterinarians to perform veterinary inspection.

In order to do that, they must have a certificate that they have passed the Veterinary Board exam and have at least three years of work experience after the exam. They must be trained in principles of inspection and administrative rules. They are appointed and deployed by the head of the State Veterinary Inspection Directorate, have a badge verifying their status and their official number, and when performing official inspection, are paid according to the number of work hours from the Veterinary Inspection budget. All decisions they make have the same power as decisions made by state-employed inspectors.

In case of appeal to their decisions, regional state-employed inspectors issue decisions. The third and final level of decision is made by the State Veterinary Inspection Directorate.

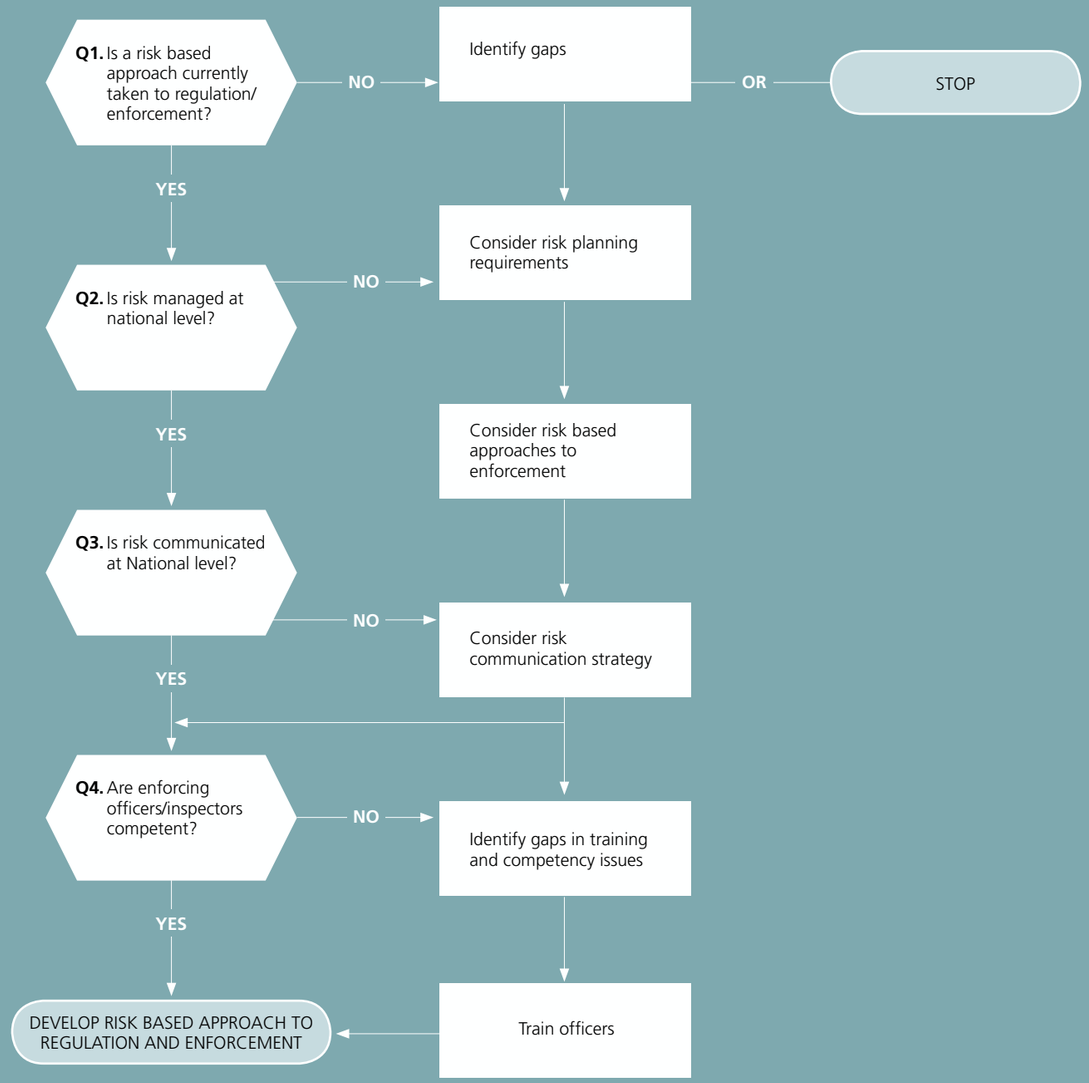
FBOs can appeal to the court on decisions of the third level.

Key messages

- Primary responsibility for food safety lies with food business operators.
- Inspectors control how food safety is secured by food handlers and whether regulatory requirements are met.
- Inspectors advise food business operators how to meet regulatory requirements.
- Inspectors must be well trained in order to recognize which non-conformities may pose health risks.
- Inspectors must identify the level of risk associated with certain non-conformities and impose measures accordingly.
- In deciding which measure to apply, inspectors should take into consideration:
  - the risk to public health;
  - the past record of cooperation of the food business operator; and
  - the level of non-conformities found.
- Measures imposed by inspectors have to be proportionate to the level of health risk, not unnecessarily strict, and should in no way be proposed for reasons of securing monopoly to some producers on the market or due to conflict of interest.
- The goal of inspection should be to support food business operators and enable them to improve safety of their products and at the same time to prevent food that was proved to be unsafe to reach consumers.

Further details can be found in specific World Bank Group and OECD publications:

- World Bank Group, Study of Food Safety Inspections 2009
  https://www.wbginvestmentclimate.org/uploads/Study%20of%20Food%20Safety%20Inspections%202009.pdf
- World Bank Group, How to Reform Business Inspections 2011
  https://www.wbginvestmentclimate.org/uploads/How%20to%20Reform%20Business%20Inspections%20WEB.pdf
- OECD Inspections Reforms - Why, How and with What Results? 2013
  http://www.oecd.org/gov/regulatory-policy/Inspection%20reforms%20-%20web%20-F.%20Blanc.pdf



Dairy sector example

Q1. Regulation must be risk based if food safety is to be controlled adequately in this sector. Too much emphasis on issues not related to food safety and more about quality or standards can result in risks being ill-considered. Critical issues in food safety in this sector are well documented in many guidance and standards documents (for example, time and temperature controls for processing). This should be used as a basis to support risk- based regulations and enforcement, and dairy sector-specific, risk- based regulations and enforcement in this area.

Q2. Risk responsibility will need to be established for the dairy sector. Which ministries, individuals or organizations are involved? How much expertise do they have ?. What is the relationship between national and local risk management and are international agencies involved? Who? When? Where? What? How? Are the questions that need to be asked in the context of this sector?

Q3. If risk is communicated at national level what role do businesses and citizens play in this and how is the information circulated? Is communication strategic? What does the process of communication of risk look like? Are there any gaps?

Q4. Competency of officers in this sector is paramount to good regulatory delivery and supporting the risk framework. Expertise needs to be at the technical level with respect to dairy sector specificity- an understanding of the hazards associated with this sector and how they need to be managed. What prerequisite requirements need to be in place and what constitutes effective implementation of food safety controls?

ACRONYMS

APLAC	Asia Pacific Accreditation cooperation
BAP	Best Aquaculture Practice
BRC	British Retail Consortium
CAC	Codex Alimentarius Commission
CAS	Country Assistance Strategy
CFIA	Canadian Food Inspection Agency
CPS	Country Partnership Strategy
EAL	European Cooperation for Accreditation of Laboratories
EC	European Commission
EAC	East African Community
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agricultural Organization
FBO	Food business operators
GDP	Goss Domestic Product
GAP	Good agricultural practices
GFSI	Global Food Safety Initiative
GHP	Good hygiene practices
GMO	Genetically modified organisms
GMP	Good management practices
GRMS	Global Red Meat Standard
HACCP	Hazard Analysis Critical Control Point System
ILAC	International Laboratory Accreditation Cooperation
KDB	Kenya Dairy Board
KEBS	Kenya Bureau of Standards
LIMS	Laboratory Integrated Management System
NGOs	Nongovernmental organizations
ILAC	International Laboratory Accreditation Cooperation
IPPC	International Plant Protection Convention
OECD	Organisation for Economic Co-operation and Development
OIE	World Organization for Animal Health
PCB	Pest Control Products Board
PRPs	Prerequisite Programs
RFID	Radio frequency identifier
SBA	Sustainable Business Advisory
SPS	Sanitary and Phytosanitary
SQF	Safe Quality Food
USAID	U.S. Agency for International Development
USDA	U.S. Department of Agriculture
WHO	World Health Organization
WTO	World Trade Organization

LIST OF FIGURES, SNAPSHOTS, BOXES, AND TABLES

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