Food Safety Toolkit
Introduction and Quick Start Guide
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Demand for food safety regulatory reform can come from many quarters: domestic businesses, exporters, traders, retailers, foreign investors, and most importantly, consumers. Well-crafted regulations can guide and assist domestic farmers and firms to effectively compete with imports or allow them to access new export markets. As the agricultural sector in a developing country evolves and the quality and breadth of food processing increases, establishing a viable food safety system is a key element of success.

This Toolkit aims to empower reformers with a suite of tools to assess market potential, build capacity, and assist in mitigating barriers to development in the area of food safety. The Toolkit tackles each step in the reform process. It examines the related system development in a strategic way supported by best practice examples and sound principles of institutional structure and legislative reform. Risk-based approaches to regulation and regulatory delivery are considered alongside the need for flexible and proportionate responses to both.
Design of the Investment Climate Food Safety Toolkit builds on the IFC’s Sustainable Business Advisory Food Safety Toolkit which sets out practical tools and techniques for verification of effective food safety systems at the firm level. These two complementary tools, addressing both public and private sector dimensions to the development and implementation of effective food safety systems, can form the basis of a public private partnership that fosters reform and growth. Products, sectors and entry points may vary but the need for confidence in the safety and quality of the products produced for the benefit of both markets and citizens remains constant.

Pierre Guislain
Director
Investment Climate Department
World Bank Group

Foreword
The Investment Climate Department wishes to thank the Swiss Development Agency (SECO) and the United States Agency for International Development (USAID) for their generous support in funding the Investment Climate Food Safety Toolkit.

The preparation and publication of this toolkit has involved the participation and efforts of a significant number of dedicated people.

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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
GMG 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 Non-governmental 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
Introduction and Quick Start Guide

MODULE 1
Introduction and Quick Start Guide

Guiding principles of food safety reform

For all projects related to food safety reform, the following guiding principles should be kept in mind:

- Regulation and official controls by themselves cannot ensure food safety.
- Primary responsibility (and liability) for the safety of food rests on food business operators.
- Food safety should be secured across the entire food chain.
- A preventative and risk-based approach should be the basis for regulatory reform, decision making, and control and self-control of food safety.
- International standards and scientific justification should form the basis of all regulatory measures.
- The impact of food safety reform on trade, consumer prices, economic output, and jobs should be carefully considered – costs and negative impacts can be significant from an economic perspective.
- The food safety system will always involve multiple players; coordination and collaboration are vital.


MODULE 2
Legislative reform

For a food safety reform project to be successful, it is not enough to alter only texts in legislation, or structures in the government or processes in inspectorates. It involves a different way of thinking by many people and a change in attitudes and behaviors. This can be the most difficult part of the project and easily underestimated or even overlooked. Applying food safety reform can in many countries be an extremely radical change in fundamental assumptions about safety and about the role of the state.

It is important to be clear about the starting point and destination. For countries that are realistic candidates for European Union accession, the destination is a pre-existing package of legislation within the EU system and this path has been followed by a number of other accession countries previously. For countries not in line for EU accession the destination may be joining other trade agreements and there may be in some cases similarly clear packages of food safety regulations to adopt. For other countries, getting a clear vision of the destination can be difficult and the timescale for that journey can be challenging and often insufficiently thought through. The World Trade Organization Sanitary and Phytosanitary (WTO SPS) agreement provides a general framework, but many details have to be fleshed out in each specific case.
Institutional structure

Start from a map of the current distribution of responsibilities and roles, which are likely to be spread across a range of ministries, agencies, and inspectorates. The field of food safety impinges on many other policy areas, and the particular distribution of roles in a country is likely to be unique in its detail but common in its complexity. Many agencies are typically in charge of various aspects of the food safety issue – from animal breeding through plant protection chemicals, processing, transport, catering, up to human health at the end of the chain.

It is generally easier to try to unify the implementation part of the food safety system (control, inspections, supervision, testing, enforcement) than the policy inputs (that is, setting rules and requirements on all aspects (production, animal health, chemicals, water, residue levels in food). Therefore, much can be done with a single inspectorate, even if regulations are issued by more than one ministry or agency.

There may be a strong desire to try and set up a single food safety agency that covers policy and implementation, but such institutions are quite rare. It may not be appropriate or feasible for a particular country, or the political opposition may be too great.

Although there is probably a preference internationally for a single agency, at least in terms of inspections, it does not have the status of international best practice, precisely because of the complexity and peculiarities of other government structures. It is very rare in practice to have an agency that covers the entire food chain from primary production (veterinary, phytosanitary) to retail and catering. Most “single” agencies cover only a part of the chain (even though a major one).

It is essential to aim at consolidation as much and as effectively as possible in the context, and in the perspective of what the Food and Agricultural Organization (FAO) defines as the “integrated model.” Under such a model, all institutions involved in food safety regulation have clearly defined and articulated roles, and are fully interconnected so that regulation and supervision are not overlapping or duplicated, and are coherent and consistent throughout the food chain. Ensuring that there is no duplication or overlap in control and supervision should be a priority – and, where possible, consolidation of as many of the control and supervision functions in a single food safety inspectorate as well. If further consolidation can be achieved, it will be a positive step. But if consolidation is politically difficult or impossible, many other aspects are important and the reform team should not expend all energies on this goal to the detriment of others.
Institutional change alone will not bring success without also reforming the approach taken to inspections, both by the inspectorate in terms of process and the inspector in terms of attitude. Institutional change may help in tackling these other issues, but it should not be expected to transform them by itself. In fact, excessive attention given only to the institutional framework can distract from looking at real inspection practices, which is a real risk for project success.

The person who is asked to change the most is the inspector. Again, it can be presented as leading to greater job satisfaction and increased respect and status but that may seem unrealistic to them, whereas the likelihood of losing the opportunity to supplement an often extremely low salary is a much more immediate and real prospect. Additional difficulty comes from the fact that achieving broader reforms that would improve the status and compensation package of inspectors is often very difficult for political, financial, and other reasons. It is important that the project provides good quality training to equip inspectors for a more challenging role and, ideally, entitle him to an increased salary, if the context allows. Developing the competence of individual inspectors can be one of the fundamental aims of the project. In many countries, the inspection system is geared more towards opportunities for rent-seeking then a serious attempt to tackle the risks arising from unsafe food. The more often an inspector has some justification to go into a business, the greater the opportunity for collecting rents.

In most unreformed systems, it is assumed that blanket inspection is the best way of providing protection but modern thinking and experience has invalidated that model. Comprehensive inspection of each and every product and establishment is impossible in practice because it requires resources to be spread too thinly. Trying to control all products and premises through inspection of each and every product and establishment is impossible in practice because it is a major change that will often be difficult to achieve. The basis for food safety reform of inspections is the application of risk in identifying which establishments and products are most likely to present the greatest danger. Applying this approach requires designing risk criteria suited to the dangers being tackled, information about the compliance record of businesses, and the likelihood of their continuing compliance. This practice will lead to a risk matrix and data that will allow establishments to be categorized as high, medium, or low risk. The categorization then allows for a plan of inspections that starts to make the process more transparent and targeted.

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The HACCP system relies on the existence and implementation of functional “prerequisite programs,” fundamental hygiene and safety requirements have long been enough to ensure an adequate level of food safety in most contexts. For many small businesses, applying these is enough to secure safety of products since their operations are simple and number of inputs limited. Laboratories are an opportunity and a challenge to the project because they are both important and expensive. It is impractical to use them for blanket testing of products and, again, scarce resources need to be targeted where they will be most effective. Depending on distances to be covered, it is preferable to have a network of laboratories where some will specialize in particular tests or products (“reference laboratories”). This is a more effective way of organising scientific infrastructure but does not work if it takes three days for the sample to reach it.

Laboratories carry out testing to:
- confirm whether a suspected product is in fact dangerous; and
- provide certification of food in a way that will ease external trade and avoid further re-certification procedures in the importing country

Unfortunately, the latter is possible only if the domestic laboratory has international accreditation and this is usually beyond the resources of developing countries.
The question of scientific underpinning and infrastructure is difficult because it relates so strongly to the country’s capacity at the government and business levels, and also because it may involve very significant involvements. For that reason, reform efforts need to have a clear view of the issues and needs, but be realistic about what can be tackled. In this situation, coordination with other donors is essential.

The cornerstone in making the food chain work is that of “producer responsibility.” Individuals at each stage of the chain are responsible for the safety of the food under their control. Each person is accountable to the next party in the chain, who in turn is responsible to the next. If there is choice, there is competition to both buy the best and sell the best and, in this way, the chain reinforces safety. If there is no choice or if there is a very short supply chain, the system is less effective, although the principles still apply.

“Producer responsibility” is a major change for many countries, where the existing model is the outdated “regulator responsibility” model where safety is expected to result from a high level of state controls by regulators. This shift toward producer responsibility is both essential and very difficult to achieve.

The businesses themselves also need to understand their new responsibilities and the new dynamics in the market. It is fortunate that these reforms are generally in the commercial interests of business development, at least in the long run. But in the short term, or for many existing businesses, the costs may outweigh the benefits, if things are not properly designed and planned. The businesses also need to understand their new responsibilities and the new dynamics in the market and that at the end of the day, businesses that implemented food safety principles will be better able to compete in the market race. Applying internal control systems may seem to be an unwelcome overhead but they tend to be excellent business investments. There is a selling job to do with businesses but the emphasis is strong on evidence. It is about to start a business of a particular kind. That brings the FBO within the system. Checks on its suitability and compliance can be performed later, rather than before business startup, which poses a barrier to entry.

Some FBOs dealing with particularly high risk processes or products do still require approval to enter the market (for example, slaughterhouses, meat and dairy processing factories) but, for non high risk FBOs, registration should simply be a matter of informing the authorities that it is about to start a business of a particular kind. That brings the FBO within the system. Checks on its suitability and compliance can be performed later, rather than before business startup, which poses a barrier to entry.

The principle of traceability is also needed to make a food chain work. At each link in the chain, the FBO needs to know who supplied specific products and needs to record the next recipient of these products. This “one step down – one step up” approach should not be a particularly burdensome overhead in a well-run business (although it can start to become complicated in

Implementation, monitoring and evaluation

Although the reformed system is actually putting in place a far stricter and far greater number of tests because it works through the internal systems of the producer, what may be visible to the public is an apparent reduction in official testing and inspections. Given that the previous system was based fundamentally on extensive testing and inspection, this may understandably give the impression that the state is abdicating responsibility and that it is a free-for-all for unscrupulous businesses. It is therefore very important for the project to support public discussion and communication prior to reform to demonstrate the ways in which the “pre-reform” system is not really effective in securing consumer safety (even though data may be sometimes difficult to find come by, this is usually possible).

Practitioners also need to build in the capacity for monitoring and evaluation (M&E) as they design and develop the project, rather than M&E being an add-on. Module 7 makes the vital distinction between outputs and outcomes and suggests various outcome measures.

Case studies

Module 8 has various case studies to inspire and guide. They were selected to reflect experiences in various regions and give examples of different approaches, models, issues, and challenges covered in this toolkit.
Importance of food safety regulation to private business development

Food safety is primarily, by its nature, a public health issue, which means that the involvement of the Investment Climate Department of the World Bank Group in this sphere may seem far from obvious. To most, food safety does not readily appear to be a private sector development or an investment climate issue. In fact, the ability to produce safe food and to be trusted by potential customers is crucial to integration in international trade for food producers – meaning that food safety systems are a key issue for the private sector. At the same time, food safety regulations can also impose a heavy administrative burden on businesses. There are thus several perspectives from which food safety is a highly relevant issue to the Investment Climate Department of the World Bank Group.

Ensuring that the food safety regulatory system works effectively, efficiently, and with the least possible burden is in fact key to private sector development in more ways than one. First, an effective food safety system is key for access to external markets. Second, a robust and trusted food safety system is key to growing the country’s own internal market, and the ability of local firms to position themselves on higher value-added market segments. Even though there are other important aspects in which food safety impacts private sector growth, these are the most essential in terms of involvement by the Investment Climate Department of the World Bank Group.

Access to international markets and competitiveness

The existence in a given country of a robust, reliable and effective food safety system, and one that is (a key point) recognized as such by foreign countries, is crucial to the realization of this country’s export potential. For certain types of food products, having such a system is a requirement for access to certain markets (for example, the EU). In all cases, whichever the product, not having such a system means a serious competitive disadvantage for a country’s producers, who will gener-
ally be confined to the lowest-profit markets, lowest-margin types of products, and mostly excluded from international supply chains.

This is an essential development issue because many developing countries and emerging markets have considerable, but incompletely realized, potential for agricultural or animal production and transformation thereof into processed food products. In many of these countries, however, the food safety system suffers from one or several weaknesses:

- Requirements and norms are not in line with internationally accepted practices.
- Laboratory testing and monitoring of animals and foodstuffs is unreliable.
- Inspections and controls are poorly planned, implemented, and coordinated.

As a result, these countries’ food safety regulatory systems are seen by potential customers as not offering acceptable guarantees. For more hazardous types of goods (for example, foods of animal origin) and the most demanding markets (for example, the EU) it means exporters from these countries may be entirely barred from access, or be allowed access to a narrow range of goods.

For less hazardous goods such as rice, weak food safety systems may not mean access to the richest markets is entirely impossible, but it is made more difficult, and with a worsened competitive position. Producers from these “low food safety” countries will usually only be able to sell their products through middlemen that blend them with other products (and do so in establishments located in more reliable countries in terms of food safety), or as lowest grade, lowest price goods. In fisheries, the lack of a reliable food safety system often means that natural resources are harvested by others’ fleets, with only minimal income left in the country, if any (for example, the current situation in Guinea).

Even major markets, to which exporters from “low food safety” countries have traditionally had access, such as the Russian Federation, are now gradually tightening their requirements. This means the position of exporters from these countries may be confined to the lowest-profit markets, lowest-margin types of products, and mostly excluded from international supply chains.

The priority level of food safety regulation improvements for the private sector thus to some extent depend on the type of products to be exported (animal or plant) and the target markets. But increasingly, even for lower-risk products, not having appropriately trusted food safety systems in the country means that exporters are shut out of the main supply chains that lead to the major wholesalers and retailers, and confined to regional markets, with lower prices. Weak food safety systems also mean that processing of any kind will not take place in the country. Instead, only raw foodstuffs will be exported to be processed and conditioned elsewhere, thus taking a large portion of the potential value-added out of the country.

An unreliable food safety system is not only harmful to a country’s ability to access and compete on world markets, it can also seriously burden firms in country, and also harm the development of the internal market.

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Purpose of the Toolkit

The purpose of this Investment Climate Food Safety Toolkit is to provide reformers, project teams supporting reforms, and policymakers with an overview of the principles of food safety reform, the primary objectives, key instruments and critical success factors, as well as provide a number of specific examples and case studies. The Toolkit is aimed at supporting work on food safety and inspections reform to support development of the agribusiness sector.

This toolkit may also be used as a guidance document for external audiences, such as partners and stakeholders in reform programs, so that they can understand the scope of food safety reform, the importance of collaboration of public and private sectors, the value of education of all involved parties, the importance of transparency, and the strength of the market-driven approach.

This toolkit focuses on the overall architecture of food safety regulation and answers the following questions:

- What does it entail?
- What other components form the “food safety system” and are essential for it to work effectively?
- What are the key elements of best practice (and what elements are disputed)?
- What can interventions by the Investment Climate Department of the World Bank Group focus on (and achieve)?

This toolkit emphasizes the roles of all players in the food chain, including food business operators and states providing the regulatory and control environment.

The Toolkit emphasizes solutions and approaches that are realistic, and conducive to private sector development and broad-based, inclusive growth. At the same time it warns against potential pitfalls, including the danger of “gold plating” and the introduction of regulatory requirements that are not commensurate to the level of development of the country or of its businesses.

Finally, it should be noted that the Toolkit does not attempt to provide full, in-depth prescriptions on all aspects of food safety regulations, as this would both make the Toolkit unwieldy and duplicate information readily available in public documents.
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Guiding principles

The whole architecture of the food safety regulatory system needs to be built upon the following key elements:

• Food safety is not ensured by adhering to external, visible rules such as statutory legislation or other elements such as private standards requirements – they cannot be enough. Food safety results from a constant attention to processing specific hazards and how they relate to products.

• Problems will occur, since there is no fail-proof system. It is essential to build the system around rapid detection of contamination and outbreaks and appropriate reaction, including recalls and swift and effective communication.

• Food safety results from consideration being given to the entire food chain. No part of it can be viewed in isolation because all are essential to total product safety.

• Regulatory and enforcement resources are limited, as are private sector resources, so there should be risk evaluation and analysis. The focus should be on critical risks that are both product and process specific, rather than on trying (and failing) to address everything, everywhere, all the time. A food safety regulatory system needs to provide for:

  - risk assessment – the process of identifying food safety hazards, assessing likelihood of occurrence and severity, and evaluating the significance;

  - risk management – the coordinated and economical application of resources to minimize, monitor, and control the probability and/or impact of food-borne incidents; and

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

• Harmonization of rules and measures with international standards is essential for implementation of a scientifically sound system.

• Transparency in decision making enhances the consumers’ and trade partners’ trust in the food safety system.

• Everyone has a role to play in ensuring food is safe, including food business operators, their employees, regulators, and consumers. The concept of shared responsibility with responsibilities should be clearly defined.
**Fundamental pillars**

Food safety reform should be based on eight fundamental pillars:

**PILLAR 1**

Food safety should be secured along the entire food chain (plough to plate, farm to fork, stable to table) thus covering all potential hazards emerging from primary production, processing, transportation/distribution, retail, catering, food service and home use of food. One of the issues is that each link in the food chain has limited or no ability to control other links in the chain. Good regulation and enforcement can help to address this. Production of raw materials, all inputs and outputs in food production, and all materials coming into contact with food should be covered by regulatory frameworks. Regulations should be implemented and enforced in line with food law and enforcement codes of practice.

**Figure 2.1: Food Chain Model**

**PILLAR 2**

Regulation by itself cannot ensure food safety. The overarching principle of effective and efficient food safety regulation is that regulation by itself cannot ensure or deliver food safety. It is only one of several elements in the food safety system. In most countries engaging in reform, the pre-existing situation is very much the opposite: everyone (consumers, regulators, businesses) assumes that safety is something “externally imposed” by rules and enforcement (effectively or not, and very often not effectively).

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Pyramid B in Figure 2.2 demonstrates that when the drivers for change in respect of food safety are all externally imposed there is instability and potential for the program to be unsustainable when external priorities change. The sustainable model triangle A shows a firm foundation of internal commitment supported by training and education, appropriate resources and infrastructure, and aligned to the external requirements.

In a food safety system, primary responsibility (and liability) for the safety of food rests on food business operators - primary producers, processors, retailers, and food service operators. The food industry has a responsibility to do everything possible to prevent unsafe food being sold to the consumer by developing and implementing food safety management systems, training and educating the workforce, and communicating issues quickly and transparently in the event of a problem. Industry has a responsibility to design and develop products that are intrinsically safe, to follow defined procedures based on risk, and to take corrective action when necessary. There are best practices in the food industry in all parts of the world that can be shared. Food safety should not be seen as a competitive advantage by developed nations used to restrict trade with less-developed nations.  

The role of consumers is also strongly emphasized, as they form the most potent force to drive food safety improvements: market power. Consumers are also essential because the safety of food can only be ensured if the final consumers themselves have safe practices. Consumers must handle food in a hygienic manner and follow manufacturer’s instructions for preparation, storage, and re-use. Consumers and customers should quickly report any deficiencies to FBOs and be open to new technologies that are valuable to food safety. Regulators have the responsibility to design and develop products that are intrinsically safe, to follow defined procedures based on risk, and to take corrective action when necessary. There are best practices in the food industry in all parts of the world that can be shared. Food safety should not be seen as a competitive advantage by developed nations used to restrict trade with less-developed nations.  

The primary role of regulators is to ensure that food safety practices are required by law, acceptable, and in place.

### Figure 2.2: Panisilio Pyramids

A

- **PILLAR 3**

In a food safety system, primary responsibility (and liability) for the safety of food rests on food business operators - primary producers, processors, retailers, and food service operators. The food industry has a responsibility to do everything possible to prevent unsafe food being sold to the consumer by developing and implementing food safety management systems, training and educating the workforce, and communicating issues quickly and transparently in the event of a problem. Industry has a responsibility to design and develop products that are intrinsically safe, to follow defined procedures based on risk, and to take corrective action when necessary. There are best practices in the food industry in all parts of the world that can be shared. Food safety should not be seen as a competitive advantage by developed nations used to restrict trade with less-developed nations.  

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The primary role of regulators is to ensure that food safety practices are required by law, acceptable, and in place.

### Figure 2.3: Risk Approach Throughout the Regulatory System

![Figure 2.3: Risk Approach Throughout the Regulatory System](image-url)

**PILLAR 6**

A preventative and risk-based approach should be the basis for regulatory reform, decision making, control, and self-control of food safety. Capacity building for risk assessment should be an important part of any reform process. A risk-based approach should be applied at all stages of regulatory design and delivery. This includes the design of legislation using a scientific risk based approach, the requirements for regulatory agencies to plan and prioritise activity in a risk based manner, and the implementation of risk based approaches to inspections of premises ensuring that inspectors focus on activities that pose the highest risk. The use of non-risk based regulation leads to unnecessary burden and costs for the food industry and ultimately consumers. The concept of focusing on risk at each stage of regulatory activity is illustrated in Figure 2.3 below:

- **STRATEGIC RISK**
  - Police and statute – designing legislation based in a scientific risk approach

- **OPERATIONAL RISK ASSESSMENT**
  - Choosing the most appropriate intervention according to the level of risk

- **RISK BASED TARGETING**
  - Risk based inspections

- **SANCTIONING BY RISK**

Risk assessment should be based on internationally available scientific data, for example using data on process-specific hazards and known accepted controls to inform potential risk posed by the hazard at a country level. This should be performed taking into consideration available epidemiological and economic data from international notification resources and trade partners. A proven methodology for risk assessment should be used, and measures implemented for risk management should be appropriate to the level of risk. This is discussed in further detail in Module 6.

**International standards and scientific justification** should form the basis of regulatory documents and measures. Much of the global guidance for food safety resides in the United Nations-based organizations. The FAO is primarily involved in food security with some aspects of food safety, the WHO is primarily involved in public health. Both are supported by the Codex Alimentarius Commission, which develops standards and guidelines to assist in the protection of consumer health and ensure fair trade. The OIE is responsible for animal health and food safety for products of animal origin, while the IPPC allows countries to analyze risks to their national plant resources and to use science-based measures to safeguard their cultivated and wild plants. The many drivers for change in the global food supply chain include economic, social, and environmental factors. Therefore, consideration should also be given to the recommendations of the IPPC.

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2. Ibid.
The impact of food safety reform on trade should be carefully considered. Supporting the development of national and international trade requires government regulators and policymakers to consider their approach to food safety regulation very carefully. Lack of uniformity of regulations around the world and poor regulations lead to trade restrictions that stifle economic development and growth. The rejection of imported foods as a result of food safety violations is an important economic consideration. Recent food safety issues in global trade have included microbial pathogens, presence of heavy metals, undeclared allergens, foreign material contamination, and economic adulteration. In addition, recent consumer concerns that have also been seen to influence policy direction include non-permitted additives, avian influenza, and the use of biotechnology. However, these are not always the real food safety issues.

Bilateral and multilateral agreements may sometimes regulate certain aspects of trade differently than WTO, but then such provisions apply only for food traded in a narrow group of countries. Mostly, in international trade, WTO agreements are followed. They recommend implementation of international standards set by the WHO, FAO, OIE, IPPC and other relevant international organizations and conventions when developing national rules and measures. There may be no need for new standards as plenty of them exist, but the necessary coordination and integration of them is essential to the development and implementation of appropriate regulation.

Food safety regulation will always involve multiple players; co-ordination and collaboration are vital. The development and implementation of food safety regulation occur in a complex setting of critical public health, animal health, and environmental protection agendas. Factors such as climate change, population growth, and food availability lend further difficulty to the task of developing and implementing regulations that will protect our food supply.

Institutions linked to the state that are active in the food safety sphere are multiple and not single. These are:

- "regulators" proper, for example, the ones who set the regulations (can be a single agency, or multiple ministries, or any combination thereof); and
- "regulatory delivery" a.k.a. "enforcement" or "inspection" bodies (can be combined with "regulators," or separate – can be a single agency, or several, more or less coordinated);
- extension services such as veterinary networks, which can be of varying statuses (private but regulated, public, private, and mostly unregulated) and focus on the animal health aspect of the food chain (in some cases veterinary surveillance is part of the "inspection" function above, but this is far from universal, and in general there are many veterinarians outside of the inspectorate(s), who also all play a role in surveillance and need to be able to enforce rules and measures). Also, agricultural extension services (public or private) that play a key role in protection of plant health and implementation of good practices in application of agronomy measures and chemicals.
- health care systems, which have the crucial role of detecting outbreaks and carrying out reliable epidemiological investigations of them. Countries should in turn request assistance from relevant organizations and donors (such as WHO, IFIs) to develop good epidemiological services and database, to be used in risk assessment. Water used in production and serving of food can be a major source of hazard. The donor projects’ plans for drinking water quality and safety should be investigated.

Figure 2.5: Temple of Food Safety


Coordination, cooperation, and collaboration among these institutions are essential, as is fluid communication. Building a single food safety agency (if this approach is taken) may never be enough, because this agency could never consolidate all the functions of veterinary medicine and human health care, with which it needs to have a constant interface. There is no such thing as an agency that would really cover all aspects of food safety even if it purports to do so. Conversely, national governments that have food safety responsibilities spread among several different departments or agencies may encounter issues of overlap and potential communication difficulties. It is critical to the effective management of food safety as a public health issue that whichever approach is taken, the benefits and deficits of each approach are recognized and understood. Certainly, having oversight of issues at government level, such as the following, as part of a combined strategy is beneficial:

- Public health
- Animal health
- Environmental sustainability
- Food safety
- Food security
- Food defense

A collaborative relationship between the food industry, academia, national, and non-governmental and intergovernmental organizations is needed to improve food safety and public health protection.

Further detail on the benefits and issues with both the single agency and multi agency approaches are discussed in more detail in the Module entitled “Food Safety Risk Assessment, Enforcement, and Inspections.”
Q1. In many entry level countries, the farm-to-fork assurance will not exist. In the dairy sector, it will start with animal husbandry and welfare, animal feed, and move into primary production of milk, then secondary processing of the milk into added value dairy products, such as cheese, cream, butter, and yoghurt. Hazards and risks associated with each step may not be fully understood or adequately covered by legislation or enforcement. Sampling regimes may also be limited and data collation and distribution minimal or non-existent, making it difficult to know if any sector-specific problems exist.

Q2. External drivers for this sector would be rules and regulations imposed by national or local agencies. (See Figure 2.3 of Module 2 of toolkit).

Q3. If primary responsibility for food safety does not rest with the food business, then this is a problem that needs to be resolved. Regulation alone will not ensure food safety in this sector.

Q4. The farm-to-fork approach must take account of the whole dairy supply chain but some aspects of it will be more high risk than others. This needs to be factored into capacity building requirements on risk.

Q5. The role of the consumer needs to be considered in helping support reform. Who are the intermediate customers and who are the final consumers? What food safety knowledge or culture is there likely to be amongst consumers?

Q6. Local and national regulations need to be cross-referenced with international standards to make sure the main risks have been identified and are covered by the legislation. Critical food safety controls, such as time and temperature parameters for high-risk processes, need to be included in the legislative requirements for this sector.

Q7. Dairy sector trade requirements will be broad and cover the entire supply chain. There will likely be gaps such as food safety management system requirements and product testing regimes.

Q8. There could be a single or multiple agency approach to dairy sector legislation as entire supply chain needs to be covered that will include animal health and feed 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 Accreditation for Accreditation of Laboratories
EC  European Commission
EAC  East African Community
EFSA  European Food Safety Authority
EU  European Union
FAO  Food and Agricultural Organization
FBQ  Food business operators
GAP  Good Agricultural practices
GDP  Goss Domestic Product
GFSI  Global Food Safety Initiative
GHP  Good Hygiene practices
GM  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  Non-governmental organizations
IPPC  International Plant Protection Convention
OECD  Organisation for Economic Co-operation and Development
OIE  World Organisation 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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Food Safety Toolkit
Legislative Reform
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Introduction

Legislation based on international standards and harmonized between trade partners facilitates trade and enables products from developing countries to be competitive in the international market. Countries looking to export to the EU should aim to harmonize legislation with EU rules. If exporting to EU markets is not a priority, countries should follow requirements of the WTO SPS agreement and thus ensure that their products can access markets of all WTO member states.

Both the EU and WTO legislative models for food safety require a risk-based approach to food safety controls, prioritizing funds and activity on the most risky areas.

Reforms in this area should be primarily focused on ensuring food safety, although ensuring that consumers are receiving the quality of food that they expect is also a consideration. When planning legislative reform, the burden on business should be carefully considered, and consultation with the business community is strongly recommended to obtain a good understanding of the business perspective. The benefits to private sector development discussed in Module 2 should also form part of this discussion.

Public awareness on the need for reforms can be important and it is essential to outline the benefits of improved food safety legislation to consumers and their representative bodies as they can help to support reforms and sustain their results.
Legislation to facilitate international trade of food

Trade of food is highly dependent on mutual recognition of legislation and practices between trade partners. If the legislation of a country is not harmonized with a recognized international standard, businesses may face problems in trading internationally.

WTO requires harmonization (in particular with the SPS agreement), but so do various regional trade agreements, where partners recognize each other's legislation or practices. These include the Custom's Union between Belarus, Kazakhstan, and Russia; the East African Community; free trade agreements such as the European Free Trade Association, North American Free Trade Agreement, Association of Southeast Asian Nations, and the Central European Free Trade Agreement. The EU has legislation harmonized between member states and so-called "third states" — those wishing to export to the EU.

Since both the EU and the United States are important export and import markets for the rest of the world, they require their trade partners to harmonize legislation and measures with international principles on which their own legislation is based.

Sometimes countries try to protect their consumers from products coming from a certain country, or a certain market either by giving preferential status to their own products or by putting bans on imports of products with certain attributes. If the same ban does not exist in their own legislation, this causes non-tariff barriers to trade. If there is no scientific justification for the ban, a dispute at the bilateral level or at the level of the WTO may follow.

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1. EAC-Kenya, Uganda, Tanzania, Rwanda and Burundi
2. EFTA-the European Free Trade Association between Iceland, Liechtenstein, Norway and Switzerland
3. NAFTA-North American Free Trade Agreement between United States, Canada and Mexico
4. ASEAN-Association of South East Asian Nations - Brunei, Cambodia, Indonesia, Lao People’s Democratic Republic, Malaysia, Myanmar, Philippines, Singapore, Thailand, Viet Nam
5. CEFTA-Central European Free Trade Agreement between Albania, Bosnia and Herzegovina, Croatia, Former Yugoslav Republic of Macedonia, Kosovo, Montenegro, Moldova, Serbia
6. EU-27 European Union with 27 Member States
7. According to the WTO-TBT Agreement, these are policy measures, other than tariffs, that can potentially affect trade in goods.
Food policy

Legislation should be based on the relevant existing food safety policy of the country. Food safety policy is often found as a part of an agricultural policy, or sometimes as “food quality and protection of consumers’ health” policy.

Food policy is often oriented more to quality of food and providing enough food, over prevention of direct and detrimental health effects of microbiologically, chemically or physically contaminated food.

Therefore, the three areas of focus of food policy should be distinguished:

• **Food safety** ensures that food is fit for human consumption and not injurious to human health. Food safety is most often under the competence of veterinary, health, or agricultural inspectors.

• **Food quality** is a market category, and distinguishes different levels of quality of a particular product. Low quality does not mean the product is unsafe. For example, eating the lowest quality product does not mean the consumer will get sick, if at the same time such a product is safe. Food quality includes nutritional value, health concerns, as well ensuring that customers receive the quality of the food that was expected. Food quality can be the responsibility of food or market inspectors.

• **Food security** has a financial and social aspect. It means that in a certain country there is enough food for the population and no one is under the poverty line.

It must be emphasized that human health is endangered both with lack of food, but also, with the access to unsafe or polluted food. In developing countries, the middle class has access to highly perishable foods such as meat, milk, eggs, and fish. In some countries, even the poorest have access to such food, as highly perishable foods represent the staple food for certain nations (for example milk in Kenya, fish in coastal areas of Africa, Asia, and South America, and eggs in Kyrgyz Republic). Foodborne diseases, which are mostly caused by consuming unsafe food and water, thus target all sectors of the society, significantly raise the burden of diseases, and should be considered by policymakers as a priority. Some countries may be giving priority to sensory aspects of food (consistency, shape, appearance) or content of nutrients, over possibilities for direct and detrimental health effects of microbiologically, chemically or physically contaminated food.

Types of legislation

There are two major types of legislative systems in relation to food safety – a system based on standards often called “technical standards,” and a system based on a risk-based scientific approach.

Standards based (often called “Technical Standards”). This type of system will typically stipulate technological processes, nature of the products (size, shape, content of nutrients, content of additives, weights, even type of packaging), microbiological and chemical contaminants, and labeling. It is often not flexible, can produce problems in international trade, and requires experts, for example, to manage the legislative documents and find the appropriate standard for a certain type of production. Such a system is usually very fragmented, difficult to manage, and mostly oriented to quality issues. Being over-prescriptive, the system is not suitable for modern food production, where technologies that are less costly and better performing are desired. Sometimes it is difficult to reach some standards, or there are no capacities in place that can prove that standards are reached. The standards can then become trade barriers.

Risk-based scientific approach. This type of system will focus on managing risks and will typically containing general regulatory legislation setting out the principles of food safety and hygiene alongside some-sector specific legislation where higher risks exist.

A risk-based scientific approach is the international standard for food safety legislation. The EU, United States, and other developed countries have legislative frameworks that embed a risk-based approach to food safety controls.
Models of food safety law

Generic food safety law model

The FAO and WHO have developed a generic model for food safety law\(^\text{11}\) that countries can base their food laws on. In addition, WHO has developed guidelines specifically for African countries on how to develop a food law.\(^\text{12}\) This FAO–WHO model provides a structure and international principles that should be followed.

EU Regulation 178/2002 can also be considered as a generic model for food law; all EU member countries developed their national laws from this regulation. However, if harmonization with the EU is not a priority for the country, the FAO–WHO model is a simpler model that incorporates all the necessary provisions for a food safety law.

Countries may wish to make new food safety legislation based on a generic food law model, or alternatively adapt their existing legislation. If the existing legislation differs substantially from the models, or if the major goal of the law is not protection of consumers’ health, then a new law should be developed respecting provisions given in models.

Box 3.1 Generic Food Safety Law Models

<table>
<thead>
<tr>
<th>Generic food safety law models cover:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsibilities of the public sector (issuing and enforcing regulations)</td>
<td></td>
</tr>
<tr>
<td>Responsibilities of the private sector (overall responsibility of food safety lies on food handlers)</td>
<td></td>
</tr>
<tr>
<td>Responsibilities in cases of emergencies and recall</td>
<td></td>
</tr>
<tr>
<td>Export/import of food</td>
<td></td>
</tr>
<tr>
<td>Principles according to which food safety should be ensured and controlled</td>
<td></td>
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<tr>
<td>Penalties</td>
<td></td>
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<tr>
<td>Repeal</td>
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</table>

Food safety legislation in the European Union

The EU market is very attractive as an export destination, and in order to place their products in the EU member states, countries have to comply with EU requirements. In the EU, food safety is a strong concern of both the public and the private sector. This is especially the case because of the outbreak of bovine spongiform encephalopathy (BSE) and other problems such as dioxins, toxic oil, and recently, Enterohaemorrhagic E. coli strain.

### European Legislative Model

The EU legislative model consists of:

- horizontal legislation, which covers aspects of food that are common to all foodstuffs (see Table 3.1 for examples); and
- vertical legislation, which deals with aspects of specific high-risk products or manufacturing methods as well as foods with specific attributes that need to be regulated.

### Box 3.1 European Union Legislation

<table>
<thead>
<tr>
<th>Examples of horizontal legislation</th>
<th>Examples of vertical legislation</th>
</tr>
</thead>
<tbody>
<tr>
<td>General food safety law that sets basic principles of food safety across the whole food chain</td>
<td>Rulebooks on certain commodities: eggs, grains, mineral water, fruit preparations, sugars, milk and dairy products, cocoa and chocolate products, etc.</td>
</tr>
<tr>
<td>Regulations on hygiene that cover all types of food premises across all sectors (Reg EC 852/2004)</td>
<td>Rulebooks on certain veterinary health measures</td>
</tr>
<tr>
<td>Regulations on phytosanitary issues</td>
<td>Rulebooks on certain plant health measures</td>
</tr>
<tr>
<td>Regulation on veterinary issues</td>
<td>Organic food</td>
</tr>
<tr>
<td>Reg. on microbiological contaminants in food</td>
<td>GM food</td>
</tr>
<tr>
<td>Regulation on chemical contaminants in food</td>
<td>Food produced under traditional methods, fortified food (with vitamins, minerals, lactic acid bacteria, other)</td>
</tr>
<tr>
<td>Regulation on additives</td>
<td></td>
</tr>
<tr>
<td>Regulation on inspection of food across all sectors (Reg EC 882/2004)</td>
<td></td>
</tr>
<tr>
<td>or in one sector (Reg EC 854/2004)</td>
<td></td>
</tr>
</tbody>
</table>

More information about EU legislation is included in Annex 1.
The U.S. legislative system

The United States has a decentralized system of legislation due to its specific constitutional governance structure. Both federal and state legislation govern food safety. Federal laws that apply in all states include:

- Federal Food, Drug, and Cosmetic Act
- Food and Drug Administration Food Safety Modernization Act
- Federal Meat Inspection Act
- Poultry Products Inspection Act
- Egg Products Inspection Act
- Food Quality Protection Act
- Public Health Service Act

Food is primarily regulated by two federal agencies and 50 states. FDA has jurisdiction over all food, the U.S. Department of Agriculture (USDA) has jurisdiction over products containing more than “small amounts” of meat and poultry. Although state regulation may be pre-empted by federal law, states have some autonomy and concurrent jurisdiction. The differences in statutory authority and regulatory philosophy of the federal and state agencies with jurisdiction sometimes result in inconsistent regulation.

The FDA Food Safety Modernization Act, which came into force in 2011 as an amendment to the FD&C Act, deals with food safety. The new legislation represents a major reform of the food safety provisions of the Act. It should be noted that the new law generally does not currently apply to meat, poultry, or egg products regulated by the USDA.

The Act highlights four main issues shown in Table 3.2

Implementation time is six months to two years depending on the measure. The Act is intended to foster enhanced partnerships with state and local agencies, train foreign producers and governments in U.S. food safety requirements and enable FDA to rely on inspection results of other agencies, thus meeting the increased demand for inspections.

<table>
<thead>
<tr>
<th>Preventive principle</th>
<th>Inspection and compliance</th>
<th>New authorities in case problems emerge despite preventive controls</th>
<th>New requirements for importers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Having a written preventive control plan in all processing facilities</td>
<td>Defined inspection frequency</td>
<td>Mandatory recall</td>
<td>Mandatory FDA control of implemented preventive programs</td>
</tr>
<tr>
<td>Regulatory documents on science-based, minimum standards for the safe production and harvesting of fruits and vegetables</td>
<td>Access to producer’s records on food safety</td>
<td>Expanded administrative detention</td>
<td>Having certificates issued by third parties that they comply with U.S. food safety standards</td>
</tr>
<tr>
<td>Regulations to protect against the intentional adulteration of food</td>
<td>Establishment of an accreditation program for laboratories to test certain tests</td>
<td>Suspension of registration</td>
<td>Mandatory third party certificates/other proofs for high risk foods</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Enhanced product tracing abilities</td>
<td>Voluntary programs for importers to qualify for expedited to U.S.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Additional recordkeeping for high-risk products</td>
<td>Authority to deny entry</td>
</tr>
</tbody>
</table>

Table 3.2: Summary of the Food Safety Modernization Act Requirements

Liabilities and responsibilities

For the food safety system to work effectively, there must be a clear requirement in the legislation that defines the food business operator’s liability, alongside legislative mechanisms for appropriate sanctions and a court system that can enforce such provisions. If the legal system is functioning in this way sanctions can work as a deterrent to businesses considering a deliberate non-compliant approach. If the legal system is fostering corruption, then taking legal action against a food business operator that has violated the law is unlikely to improve the food safety situation.

It is important to remember that issues with the legal system may require considerable changes in institutions and practices that go far beyond the scope of World Bank Group projects. Coordination with other donors and institutions can help to some extent, but it is essential to recognize that this will also create limitations on the expected success of the reforms.

Sanctions

Non-compliance with the law should be sanctioned ranging from giving advice to the food business operator on how to comply, issuing warning letters, taking legal action, or financially penalizing food handlers. The sanction will depend on the level of food safety risk caused, or potentially caused. Financial penalties should be commensurate to the level of food safety risk caused and should be published in order to ensure transparency and inform consumers on potential risks.

Sometimes food handlers choose to pay fines instead of correcting the food safety problem identified by inspectors, perhaps because it is cheaper to pay the fine than to invest in new facilities, refurbish existing ones, or implement new technologies.

Legislative reform approach

In developing countries, there are usually several types of legislation that exist alongside each other: technical regulations, some risk management documents, some pieces of legislation that protect the local market and often all are potentially aimed at different objectives.

The reform of legislation should always start by reforming the legislative documents that cover the biggest part of the food chain. Such documents, known also as framework laws, can provide a foundation for reform of other parts of legislation. Only when these are aligned with international recommendations should other sector-specific or product-specific documents be revised.

Relations to other legislation

Food safety legislation covers a broad range of activities related to food. However, food legislation is related to a number of other areas of legislation and policy. These include:

- **Food quality.** A market category defined through quality characteristics that are acceptable for consumers and that mostly define the physical and sensorial characteristics such as: taste, shape, size, viscosity, density, and color. Quality of ingredients and raw materials can also be defined and usually are graded as first, second, third, etc. Regulatory and control framework in developed countries emerges from the control over product quality to the control over process quality, because the latter directly affects the safety of products. Still, there are countries where quality requirements are almost equally important as those of safety and where enforcement is mostly oriented towards identifying diversions of products from the quality standards defined by the state. In case quality standards are prescribed by the state, diversity of products is limited and the market is thus “protected” from the entry of “low quality products.” This provides a monopoly situation for local producers and limits the development of the market. Quality control as the responsibility of the state is found in countries like Ukraine, Belarus, Armenia and Kyrgyzstan where food quality standards are in place and are enforced with the same
Table 3.3 Steps in Reform of Food Safety Legislation

<table>
<thead>
<tr>
<th>Steps in reform of food safety legislation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1 Creating a general food safety law or revising the existing one (in some countries food safety can be covered in a broader “food law” - precise legislative structure will be context-specific.</td>
</tr>
<tr>
<td>Step 2 Revising the law on food inspection (or creating a separate law on food inspection), if relevant (depending on legislative structure and context in the country).</td>
</tr>
<tr>
<td>Step 3 Identifying the framework veterinary and plant health/protection legislative documents (developing new ones or approximation of existing to international standards or EU legislation).</td>
</tr>
<tr>
<td>Step 4 Identifying, developing or revising plans for monitoring and eradication of zoonosis, plant diseases, residues of veterinary drugs and pesticides.</td>
</tr>
<tr>
<td>Step 5 Developing precise implementing measures and guidelines to follow laws (in-depth explanation of measures, principles that have to be followed, and expected results).</td>
</tr>
<tr>
<td>Step 6 Training staff from regulatory and control bodies in understanding international legislation and practices and how they should be implemented.</td>
</tr>
<tr>
<td>Step 7 Revising existing regulation on drinking water safety and quality with international standards. The EU regulation is often found to be much stricter than those in developing countries because it includes not just essential safety parameters but constraining parameters on exact chemical composition. Since drinking water can contaminate final products and is a final product by itself, it is advisable to adopt the requirements that ensure the best possible level of drinking water safety at the minimum cost.</td>
</tr>
<tr>
<td>Step 9 Revision of:</td>
</tr>
<tr>
<td>• Rules on microbiology.</td>
</tr>
<tr>
<td>• Rules for sampling of food (in line with Codex Alimentarius).</td>
</tr>
<tr>
<td>• List of additives to be used in food production (in line with JECFA).</td>
</tr>
<tr>
<td>• Methods for testing (to be ISO standardized).</td>
</tr>
<tr>
<td>Step 10 Assessment of other legislative documents</td>
</tr>
</tbody>
</table>

13 Zoonosis are animal diseases which can be transferred to humans.
14 In Belarus, EC auditors repeatedly found inconsistencies in the approach to food safety in dairy sector, due to the lack of implementing measures (each food producer and each inspector had their own understanding of international requirements and how they should be addressed in practice, yet only a few understood the principles and applied them properly). On the other hand, in Ukraine, when a guideline on implementation of HACCP was made and a check list to control its’ implementation, a consistent approach by all inspectors was achieved.
15 In Belarus a group of inspectors trained to inspect companies which applied for the EU export license for dairy products was transferred to another food sector and a group of inspectors which were never trained in the EU requirements in dairies was appointed to control potential exporters. EC auditors, when visiting companies, strongly objected to such a practice and found that control was exhibited according to national rules, instead of complying to rules of the potential importer.
17 The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an international expert scientific committee which assesses risks from additives, flavoring agents, residues of animal drugs, natural toxins and contaminants.

level of scrutiny as food safety requirements. Regulators sometimes intentionally scare consumers that if they do not control the quality, number of foodborne diseases will rise. Usually, it is connected with their fear of losing potential areas for control and bribery.

• **Food standards.** Prescribed process control standards that most commonly apply to specific sectors. These may be developed nationally, internationally and then adopted or be the intellectual property of a particular business/ trade body. These standards can be useful in helping to support new business development if they are freely available and recognised by inspecting authorities as assured guidance however they can also be used less constructive-ly to ‘gold plate’ requirements for certain sectors causing market restriction. Consumer protection rules and laws lay down responsibilities of sellers and buyers based on contractual (private) law. They regulate the rights and duties of traders and consumers, define responsibilities for defective products, misleading information, guarantees and pricing, and thus transferring the burden of proof to producers or sellers (traders). This legislation needs to be separate from food safety legislation, since food safety issues directly influence public health, while consumer protection problems influence other types of consumers’ rights. Consumer protection legislation can be related to food quality – for example customers should expect to get the quality of food that has been advertised when they buy a product.

• **Ingredients, packaging and labelling.** Rules on packaging and ingredients such as additives, enzymes, and other inputs in food production are developed according to relevant international standards. Labelling regulations aim to ensure that the appropriate information in relation to food safety as well as allergen labelling is displayed on the label.

• **Nutritional characteristics** provide information on basic ingredients and composition of a product and support public health objectives by promoting healthy food choices. They are usually regulated by legislation on labelling.
• Food defense and emergencies:
  • Food defense rules define actions in agriculture in case of terrorist, malicious, or criminal acts as well as programs on adequate response to such acts. The U.S. Food Defense Programs are examples of such actions, where the government, federal states, associations, private industry have specific responsibilities and roles in executing those programs.
  • Emergency rules in case of epidemiological emergencies define actions to be taken by all levels: the government and their inspection agencies, producers, retailers, caterers when preventing/eradicating a contaminant, pest or disease.

• Environmental protection. Disposal of solid and liquid waste can endanger safety of food products and pollute the environment, while different sources of environmental pollution can enter the food chain (dioxins and PCBs from industrial operations, radionuclide, lead, fluoride, nitrates).

• Water. Rules regarding drinking water are directly associated with food safety, since drinking water is considered as food and participates in all steps of food production. In countries where appropriate legislation is lacking, requirements can be given in the separate section of the food safety law, while in countries where sufficient expertise and resources are present in the relevant ministries, it should be regulated in the separate legislative document.

• Customs. Import and export procedures for food have to be developed in consultation with relevant food control bodies, since food should not be cleared for import/export before a valid clearance is issued by the food control body. A revision of the customs rules may be needed.

• Food derived by new technology. Food producers are constantly searching for new technologies to improve characteristics (durability, resistance to pests or microbiological pollutants, change sensorial or technological properties) or enhance nutritional value. New equipment and technological processes can also alter some properties of food. All these processes/technologies can only enter regular food production after rigorous, long-term experimental phases where potential effects on human, animal health and environment are assessed.

• Genetically modified organisms (GMOs). Legislation is often in place to regulate the production of GMOs. In the United States, production of GMOs doesn’t require preapproval, while in the EU, authorization must be obtained. The European Food Safety Authority (EFSA) is responsible for providing the scientific opinion on health risks of GMOs, while national authorities issue authorization for cultivation and perform environmental risk assessment.

• Novel food and novel food ingredients are those which have a new or modified primary molecular structure or consist of micro-organisms, fungi or algae; or are isolated from plants and/or from animals; or are those whose nutritional value, metabolism or level of undesirable substances has been significantly changed by the production process. Specific legislation often exists for novel foods, for example in the EU a preauthorization from EFSA must be obtained before placing such products on the EU market according to Regulation (EC) No 258/97.

18 Perspectives and guidelines on food legislation, with a new model food law. FAO Legislative Study 87.

19 Directive 2001/18/EC on the environmental release of GMOs and Regulation (EC) No 1829/2003 on GM food and feed on the pre-marketing authorization of GMOs.

20 Regulation (EC) No 258/97 concerning novel foods and novel food ingredients.
Dairy sector example

Q1. Does current food policy consider food safety?

Q2. Is legislation based on international standards WTO/SPS?

Q3. Is legislation standards or risk based?

Q4. Could existing legislation be revised to comply with a generic model of food law?

FS policy development required

Identify gaps

Identify issues

STOP

REFORM LEGISLATION

Q1. Policy in this sector must identify food safety as a priority and it must be stand alone due to the high-risk aspects of the dairy sector, such as milk pasteurisation and added value production such as cheese. Food safety policy should not be bundled up with food quality, standards, or sustainability but distinct and strategic.

Q2. It is possible that many entry level countries will base their national legislative framework on international standards as it is so well established and a shared understanding of best practice application is global. WTO/SPS should be considered alongside Codex.

Q3. If standards based likely to be overly prescriptive about other issues such as quality and standards i.e. size of milk carton and labelling requirements as opposed to be food safety focussed and risk based i.e. mandating critical limits for tie and temperature control. There is a need to review and determine whether sector legislation is standards based and revise to risk based for all aspect of the dairy sector.

Q4. If revisions to existing dairy sector legislation can be made, a generic model of food law could be used to do this (see Module 3 of the food safety toolkit).
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  
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  
PRA  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

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Snapshot 3.1  An Example of the 'Technical Standards' Type of Legislation  
Box 3.1  Generic Food Safety Law Models  
Table 3.1  European Union Legislation  
Table 3.2  Summary of the Food Safety Modernization Act Requirements  
Table 3.3  Steps in Reform of Food Safety Legislation
In developing countries the capacity of the state to regulate and control food safety in a risk-based approach will usually need to be strengthened. Reforming the institutions with responsibilities for regulating and controlling food safety may be a necessary step.

The role of governmental institutions that are responsible for controls on food safety (sometimes called “competent authorities”) will include making food safety policy and regulations, analysing evidence to implement a risk-based approach as well as carrying out the checks that the regulations are being implemented. Often the policy and rule making is carried out in one government institution (such as a ministry) and the checks on implementation of the rules are made by other institutions, such as inspectorates and laboratories.
Responsibilities of government agencies

For the government to have an effective role in food safety requires one or more ministries or regulatory agencies to have the following responsibilities:

- **Food policy** – developing food policy based on international standards and available evidence.
- **Food legislation** – drafting, updating, and owning the regulations, acts, and measures in the food safety area.
- **Food safety controls** – assessing and encouraging business compliance with the law, and enforcing the law.
- **Collecting and analyzing data** for monitoring and risk analysis on a national basis.

Regulatory agencies are usually linked with either the ministry in charge of health or the ministry in charge of agriculture, but in many countries both ministries share responsibilities in this area.

Sometimes, ministries in charge of consumer affairs, or even economy or trade, participate in regulating and control of the food area, mostly dealing with food quality issues and prevention of fraud. Since agriculture and food production have an impact on the environment, the ministry of the environment is often included in regulation of certain issues in connection with food safety (mostly in disposition of solid and liquid waste, but there are cases when this ministry regulates water to be processed into drinking water as well).

Regulatory agencies should divide responsibilities for regulating certain areas. Issues that are of the common interest for various agencies should be regulated with the collaboration of all agencies concerned.

Control is performed across the food chain, for example animal health and welfare, feed safety, plant health and food safety in food handlers. Control is exhibited through:

- single or multiple inspection agencies – governmental, private or both; and
- laboratories where samples taken during inspection or those taken during “self inspection” ¹ are tested.

The FAO guidelines on strengthening national food control systems should be considered when looking at institutional reforms relating to food.²

¹ Self inspection is performed by food handlers themselves as a way of continuous assessment of efficacy of food safety practices applied. For example, periodical review of GMP and GMP or HACCP systems in place, by producers (performed by a quality manager, or HACCP team, or internal auditors—employees trained how to audit system in place, or all of them).

² Assuring Food Safety and Quality: Guidelines for strengthening national food control systems, FAO http://www.fao.org/docrep/006/y8705e/y8705e05.htm
Chain of command

Different countries have different arrangements for chain of command for the institutions that enforce the regulatory requirements. There are two models:

- **A centralized inspection structure** where a central government agency carries out inspections and enforcement activity such as planning frequency and type of inspections. In this structure there will often be local or regional offices to facilitate enforcement activity, but as these are all parts of the same agency the strategic planning, budget, reporting, activity monitoring and complaints/appeals system will all be carried out by the central government agency.

- **A decentralized inspection structure** where local government agencies are given the responsibility of enforcing food safety law. The local government agencies will have autonomy in deciding how requirements of framework laws will be enforced, have a separate budget, plan frequency of inspection by themselves and usually only inform the central level about the number of inspections, on an annual basis. Monitoring plans are prepared, financed and effects analyzed on the central level.

The final legal decision, both in centralized and in decentralized systems, lies within the courts.

Single agency vs. multiple agencies

Depending on capacities of agencies (level of expertise, number of staff, equipment), constitutional organization of the country, level of decentralization, number of premises to be inspected and the level of development of the food safety system in a particular country, it should be decided which system should be optimal. Nevertheless, control of food safety should be performed by professional bodies (governmental or private) trained in import or export and inland inspection that perform duties in line with ISO/IEC 17020:2012 standard. Level of overlapping of different inspection bodies should be decreased to least possible/optimal level and that can be done only if clear division of responsibilities is made.

As noted, food safety-related regulation is vast, and covers a lot of issues and steps, including (and not limited to):

- risk assessment and science;
- policy making, issuing regulations;
- inspections or control of primary production including animal health, processing, transportation, storage, marketing, catering;
- health care and the feedback from health services to the rest of the chain to identify outbreaks; and
- information, outreach.

There isn’t a specific model of a single food safety agency that would cover absolutely all of these functions and very few countries where even most of these functions would be integrated. The challenges in respect of local specifics prevent the development of a universal model which could be applied everywhere.

It is essential that any model assures effectiveness, efficiency, coherence, minimizing costs and burdens and minimizing information loss. When deciding to advocate an approach consideration should broadly be given to the following:

- **Policy spheres**
  - These should be clearly defined so that there is no overlap in applicable regulations. If several ministries are involved in food-safety related regulations, their spheres of competence should be strictly defined.
  - Where possible, having a single structure in charge of science and risk assessment (whether or not combined with inspection/control functions, and/or with policy) is a good step.
  - Having a single agency doing both science/risk assessment and regulations can also be a good approach (for example, the U.S. FDA).

- **Control functions**
  - Full integration of food safety inspections in one inspection agency can be a good model as long as it is not seen as the panacea to all ills in itself. The existing political and institutional structure should be taken into consideration in this respect.
  - A “single inspectorate” could also comprise extending a “single department” into a broader “unified inspectorate.”
  - A potential variation on the models outlined above, would involve one inspectorate which controlled either primary production/phytosanitary measures/animal health or as a minimum unified control from slaughter onwards.
  - In the absence of an institutional structure that lends itself to the establishment of any of the above models, then it is essential that each agency involved in food safety control intervenes at a given stage and that there is a robust mechanism in place for multi-agency coordination.

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3 ISO/IEC 17020:2012 Conformity assessment -- Requirements for the operation of various types of bodies performing inspection
Inspectors should be penalized if their behavior breaches agreed codes of inspection practice. There should be a system in place to suspend inspectors in situations where there is evidence that they have performed their work negligently or not at all.

Regulators should be accountable to food business operators and there should be a mechanism whereby businesses or citizens can complain about inspectors and a way for complaints to be dealt with.

The National Veterinary Institute 5 – an independent, non-ministerial government authority. Prepares drafts of legislation, inspects feed, residues of plant protection products and GMOs in feed.

At the local level, 21 County Administrations are responsible for coordinating food control at the regional level and the municipal Environment and Health Protection Committees have responsibility for food control at the local level.

The authority has three levels: the central level, eight regional offices (out of which five have national competence over certain type of commodities along the whole food chain: terrestrial animals, fish and plants/vegetables) and 64 district offices. First instance decisions are mostly delegated to district offices.

Risk assessment is separated from risk management and is performed by an independent scientific committee, which has eight scientific panels (following the pattern of the EFSA) and is funded from the state budget. The participants on the panels are chosen based on their scientific merits in the appropriate field covered by the panel. Along with a reform of risk assessment and management area, a new food safety law was issued. It was used to simplify the legislative environment (provisions of 13 legal acts were merged into this law), update it in the line with acting scientific opinions, and to institutionalize the reformed regulatory and inspection area.

Lessons learned in Norway:
- The system is still developing. It takes time to perform and accept changes.
- Regional and district level agencies proved to be more ready for changes than the central level – they already collaborated closely on different issues.
- After the initial enthusiasm about reforms passed, staff from different agencies had to invest lot of energy and goodwill to work in the one single agency (to overcome cultural, professional, and other differences).7
- Reform of institutions should be followed with a reform in legislative area (to set new structures and risk based principle).

Factors to take into consideration when deciding which model is the most suitable for a specific country:
- The historical and constitutional background
- Capacities in place (staff, equipments, knowledge)
- Political will
- Level of corruption-autonomy in decision making
- Geographical distribution of food handlers
- Number of food handlers
- Sustainability of the system/agency
- Accessibility to funds
- Regional experiences and good examples

4 http://www.slv.se/en-gb/
5 http://www.sva.se/en/
6 http://www.sjv.se/swedishboardofagriculture.4.6621c2fb1231eb917e680002462.html
8 In line with Joint FAO/WHO PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR NATIONAL FOOD CONTROL SYSTEMS, July 2011
Dairy sector example

Q1. Is there a department that deals with regulation and enforcement in the dairy sector? If so, are responsibilities for animal welfare and feed controls in different settings to food safety? Many departments may be involved by identifying who is responsible for what is important so you can build a picture and identify any responsibility gaps. Re-assignment and harmonisation may be required.

Q2. If many departments have been identified, do they collaborate and are there any overlaps? How do they communicate? In the event of an outbreak, how easy or difficult would it be to investigate, trace, and alert?

Q3. If controls are not performed across the dairy sector food chain then gaps need to be identified and control needs to be established. This should be done based on risk, with the focus on ensuring food safety throughout but particularly at the point where a loss of food safety control would have serious consequences (such as raw milk processing).

Q4. If multiple agencies are involved in the dairy sector, regulatory and enforcement space that may mean an overlap of responsibility. This may be a farm crossing over between feed and animal health or later in the chain between animal health and raw milk processing. Overlap should be avoided as it wastes resources, impedes communication, and may burden business with too many inspections and inconsistent advice and guidance.

Module 4: Institutional Structure
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
GRMS Global Red Meat Standard

HACCP Hazard Analysis Critical Control Point System
ILAC International Laboratory Accreditation Cooperation
FDA Food and Drug Administration
KDB Kenya Dairy Board
KEBS Kenya Bureau of Standards
LIMS Laboratory Integrated Management System
NGOs Nongovernmental organizations
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
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

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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 regulatory delivery.

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

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.

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;
- 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);
- 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.

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 in countries this question is high on the agenda when deciding on new regulations or measures);

- 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.

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.”

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 higher standards. The standards should not be implemented to limit trade and should only be rigorous enough to prevent the hazard.3

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.

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

Glossary of Key Terms in Risk Assessment

- **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:

\[ \text{risk} = \text{hazard} \times \text{likelihood of non-compliance} \]

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.
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 it to move between ratings, and what that means for the 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.

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.

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 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 type of safety and quality management system they have. Priorities are reviewed after each inspection according to type of safety and quality management system they have. Priorities are reviewed after each inspection according to type of safety and quality management system they have. Priorities are reviewed after each inspection according to type of safety and quality management system they have.

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.

Table 5.1 Example of Risk Assessment Categorization from the United Kingdom

<table>
<thead>
<tr>
<th>Level of Hazard</th>
<th>Very Low</th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
<th>Very High</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH</td>
<td>LOWER MEDIUM</td>
<td>UPPER MEDIUM</td>
<td>UPPER MEDIUM</td>
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<tr>
<td>UPPER MEDIUM</td>
<td>LOWER MEDIUM</td>
<td>LOWER MEDIUM</td>
<td>UPPER MEDIUM</td>
<td>UPPER MEDIUM</td>
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</tr>
<tr>
<td>LOWER MEDIUM</td>
<td>LOW</td>
<td>LOWER MEDIUM</td>
<td>LOWER MEDIUM</td>
<td>UPPER MEDIUM</td>
<td>UPPER MEDIUM</td>
</tr>
<tr>
<td>LOW</td>
<td>LOW</td>
<td>LOW</td>
<td>LOWER MEDIUM</td>
<td>LOWER MEDIUM</td>
<td>UPPER MEDIUM</td>
</tr>
</tbody>
</table>

Table 5.2 Estimation of Risk Associated With Individual Food Business Operator

<table>
<thead>
<tr>
<th>Establishment</th>
<th>Compliance Profile</th>
<th>Product Risk Profile</th>
<th>Inspection Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>1</td>
</tr>
<tr>
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<td>Low</td>
<td>High</td>
<td>2</td>
</tr>
<tr>
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<td>Low</td>
<td>2</td>
</tr>
<tr>
<td>High</td>
<td>Low</td>
<td>High</td>
<td>3</td>
</tr>
</tbody>
</table>

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

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 interventions 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

INTERMEDIATE SANCTIONS
- Fines
- Reduce Capacity or Reduce Admissions for Cause (Probationary Status)
- Stipulated Consent Agreements
- Technical Assistance, Training, Consulting Violation of Corrective Action Plan

PREVENTIVE AND CORRECTIVE STRATEGIES
- Compliance Monitoring
- Emergency Closure
- Denial or Revocation of a licence
- Reinstatement
- New or Additional Permission

TERMINAL SANCTION
- Petty for Court intervention
- Denial or Revocation
- Emergency Closure
- Disposal of Residues
- New or Additional Permission
- Reinstatement
- Compliance Monitoring
- Emergency Closure
- Denial or Revocation of a licence
- Reinstatement
- New or Additional Permission
- Petty for Court intervention
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

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

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 remain 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.

Moving to a risk-based approach to enforcement and inspections is usually a considerable change compared with the existing situation in many developing countries. 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 food-borne 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.
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 likelihood; 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 operators6

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.

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.

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6 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

7 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

8 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 5.3
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, multinational 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
- OECD Inspections Reforms - Why, How and with What Results? 2013
Module 5: Risk Assessment, Enforcement and Inspections

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?

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.

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<th>Description</th>
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Food Safety Toolkit
Principles of Food Safety Management
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Prerequisites and Hazard Analysis Critical Control Point

Prerequisites

Several elements have to come together to make a world-class food safety program without which any food safety management system, HACCP or otherwise, will fail. These include:

- Safe recipe design and development
- Prerequisite programs – good hygiene practices, (GHPs), good management practices (GMPs), good agricultural practices (GAPs)
- Management commitment

The term prerequisite program (PRPs) has evolved to be most frequently used to describe the systems that support HACCP. The importance of prerequisite programs in this context cannot be overstated.

Prerequisite programs are good agricultural, manufacturing and/or hygienic practices that create the foundations for the production of safe food.

The internationally accepted requirements for prerequisites are defined in the Codex General Principles of Food Hygiene (Codex 2009a). The PRPs listed in this document grouped as follows:

- Establishment: Design and Facilities
- Control of Operations
- Establishment: Maintenance and Sanitation
- Personal Hygiene
- Transportation
- Product Information and Consumer awareness
- Training

The intended scope of the Codex guidelines is the provision of a baseline structure for application to the entire food chain. The document offers guidance to governments on the essential elements they should encourage food businesses within their jurisdiction to apply. The Codex guidance describes the elements of food hygiene systems that should be applied as minimum standards to provide safe food and to maintain confidence in internationally traded food products.

It should be noted that Codex guidance provides only an overview of the requirements and so more detailed guidance may be required to assist FBOs in developing robust systems.

GHPs and GAPs are alternative ways of describing prerequisite programs. In a company that has designed its food production operation with good hygiene in mind and that has a positive desire to make safe food by doing things right, most of the requirements for food safety management are there and need to be supported by the right advice and guidance.
The Hazard Analysis Critical Control Point System

The Hazard Analysis Critical Control Point (HACCP) System is internationally recognized as a preventative, systematic approach to food safety management applicable to all food operations. Comprising of seven key principles, the system seeks to identify microbiological, chemical and physical hazards at each step in the food related process and then to determine their significance in respect of food safety by a process of assessment of likelihood of occurrence and severity of effect.

All PRPs are important for food safety assurance and it is essential that they are fully implemented in practice. In practical food business settings they can be translated into a range of procedures such as the example shown in Figure 6.1.

Example 1: food poisoning bacteria can proliferate on high-risk foods such as protein-based products that are stored at ambient temperatures. This hazard can be controlled by storing the food under refrigeration.

Example 2: Food can become contaminated with foreign bodies, such as nuts and bolts, from machinery on a production line. This risk can be controlled by regular maintenance of equipment and metal detection at the end of the final production line. This risk can be controlled by regular maintenance of equipment and metal detection at the end of the final production line.

Box 6.1.1 USDA’s HACCP System


Key issues

- Commonly known as the “megareg,” this lengthy document required no critical control points to enhance the safety of raw meat and poultry products.
- Required conformance to a number of statistical sampling plans that permitted the presence of salmonellae.
- Monitoring compliance with the standard required 53 consecutive days of analysis in some products.
- If fewer than five samples of salmonellae were found during this period the facility was judged to be in compliance with its HACCP plan. Three consecutive rounds of failure would result in regulatory action being considered.
- Several years could elapse before enforcement action was taken.
- A great deal of money and labour was necessary to conduct and enforce such a program.
- The regulation contributed to the issues in respect of the ‘cost’ of implementing HACCP and enforcing HACCP based regulation.
- Sampling procedures and delayed or non-existent enforcement actions are unrelated to HACCP.

The seven HACCP principles as defined by Codex are:

- Principle 1 – Conduct a hazard analysis
- Principle 2 – Determine the critical control points (CCPs)
- Principle 3 – Establish critical limits
- Principle 4 – Establish a system to monitor control of the CCP
- Principle 5 – Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control
- Principle 6 – Establish procedures for verification to confirm that the HACC system is working effectively
- Principle 7 – Establish documentation concerning all procedures and records appropriate to these principles and their application

The HACCP approach to risk management within the food industry ensures that any identified risks can be either eliminated or controlled to an acceptable level. It requires that a food business identifies all potential hazards and stages of a process where bacterial or foreign body contamination, proliferation, or survival of food poisoning bacteria might occur. Control measures are then identified that either remove the hazard or reduce it to an acceptable level.

Example 1: food poisoning bacteria can proliferate on high-risk foods such as protein-based products that are stored at ambient temperatures. This hazard can be controlled by storing the food under refrigeration.

Example 2: Food can become contaminated with foreign bodies, such as nuts and bolts, from machinery on a production line. This risk can be controlled by regular maintenance of equipment and metal detection at the end of the final stage of production.

The global spread of HACCP as the preeminent system of food safety management was greatly facilitated by the Codex report of 1997. Jointly chartered by the FAO and the WHO of the UN, the Codex Alimentarius Commission’s reports have the effect of law among UN trading partners who are signatories to the WTO. International publications such as the ‘International Commission on Microbiological Specifications for Food’ (ICMSF) also helped to facilitate and foster an acceptance of HACCP as the global food safety management system of choice.

Despite the obvious benefits of FBOs engaging in food safety management systems based on HACCP principles, HACCP has sometimes been misused and become burdensome and disproportionate as it was incorporated into regulations. Three prominent examples illustrate this situation in the United States (Sperber 2005a).

Figure 6.1 The HACCP Support Network


3 Commonly known as the “megareg,” this lengthy document required no critical control points to enhance the safety of raw meat and poultry products.

Lessons learned from major food safety failures

If HACCP regulation and certification works so well then why are there still so many incidences of foodborne illness? We should be seeing a fall in the number of cases globally but this is far from being the case in many countries, including developed ones. Conclusions can be drawn from a review of some recent well-publicized cases (Table 6.1).

In summary, based on some of the examples given (which is only a very small number of reported cases) the following can be concluded:

- There is a global need even among developed nations to improve food safety – no country is exempt.
- Thorough risk assessment of all categories of hazard is essential in the development of safe products and processes.
- Failure examples indicate an essential focus on GHPs, GMPs and GAPs as the foundations for effective food safety management.
- Intrinsic features of product safety have to be considered, for example, water activity, acidity, alkalinity as control measures.
- Deliberate contamination of food can be an issue that HACCP alone cannot address.
- Direct and indirect costs of food safety failures are high.

<table>
<thead>
<tr>
<th>Year</th>
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<th>Cause</th>
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<td>Benzene</td>
<td>Preventative maintenance</td>
<td>160 million bottles recalled and destroyed</td>
<td>$ 79 m</td>
<td>Reuter (1990)</td>
</tr>
<tr>
<td>1994</td>
<td>USA</td>
<td>Ice cream</td>
<td>Salmonella</td>
<td>Cross contamination</td>
<td>Over 200'000 ill</td>
<td>Not known</td>
<td>Herevsy et al (1994)</td>
</tr>
<tr>
<td>2006</td>
<td>UK</td>
<td>Chocolate</td>
<td>Salmonella</td>
<td>Cross contamination</td>
<td>80 ill</td>
<td>$40 m</td>
<td>FDA food safety update 2007</td>
</tr>
<tr>
<td>2008</td>
<td>China</td>
<td>Dried milk powder</td>
<td>Melamine</td>
<td>Economic adulteration</td>
<td>54,000 children &amp; 13,000 hospitalised</td>
<td>4 fatalities</td>
<td>Congressional Research 2008</td>
</tr>
<tr>
<td>2009</td>
<td>USA</td>
<td>Peanut butter</td>
<td>Salmonella</td>
<td>Leaking roof</td>
<td>9 fatalities</td>
<td>$100 m</td>
<td>FDA 2009</td>
</tr>
</tbody>
</table>


Consideration needs to be given as to whether achieving confidence in food safety standards in developing nations is necessarily reliant on enshrining HACCP requirements in law. As we have seen, the success of HACCP as a food safety management system has prompted many governments to promulgate HACCP-based regulations. There are challenges for businesses around both the regulatory requirement for HACCP as well as the enforcement of such regulation, which can result in the stifling of business development and growth, and lead to ‘gold plating’ of requirements by inspectors. However the fact remains that key markets will very often require that FBOs demonstrate some level of HACCP compliance.

Box 6.1.2 USDA’s HACCP System

- Example 2 – FDA HACCP rules for the production of seafood

Key issues
- No critical control points were identified and required for the production of raw molluscan shellfish, the seafood category most commonly associated with human illnesses.
- Regulation bears no resemblance to Codex HACCP principles.
- Promulgation as HACCP regulations created confusion and undermined the reputation of HACCP applications.

Box 6.1.3 USDA’s HACCP System

- Example 3 FDA – FDA HACCP rules for the production of fruit juice

Key issues
- No mandatory pasteurization required for fruit and vegetable juice products.
- Exemptions granted to small producers and retailers replacing control measures with post production sampling for the presence of generic E.coli.

* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodProducts/ucm176892.htm
* http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/JuiceHACCP/ ucm073594.htm
Benefits of effective HACCP use

There are real benefits of HACCP when there is capacity and capability within a business to effectively design, implement, and maintain it as a system. But it is important to mention that these benefits are not derived through the HACCP system alone. Broad-reaching prerequisites and management commitment are essential. Key benefits of HACCP include but are not limited to the following:

- There is reduced reliance on ingredient and end-product testing. HACCP will help move FBOs away from a retrospective approach to food safety to one which is more proactive. Cost reductions gained by an approach that preventatively builds safety into the process as opposed to ineffective end product testing and unnecessary waste caused by batch rejection.
- The program meets regulatory obligations and customer expectations for safe food. In terms of regulations, countries vary in their requirements. Where HACCP is not required by regulation it is still recognized by WHO as well as through trade agreements such as the WTO.

HACCP in legislation

Government’s primary responsibility is for setting policy and legislation and being transparent in the process. Regular evaluation of food safety legislation through impact assessment and review of likely effectiveness across the supply chain constitutes an additional requirement. Governments also have a hazard guidance role to play and to take a unified approach in the establishment of guidance on potential hazards by product and process, conducting risk assessments as new hazards emerge. Governments must also ensure that resources are available for rapid detection, investigation, and communication of outbreaks, to share key learning and to give advice to business on preventative measures.

There are many examples globally where HACCP has been entrenched in food safety legislation as a legal requirement for food businesses, that is, Regulation (EC) 852/2004 Article 5. The regulation of HACCP in itself is not the issue insofar as the regulation itself is not what places the primary burden on businesses. The ‘enforcement’ of the regulation is where problems can arise. The enforcement of HACCP regulation in the EU has been cited as an example of “gold plating”. For example, in the United Kingdom where inspectors were requiring food business operators to undertake training courses that were not necessary for them to comply with the law. HACCP regulation can also serve to place too much emphasis on HACCP as the panacea to all food safety ills. When HACCP was first being discussed many companies mistakenly believed that it replaced the need for solid prerequisite programs (GHPs, GMPs and GAPs). As we have seen from the outbreak data in Table 6.1 food safety failures continue to be about failures in the systems that support HACCP i.e. prerequisites not failures of the HACCP system itself.

Barriers to effective HACCP use

There is much published literature that identifies both real and perceived barriers to HACCP implementation, particularly for small or developing businesses with non-specialist in–house technical expertise. The key issues to consider are outlined below:

- Lack of knowledge. This is real barrier and includes both technical knowledge as well as broader food safety knowledge of management resulting in lack of support for food safety initiatives.
- Lack of local language materials. A genuine problem in developing countries. There is a need for local language trainers who have experience and competence in HACCP development and implementation.
- Lack of competent consultants. Consultants who lack HACCP expertise can be detrimental to the process. Weaknesses in the system can be built in by poorly educated consultants. There may be difficulties in transferring ownership to the business team.
- Insufficient expertise. Insufficient expertise for biological, chemical and physical hazard analysis (HACCP Principle 1).
- Misleading HACCP Publications. While there are many excellent publications on HACCP, there are a few that contain misleading information that could confuse or mislead new users who will not know how to differentiate between authoritative and non-authoritative authors.
- Lack of food safety control and monitoring devices. A lack of availability and cost of process control devices such as sifters, sieves, and metal detectors, or a lack of monitoring equipment such as thermometers, and pH meters can be an issue for FBOs in developing countries.
- Validation and verification difficulties. Generally verification of HACCP is not too difficult once properly understood. However, validation needs to confirm that the elements of the HACCP plan will be effective in controlling significant hazards. It includes a review of scientific literature as well as possible microbiological challenge studies and in-plant process validation. Small or developing companies may find this impossible to undertake at the appropriate level, which can be a problem a particular issue if they have to pass HACCP audit/inspection criteria.

Figure 6.2 Cost of Quality

7 Sperber 2011
Risk-based approach

Complex or high-risk food businesses will benefit from HACCP system that is specific to their premises, equipment, and processes. However, a detailed, bespoke HACCP system can be unnecessary for businesses that present a low risk for food safety. These types of businesses can benefit from the type of generic HACCP approach presented in the SFBB or BBI packs that are used in the United Kingdom (see Snapshot 1, pp. 14-15 for more information).

To develop a risk-based approach, it is important to categorize different sectors of the food industry according to risk and determine priority for intervention. Risk factors that should be considered include:

- complexity of processing; more complex processes introduce greater levels of risk;
- type of process; pasteurization or cook-chill processes are high risk;
- ingredients used; high risk products such as meat or fish;
- distribution; how many consumers are likely to be affected if an issue arises. Is distribution international, national, regional or local?
- final consumer; is it a product that is likely to be consumed by immune-compromised people such as the young, elderly or those with immunity complications?
- enforcement of HACCP.

There can be difficulties in maintaining consistency and competency in the way inspectors enforce HACCP requirements. Inspector competency in HACCP audits and the ability to administer a flexible and risk-based approach when enforcing HACCP regulations can prove to be a significant burden on business in even the most developed countries where none of the barriers to HACCP use as outlined above prevail.

The provision of HACCP-based food safety management toolkits can assist businesses in the compliance process, for example the Safer Food Better Business or the Safe Catering systems devised in the United Kingdom. These products provide a simple way for businesses to embed the HACCP approach. See the Snapshot for more details. However, businesses can still face issues if inspectors continue to insist upon a full-blown HACCP system for even the lowest risk small businesses.

What constitutes HACCP implementation?

Implementation of the HACCP plan is a crucial factor in the effectiveness of the food safety system. There is limited advice on implementing the food safety system. The assumption very often is that if companies can develop a food safety management system, effective implementation will follow. HACCP plan implementation needs to be built on strong foundations, particularly training of staff responsible for managing the aspects of the process that are critical to food safety, (for example, the CCPs).

Successful HACCP implementation requires:

- validation of the HACCP plan;
- CCP management systems such as monitoring and corrective actions;
- training of personnel;
- prerequisites gap analysis and listing of any necessary modifications to processes or equipment;
- verification of implementation by auditing the system; and
- Updating the HACCP system through controlled amendment for example planned, documented withdrawal of the existing version and issue of the revised version.

Key messages

HACCP is the most successful, widely used, and internationally recognized food safety management system in the world. If used correctly, it can be seen as a fundamental requirement in the production of safe food. Questions remain as to whether requiring HACCP by law in developing countries is a proportionate response when even the most well resourced and developed nations struggle to comply with a statutory HACCP requirement. The additional burden of enforcing HACCP based regulation must be considered in terms of the capability of inspectors in assessing the systems in line with the key principles of successful regulatory delivery, for example, risk-based, consistent, and proportionate.

Any regulatory reform work on food safety should be seen as creating the necessary foundation for successful implementation of systems such as HACCP in the private sector.

But this work should not always be about creating a mandatory “push” towards HACCP if this is not adequate for country conditions.

Following the introduction of new food hygiene legislation in the United Kingdom in January 2006, the U.K. Food Standards Agency developed a food safety management toolkit for small business to assist them in complying with the requirement for all businesses to implement a food safety management system. This should be based on HACCP principles. The Food Standards Agency recognized that this would pose a significant challenge to the estimated 400,000 small food businesses in England and Wales, and negotiated flexibility to enable small businesses to apply the new measures proportionately. The Safer Food Better Business (SFBB) pack was introduced in September 2005 as an innovative and practical approach to food safety management.

The SFBB pack was favored following extensive trials of a variety of other food safety toolkit products, such as "Cooksafe" (adopted in Scotland) and "Safe Catering" (adopted in Northern Ireland).

The Food Standards Agency designed SFBB in collaboration with caterers and local authority enforcement officers. The pack gives small businesses everything they need in one place to keep records of their food hygiene processes as required by the regulations. It also contains factsheets explaining safe methods, step-by-step, and illustrated with photos. The pull-out checklists and diary pages to record checks are very popular. Businesses using the pack can be confident they are meeting requirements without having to delive into the legal detail or research best practice for themselves.

An independent survey of 1,143 small catering and food retail businesses was carried out in 2007 to examine the use of food safety management systems (like SFBB) and the impact. Of those with a food safety management system and an SFBB pack, 92 percent said the pack helped them implement a food safety management system. And as a result of having a food safety management system, more than two thirds (68 percent) said their food management had changed for the better, and none thought it had made it worse. Many had altered their practices, especially in training (47 percent), management, stock storage, and hand washing. Moreover, those using such systems also reported wider benefits, with 87 percent saying it helped manage their business, and 45 percent even saying it had made their business more profitable.

The Food Standards Agency invested heavily on the rollout of the program to ensure that both local authorities and businesses are fully equipped to use the pack. Considerable time and thought, not just money, went into the design of the materials and the interventions to support them. In doing this, lessons were learned from the operation of the previous regulation and the particular problems that small firms had reported with complying. This involved working across relevant parts of government, and bringing together people in central policy with people in enforcement, so an understanding of national priorities could be combined with feedback about previous business experience. It also involved effective engagement with local authorities whose commitment, enthusiasm, and relationships with local businesses were key success factors.

Other adaptations of HACCP for catering include:
- Assured Safe Catering – U.K. 1990s
- Safer Food Better Business – U.K. FSA
- Safe Catering – Northern Ireland
- CookSafe – Scotland
- Simplified version of HACCP
- Some HACCP terminology used
- Provides outline flow diagram and HACCP Charts
- Provides “House Rules” – PRP guidelines
- http://www.food.gov.uk/northernireland/safetyhygiene/safecateringni/#h_2
- http://www.food.gov.uk/foodindustry/regulation/hygleg/hyglegresources/cookretailscotland/
- Managing Food Safety – US FDA
Laboratories and monitoring

Laboratory testing plays a vital role in ensuring food safety. Testing can confirm compliance with the relevant legislation or guidelines and thus provides valuable data for risk assessors. Laboratory results are also used to confirm effectiveness of food safety practices implemented by food handlers and as indicators of the level of confidence in preventive measures, systems and practices applied.

Laboratories should have adequate capacities (staff and equipment), perform according to recognized international standards, and preferably be specialized for certain analysis. A network of laboratories needs to be assessed and appropriate roles assigned to each laboratory, in line with the national food safety and quality policy.

End control vs. process control

Food safety can be approached with a focus on end-control – sampling the end product, or process control – working with preventative systems to sample at the highest risk steps in the production process. A focus on end-product testing is no longer considered effective, however, in a number of developing countries such as China, where the highest risk steps in the production process. A focus on end-control focused systems are still in use.

End product sampling is considered ineffective as it does not provide a realistic picture of the situation. A random sample of the end product is not as effective as finding products that are unsafe as sampling products during the parts of food processing that represent the highest risks for food safety. This is why there has been a move away from end product to process sampling.

Inspection and testing have traditionally been the methods used in quality control. Exhaustive inspection would appear to be the ultimate approach towards producing a safe product, at least theoretically. In practice however, it is not so. The effectiveness of this technique is reduced by several factors:

- Disruption of the employees
- The span of human attention
- People’s varying powers of observation

To detect chemical and biological hazards 100 percent testing is simply not possible because tests are nearly always destructive. Sampling plans are used instead which are based on:

- the ability to detect the hazard reliably using analytical techniques that vary in sensitivity, reliability, and reproducibility; and
- the ability to “trap” the hazard in the sample chosen for analysis.

Even when random sampling is used, the probability of detecting the hazard is low. Use of statistical techniques will increase the probability of detection but it can never be absolute unless the whole batch is analyzed.

Experiences from the Balkan and CIS countries have shown that when end product testing is used, the rate of unsafe products detected each year remains the same over time. Positive results were found in about 10 percent of all tested samples, year after year. This doesn’t indicate good food safety, but a non-sensitive sampling system. Food safety management systems such as HACCP identify where in the process the hazards are likely to occur and where it is possible to put in place the control measures required. This ensures that food safety is managed effectively and reduces reliance on the traditional methods of inspection and testing.

Process sampling should be performed along the production, processing, retail, and catering stages, and frequency of sampling should be determined according to the size and frequency of operations. If samples taken during process control have indicated that hazards are present in the product, then control measures can be taken in order to eradicate them (such as reprocessing, withdrawal, or recall of products if they have already reached the market). This is a proactive, consumer-conscious approach and should be lowering the number and seriousness of hazards in products and lower exposure to foodborne diseases.

New sampling schemes

Since the CAC adopted the General Guidelines On Sampling CAC/GL 50-200414 it became a part of the FAO-WHO recommendations for sampling of food and feed.15 EU Reg 2073/2005 on microbiology of food.16 Canadian regulations on sampling of chemical and on microbiological contaminants.17 and the USDA’s regulations of sampling on contaminants.18

The Codex sampling scheme takes into the consideration different attributes associated with the product, nature of the control, existing international reference documents on sampling of a certain type of products, qualitative and quantitative characteristics, critical and non-critical non-conformities, nature of the lot, type of the sample (composed of one unit or of several units), and different statistical types of sampling plans.

Different types of sampling plans are then used for qualitative attributes (defects on products), chemical content, and microbiological contaminants.

The sampling scheme proposed by the FVO required an increase of 670 percent in the number of samples. When this scheme was applied, costs rose dramatically, from $244,080 to $1,605,852 in 2010 and $1,652,670 in 2011. Although sampling was intensified, not a single serum was found positive on Brucellosis. The increase in number of samples was not justified by the presence of the disease in the animal population and preventive methods applied in Belarus proved to be effective. Funds used for such intensive monitoring may have been better allocated to real problems.

Experiences from other transitional countries show that simple replication of the EU sampling frequency, with no basis in preventative programs and self-control practices, may become a burden to producers and country budgets.

14 CAC/GL 50-2004
16 http://www.inspection.gc.ca/food/chemical-residues-microbiology/microbiology-eng/1324284894932/1324285064868
17 Food and Veterinary Office - a body created by the EU Commission with mandate to ensure that EU legislation on food safety, animal health, plant health and animal welfare is properly implemented and enforced.
18 Brucellosis is an animal disease which can be transferred to humans through direct contact or through milk or meat which didn’t undergo adequate thermal treatment. Screening for Brucellosis is done by testing serum of animals on the presence of bacteria called Brucella.
19 According to official Veterinary Authority of Belarus data.
Network of laboratories

The quality and availability of laboratories will vary hugely between countries and it is important to bear in mind the potential limitations of non-accredited laboratories, absence of equipment, suitably trained technicians, and validated methods. Many types of analysis designed to monitor and detect hazards may not necessarily be freely available in many developing countries. Establishing the laboratory infrastructure limitations before designing and advocating a sampling plan is crucial to ensure consistent accurate results.

 Laboratories often perform a wide range of analyses of food, feed, water, and materials coming into contact with food. Considering that the number of chemicals used in agriculture and food production is increasing, and that old and new pathogens are numerous, it is difficult to keep up the pace and implement new methods, train the staff, purchase all possible laboratory equipment, and thus maintain a “general practice” laboratory concept.

Specialization of laboratories is thus preferred. A specialized dairy or meat laboratory can serve several regions in one country. Or a specialized laboratory for testing fish can be organized, if that is the major commodity (or major export commodity) in one country. Specialized plant protection, phytosanitary, seed testing, and animal health laboratories can also be set up.

If a geographical distribution of agricultural production or food processing is such that one laboratory cannot serve several regions, and therefore businesses importing or exporting food are usually faced with the costs of double testing – once according to GOST standards and once according to international standards.

There are other regional groupings such as the Asia Pacific Accreditation cooperation (APLAC), the European Co-operation for Accreditation of Laboratories (EAL) and the Southern Africa Development Community in Accreditation (SADCA). Laboratories from different countries may engage in bilateral or multilateral recognitions, but it takes time and limits the number of laboratories or countries recognizing results. On the other hand, if a national accreditation body becomes a member of the ILAC and fulfils requirements thereof (that of the standard ISO 17011) than results coming from all laboratories accredited by that national accreditation body are internationally recognized.

A guide to accreditation of laboratories was published by UNIDO48 and gives detailed information on the process. It also explains the value of the internationally recognized accreditation and advantages of having a national accreditation body that is internationally recognized.

It should be emphasized that samples tested for official purposes should preferably be tested in accredited laboratories. It is always better if such laboratories are accredited by the internationally recognized accreditation body, since then, results can be used in international trade as well.

For small or underdeveloped countries it may be a better solution not to set up a national body, but to contract services for accreditation of its laboratories with a body with international accreditation from another country where this already exists. The other solution is to make an agreement with a laboratory abroad that has international accreditation on testing of samples of food intended for export.

Accreditation of laboratories

Quality of laboratory work depends on training of the staff, calibration of equipment, and type and accuracy of analytical methods used. According to the WTO-TBT agreement, the buyer should only accept results coming from the laboratory of the seller if they are confident that the laboratory is of an appropriate quality standard. In order to facilitate this, a global conformity assessment system was developed by the International Laboratory Accreditation Cooperation (ILAC). Conformity assessment is done according to the ISO/IEC 17025:2005 standard, an international standard for management of control bodies. The standard aims to provide continuous improvement in laboratory practices and to help information sharing between laboratories and their customers in order to improve laboratory services based on their feedbacks.

It is not an easy task to implement the ISO/IEC 17025:2005 standard, especially for developing countries and their laboratories. In certain countries, standardization offices developed a national version of this standard and it often differs from the original one. Differences that are the most common are:

- validation of methods missing or only partially performed;
- use of standards not internationally recognized (like for example GOST standards or other types of regional and/or national standards);
- lack of capacities (space, staff); and
- calibration of instruments not performed regularly.

Accreditation of a laboratory means that the methods it uses are accredited. Laboratories should choose which methods to accredit and choose methods:

- that are frequently used (at least 12 times per year);
- where costs of accreditation will not be higher than revenues;
- that are statutory and will be required for official control purposes.

In countries where national accreditation bodies exist, but do not work according to the principles of the ISO 17011: 2004, accreditation is not credible. In such cases, results coming from laboratories accredited towards national or some regional standards are often not recognized in international trade outside the region. For example GOST standards are recognized only in Russia and some former USSR countries and therefore businesses importing or exporting food are usually faced with the costs of double testing – once according to GOST standards and once according to international standards.

Laboratory Integrated Management System (LIMS)

One of the requirements of the ISO 17025:2005 is information sharing with customers. If laboratories have the electronically supported Laboratory Integrated Management System then they can easily share information with their customers (official inspection, food producers, exporters, importers). Such a system enables instant reporting of results, speeds up the process, and can be further integrated in various official databases: that of the food safety inspection/veterinary/plant protection service, on recalls, imports, on export permissions, etc. Results can also be easily retrieved for risk assessment purposes, RASFF49 and in cases of emergencies.

Such a system is costly and requires an overall control of quality in the laboratory, but for central reference laboratories or reference laboratories, it may be very useful.

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49 Rapid Alert System for food and feed (RASFF) an EC body to collect and disseminate notifications of food contamination from all members of the system (EU and non-EU).
Traceability and recall of products

Traceability of products is the ability to trace the origin of materials, parts of a product, and all inputs into production through all the stages of production, distribution, and sale. The goal of traceability is to secure transparency throughout the food chain “from farm to fork” and enable rapid and accurate recall of products in case of emergency.

Following numerous food poisoning outbreaks over the past 20 years the tracing of food and feed and all processes has become mandatory in all developed countries.20, 21, 22

Economic impacts of traceability

Food businesses have three primary objectives in developing, implementing, and maintaining traceability systems:

• Improve supply management
• Facilitate trace back for food safety and quality purposes
• Differeniate and market foods with subtle or undetectable quality attributes

The benefits associated with these objectives can include:

• Lower costs of recalls
• Better control of raw material
• Lower costs associated with securing safety of final products
• Reinforcement of the brand name
• Reinforcement of the geographical denomination of products
• Access to the international market
• Requirements of major retailers
• Higher revenues

If traceability data exists and an issue somewhere along the production chain is identified, recall can be limited to only those products that are known to include the unsafe element and therefore pose a safety risk. If the traceability data is not available, all products from the same producer would have to be recalled. Although the implementation of traceability system will have a cost attached, the benefit of the limited recall and preservation of the brand name can outweigh such costs.

A traceability system should be well integrated with food safety systems such as HACCP and third-party standards such as ISO 22000:2005, GSFI and BRC.

For the government, improved traceability can benefit economically due to:

• fulfillment of international agreements (WTO-SPS);
• better results of animal diseases control programs;
• stronger control of imported goods and prevention of smuggling and counterfeiting;
• emergency preparedness and management; and
• lower budgetary costs.

Principles of a traceability system

The traceability system in place should be:

• simple, user-friendly and globally recognized;
• applicable to the type of the industry, or to a certain country;
• “from farm to fork” – unbroken chain of steps from the first step in the production to the shelf in the retail shop, or to the restaurant;
• able to identify the amount of products produced/ shipped;
• able to identify all lots that were produced/shipped;
• able to identify the date when products were shipped/produced; and
• able to identify the last chain in the process (to locate the product physically).

The international standard set by Codex is that the EU and the United States use (for example, the U.S. Bioterrorism Act of 2002). For producers and inspectors to be able to trace products from the market back to the producer, it is necessary to have data recorded. Producers need to be able to trace all raw material and inputs they have purchased and all products they have dispatched. The retail and catering sector need to know where all their food both in storage and on retail display was purchased from. This is sometimes called external traceability. There is also “internal traceability” which refers to the requirement to document all “transformations” of food products that occur during processing. For example: keeping records of storage of raw material, processing, packaging, and final products storage.

If traceability is required at the national level, then it must be regulated and controlled by an appropriate agency. In developing countries it is usually implemented for a single product or group of products intended for export, or in a group of suppliers selling to one retail chain.

20 Toxic oils syndrome- food poisoning with cooking oil from Spain which was contaminated with mineral oil due to storage in the same warehouse. Mineral oil was found in the sunflower oil from Ukraine in 2008, also. Other oils like palm, coconut, soybean, olive can be also contaminated and such cases have happened.

21 Melamine- a toxic compound added to food and feed in order to increase the nitrogen content (quantity of nitrogen in food is the measure of the protein content). This kind of falsification of food/feed was first found in China in 2007 when high content of melamine was found in scrap (feed by feed containing melamine), than in vegetable proteins, eggs and in 2008 in milk formula. Several international companies, among them Nestle reported high values of melamine in baby formula produced from the powdered milk which has been imported from China in 2008. Later in 2010 in dairy products high level of this toxic compound was found and it is estimated that 20% of milk produced in China may be still contaminated with melamine.

22 EHEC: Toxic so called Enterohaemorrhagia E. coli is a bacterium that can cause severe food poisoning. There are various strains which were found to be causes of various poisoning like O157:H7 or O114:H4 (found in sprouts in Germany, 2011).

23 Codex Alimentarius standard CAHG/GIC/1006 "Principles for Traceability/ Product Tracing as a Tool Within a Food Inspection and Certification System”.

24 U.S. Public Health Security and Bioterrorism Preparedness and Response Act of 2002

25 Codex Alimentarius standard CAHG/GIC/1006 “Principles for Traceability/ Product Tracing as a Tool Within a Food Inspection and Certification System”.

Major retail chains require that their suppliers have traceability systems in place and even provide their own software solutions for such a system, so that their suppliers can directly upload information concerning their products. For example, Metro in Ukraine supported its suppliers to implement and maintain food safety systems and traceability as a way to ensure safe products and rapid recall. Other chains, like Carrefour, Auchan and Tesco also provide technical advice and software systems along their supply chain. They require traceability in order to reinforce the brand name and to limit recall of products only to those that are potentially (or proven to be) unsafe.
Data capture

For producers and inspectors to be able to trace products from the market back to the producer, it is necessary to have data recorded on those products. There are numerous ways to collate and capture the necessary data required to trace products in any food business including using paper records, electronic barcodes, or other electronic systems.

The simplest and the least costly way is manual recordkeeping and if strictly implemented, such a system may be very efficient. The level of sophistication is dependent on company size, with the larger companies having, and needing, more sophisticated systems.

Types of data capture:

- **Paperwork** – Information relevant to product tracing is often transmitted through commonly used paperwork such as invoices, purchase orders, and bills either in paper or electronic format.

- **Barcodes** – usually used for traceability of food/feed products. The amount of information that can be captured depends on the type of the barcode. Simple barcodes will only contain data on the producer, type of product, and the country of production whereas longer barcodes can store various other information. For example, a barcode on a package of meat may contain information on the individual animal, its genetics, farm of origin, vaccination records, veterinary treatment, date of slaughtering, laboratory control of final products, and date of dispatch to the retail store.

- **Radio frequency identifier** – RFID, radio-frequency identification (RFID) is the use of a wireless non-contact system that uses radio-frequency electromagnetic fields to transfer data from a tag attached to an object, for the purposes of automatic identification and tracking. Some tags require no battery and are powered by the electromagnetic fields used to read them. Others use a local power source and emit radio waves (electromagnetic radiation at radio frequencies). The tag contains electronically stored information which can be read from up to several meters (yards) away. Unlike a barcode, the tag does not need to be within line of sight of the reader and may be embedded in the tracked object.

**RFID tags** are used in many industries. An RFID tag attached to an automobile during production can be used to track its progress through the assembly line. Pharmaceuticals can be tracked through warehouses. Livestock and pets may have tags injected, allowing positive identification of the animal.

**Animal identification and meat/product traceability** – These are supporting measures to strengthen the animal health program and ensure that in the event of an outbreak of animal disease, individual animals or their products that may have been in contact with the disease can be identified. When products of animal origin are to be exported to developed countries, then valid evidence of identification of animals will have to be shown. Usually, importers need to be assured that an efficient system of animal identification and control of animal movement from one farm to another, from farm to the abattoir, or from one country to another is in place in the country of export.

**Molecular fingerprinting** – the most valuable brands can be protected this way: olive oil (Spain), special types of wine or other alcoholic beverages, and products of plant or animal origin that have geographic denomination.

It is important that sufficient lot identification information is easily identifiable on the products so that the lot or batch can be identified for recall purposes and the product can be handled and stored appropriately. Codex General Standard for the labelling of pre-packaged foods (Codex STAN 1-1985) should apply here.

Often, the most important information for traceability – the lot number – is missing. This results in inability to trace products once they have left the warehouse. Food companies mostly regard traceability as an addition to their existing management systems (such as inventory control, warehouse management, accounting). Also, gaps are often found between external traceability and internal traceability data, and internal traceability chain may often be found broken (disconnections between groups of data).

In retail and restaurants, establishing a system of traceability is particularly challenging because of the potential number of items purchased and utilized in the production of food, and the additional challenges with respect to consistency and quality of the supply chain. Records with lot-specific information are usually not kept. It is difficult to identify the origin and other information regarding raw material, or semi- and finalized products they produced themselves. In case problems occur, retailers and caterers often rely on suppliers for information about raw material and then if their data are not well kept, it is not possible to identify the source of a problem.

The internationally accepted requirements for product recall procedures are part of the “Control of Operation” section of the Codex General Principles of Food Hygiene (Codex 2009a).

The intended scope of the Codex guidelines is the provision of a baseline structure for application to the entire food chain and as such the document offers baseline guidance to Governments on the essential elements they should encourage food businesses within their jurisdiction to apply. In the case of industry, the Codex guidance is intended to cover the elements of food hygiene systems that should be applied as minimum standards to provide safe food and to maintain confidence in internationally traded food products. The entire range of practical issues housed under the Control of Operations heading are illustrated in Figure 6.4 below.

In the event that recalling a product is deemed necessary either as a voluntary measure by the food business or as a mandatory requirement by regulatory agencies, the primary focus must be on consumer protection and ensuring that mechanisms are in place to communicate with anyone who has been or could be potentially exposed to the harmful product. The success of this aspect depends upon several key elements:

- The ability of the food business or regulatory agency to detect the hazard;
- The ability of the food business to be able to identify (trace) where all contaminated products have or could have gone (this includes the product potential being used in other products as well as any reworked product); and
- The ability of the regulatory agency to be able to communicate swiftly and effectively ensuring that any at-risk consumers are informed as quickly as possible. Consumer information is thus indispensable to a recall system. Consumers need to be informed about which foods are unsafe, and of what to do if they have purchased or consumed these products.

Consumers generally need to know:

- the specifics of the food safety hazard;
- risks posed to human and/or animal health;
- the product(s) affected;
- what to do if they believe they or anyone they know has consumed the product;
- what to do with any unconsumed product; and
- where to go for more information.

How successful the recall process is will depend upon all of the key elements identified above being effective through the development and implementation of risk communication mechanisms via regulatory agencies. As previously stated any recall strategy will work in tandem with any procedures food businesses may have in place to manage traceability of their products.

It is essential that the development and testing of suitable recall procedures that verify that products can be effectively withdrawn and recalled in the event of a food safety problem arising is highlighted. Withdrawals, public warnings using a variety of media, and secure control of recalled products prior to destruction or other suitable disposition are all factors in providing a safe and effective recall environment.

Recall mechanisms are indispensable in responding to instances of contamination and unsafe food. The onus should be on the producers and importers to organize and pay for recalls. But the regulators, or inspecting or enforcing institutions, (depending on the framework) should have clear authority to impose recalls or suspend sale of products (for example, impound goods).

Industry-specific voluntary standards

There are often a series of voluntary standards that private sector businesses are expected to implement, in order to fulfil demands of their trade partners. Implementation of such standards is often very demanding for companies, especially for those from developing countries. These standards can also play an important role in ensuring food safety (indeed, in developed countries, they do – and private businesses or consortia, such as the British Retail Consortium (BRC) conduct their own “private inspections” of suppliers) – but they can also be disproportionate and unnecessarily demanding for developing countries. They should thus be used with caution and with a view to striking the right cost/benefit balance. Moreover, many industry standards relate to the “quality” and not the “safety” of goods – while they are necessary for the supplier-customer relation (the customer needs to have certainty on what is being purchased), they are irrelevant to public regulation (such as precise recipe and composition of certain processed foods).

In many countries, such as the former Russian states, or Kenya, standardization bodies have succeeded in persuading governments to make some or many industry standards mandatory. Having a certificate on certain, or sometimes several, industry-specific standards is believed to resolve all possible questions about food safety. On the other hand, basic principles of hygiene and food safety that are prerequisites for such standards can be neglected. Such a trend will only slow reforms of national food safety systems and draw them to a very expensive, yet least efficient path. Without profound basis in GHP and GMP, GAP and (where possible) efficiently implemented HACCP, no single industry-specific standard will be successful or useful.

Whilst implementation of industry specific standards in a retail chain may serve as a model of how robust food safety systems can be achieved, it cannot take the place of reforming the food safety system of a country and will not have an effect on exports from a country with an unreliable food safety system.

Industry-specific standards should be discussed in light of serving as a good model of how the food chain needs to be controlled and reformed from “farm to fork, stable to table.”

The number of regulations in food safety at the global level is constantly rising, and food trade between different regions in the world has become dependent on harmonization of rules and practices and recognition of each other’s measures and approaches. In order to cover the whole food area, a number of standards were developed at the international level to set recommendations for food safety. Retail chains operating on a global scale were faced with different requirements and ways of responses to international standards in different countries. In order to show their own due diligence, they created numerous standards that their suppliers were supposed to follow. It has become a burden for suppliers to have to certify against different retail standards in order to trade with them and at the same time apply mandatory food safety systems required at the national level.
ISO 22000: 2005 – Food safety management system standard

This standard can be applied along the whole food chain, in any food organization regardless of size. It gives general requirements for food safety, while prescribing that prerequisite programs, those of GMP and GHP, are in place. ISO 22000 combines requirements of the Codex Alimentarius HACCP system, traceability, and those of the general ISO 9001 management system.

ISO 22000:2005 specifies requirements that help an organization to:

- plan, implement, and update a food safety management system;
- effectively communicate with suppliers and buyers;
- keep command of all activities aimed at keeping food safe using prerequisite programs and HACCP; and
- continually improve food safety.

ISO 22000: 2005 is followed with guidance on how to implement it, rules to certify and audit the system, and principles and requirements for a design and implementation of a feed and food traceability system.

ISO 22000: 2005 is not benchmarked to GSFI and that is why some major retailers (such as Metro) require from their suppliers who have this standard to be additionally certified towards GSFI standards.

Standards developed by major retailers

A solution at the retailer side was found in adopting the GSFI, according to which other retail standards were benchmarked. Standards developed by major retailers include:

- British Retail Consortium standard (Edition 5) was made as a standard for suppliers of U.K. retail chains and is accepted outside the United Kingdom as a global standard. It is also used by many companies that successfully manage their supplier chains based on this standard. Starting with the general technical standard, BRC also published a Packaging, Storage and Distribution and Consumer Products Standard, thus covering a wide range of activities.
- Food Safety System Certification, FSSC 22000 Food Products is a certification system that promotes food safety systems and certification of those systems worldwide. The certification scheme is based on several standards: ISO 22000 (the food safety management system), ISO/TS 22003 (the standard on bodies providing certification of the food safety management systems), along with Public Available Specifications PAS 220:2008 (Prerequisite programs to assist in controlling food safety risks within the manufacturing processes of international food supply chains) and PAS 223:2011 (Prerequisite programs and design requirements for food safety in the manufacturing and provision of packaging food).
- Global Aquaculture Alliance Seafood Processing Standard is the standard developed by a group of traders from Europe, Asia, and the Americas. It provides requirements for the Best Aquaculture Practice (BAP) and specifies the food safety and quality criteria to be in place within a seafood manufacturing or processing organization to achieve certification to the BAP.
- Global Red Meat Standard is a Danish scheme specifically developed for the meat industry (beef and pig), from slaughter to retail, describing requirements for food safety, quality, and hygiene that are specific for this sector.
- GlobalGAP This is the agricultural standard now recognized in more than 100 countries consists of a standard for Good Agricultural Practice (GAP) and a worldwide certification of it. The standard is based on best practices in farming, which secure safe products, sustainable environmental protection, and effective results.
- CanadaGAP (Canadian Horticultural Council On-Farm Food Safety Program). A scheme for certification of companies that produce, pack, and store fruits and vegetables based on the Codex Alimentarius HACCP principles.
- Safe Quality Food (SQF) certifies against SOF 1000 standard for primary producers and SOF 2000 standard for manufacturers and distributors. They are globally recognized food safety and quality certification programs.
- IFS standards (Version 5) Several standards exist under this scheme for auditing companies that process food and handle loose food or perform the primary packaging. Companies can be certified against IFS standards. Both standards and guidelines are available free of charge on the website.
- Primus GFS – a private scheme for certification of food safety management systems.

Sustainability and organic standards

The safety of food from a microbiological and chemical perspective is only one of the aspects that is important for consumers. Increasingly, because of health and environmental concerns, consumers want to know the food they purchase is sustainably produced – with limited environmental impact, and “fair trade” for producers. As a result, major retailers are increasingly seeking to procure food that is both reliably safe and, as much as possible, sustainably produced.

That said, there clearly are some trade-offs between safety, sustainability, and price. Control and enforcement of sustainability standards can be difficult and is not universally consistent, leading to labels sometimes being used misleadingly (legally or illegally, knowingly or unknowingly). Furthermore, the drive for increasingly “safe” food (from a microbiological perspective) is in many ways at odds with the desire to have more “sustainable,” “wholesome,” or “traditional” food. Thus, these different objectives need to be understood as separate – sometimes compatible, sometimes complementary, but also sometimes conflicting.

There are a number of different standards covering the sustainability issue – some well accepted and known, sometimes taken up and supported by national or international legislation (in the EU, for example), some newer and emerging. Producers and retailers are mostly seeking to use standards and labels that are well known and accepted by consumers, such as organic and fair-trade standards. It would be out of the scope of this toolkit to discuss any of these in depth, but it is important to highlight some of the main features, including where there may be some “friction” with food safety requirements.
Organic standards: Various standards based on the International Federation of Organic Agricultural Movements (IFOAM) principles.38

There is a trend in the production of raw products to move towards organic production, where no inorganic substances/chemicals are used in agriculture. Organic production is regulated by various national and private standards and producers who meet those requirements are allowed to label their products as “organic.” In the EU, products of organic farming are visibly marked with the logo, which is mandated by legislation and it must be used, as per legislation.39

It is often found that developing and transitional countries expect organic production to increase their profits from the export of agricultural products to developed markets. Before launching this type of production, a cost benefit analysis of the transfer from conventional to organic production should be performed. Also, data on soil contamination with chemicals need to be assessed. Only after these data are assessed, should the decision on launching organic production be made. Often in developing countries, organic production is only taken up for a limited number of products and the majority of food continues to be produced according to the conventional agricultural methods.

Common Code for the Coffee Community42 – a common code of farmers, societies, traders, and civil society organizations to improve living conditions of those involved in the coffee cycle.

Waste management standards in line with waste hierarchy44 (prevention, preparing for re-use, recycling, recovery-like energy recovery, disposal).

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38 http://www.ifoam.org/
42 http://www.4c-coffeeassociation.org/
43 http://www.fairtrade.net/about_us.html
Dairy sector example

Q1. Check to see if there is any data on dairy related outbreaks or a documented and trending issue in food safety in this sector such as high levels of aflatoxin in milk, high histamine in cheese or outbreaks implicating milk and dairy products contaminated with Salmonella or Listeria. If there is no data in country, look at data for other entry level countries and see what the prevailing issues have been.

Q2. Even if HACCP is a regulatory requirement without sound prerequisite programs in place HACCP will fail. The dairy sector will require a HACCP-based food safety management system to be applied to certain processes but for lower risk part of the dairy supply chain such as primary production this may not be necessary.

Q3. Benefits and barriers of HACCP as a legal requirement need to weighed. Costs burden can be outweighed by safety benefit and best practice in line with international standards can be encouraged to increase protections without over burdening an entire business sector.

Q4. Some aspects of the dairy sector would be high risk and would need to have taken a HACCP based approach to managing food safety, whereby the hazards are identified and appropriate risk based control measures are established and monitored. The focus first MUST be on ensuring that the hygienic foundations for food safety control in the dairy sector are well established by way of sound prerequisite programmes (see Module 7 of the Toolkit for details) In some lower risk aspects of the dairy sector supply, chain prerequisites may be enough to manage food safety without the need for HACCP based 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
GAP   Good agricultural practices
GDP   Goss Domestic Product
GSI   Global Food Safety Initiative
GMP   Good management practices
GMO   Genetically modified organisms
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
IPPC  International Laboratory Accreditation Cooperation
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

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Potential pitfalls – and what to avoid

This section highlights the potential pitfalls to avoid when undertaking a project related to food safety reform.

Gold plating

Gold plating refers to the development of a regulatory framework that mandates higher standards than those that are required to ensure safety. Gold plating can also mean allowing inspectors to require food business operators to demonstrate higher standards than the law requires. This is the prime pitfall, and the first issue to remember.

Food safety reform needs to be seen in the context of a country’s development level, and the types of businesses that operate there. Developing a regulatory framework that is not suitable for the types of businesses that operate in the country is counter-productive both to food safety outcomes as well as to private business development. For example, if the regulatory requirements are impossible for the business to meet without incurring considerable costs, and then passing them on to the consumer, there is a risk that the food may become unaffordable. This would of course mean that the reform will not have achieved its objectives.

When considering approaches to reform it is important to consider what investment and capacity is required from businesses to implement the requirements, and choose approaches that minimize the business burden while still ensuring safety. Mandating the use of HACCP systems for all types of businesses could be seen as a type of gold plating, as discussed in Section 7.

It is important to remember at all stages of the project that the two key outcomes of food safety reform are to ensure that food is safe to eat while also providing a regulatory environment where it is possible for businesses to be successful.
Over-ambitious reforms

Projects need to have realistic objectives for reform to improve the likelihood of success. Reform of the entire system in one project is likely to be an extremely long and difficult process. The food safety system is linked with several other issues, and without fully considering all these related issues (including legal, institutional), reform of the entire system is impossible.

Timescales are another area where it is important not to be too ambitious.

It is easy to be over optimistic, detailed project planning and exploring the issues with in country contacts will help you to understand the likely sticking points where reforms may take longer to proceed than you would expect and assist with developing a realistic plan.

Objectives of the reforms should be agreed at the outset of a project and budgeting should be considered carefully to ensure that it is possible for the project to deliver its planned objectives within the time and budget allocated.

Insufficient attention to stakeholder needs

Not involving stakeholders that are relevant for food safety reform projects is a key pitfall. Due to the cross-cutting nature of food safety reforms there will often be a large number of interested stakeholders. They can risk the success of the project if they are not properly engaged in the reform effort.

Regulators and inspectors often have vested interests in continued enforcement. They can strongly oppose the reform. For these reasons, it is essential to properly map every important stakeholder, their position and vision, and to try and gather as much support as possible from all sides, by explaining the logic of the reform, and making the elaboration of the reform open and transparent. Partnering with others is essential (including of course the private sector).

Insufficient focus on implementation

Changing only the legislation or top-level institutional structure will achieve little, if anything without a focus on how changes are implemented. Working with regulatory agencies to build capacity for implementing new procedures and ways of working is very important to ensuring that the reforms achieve the desired outcomes.

Areas of focus could include ensuring regulatory agencies have the capacity and capability to plan and conduct inspections in a risk-based manner, gather and use intelligence and data in a meaningful way, have internal procedures and information systems that allow them to deliver, and have staff with the right skills to deliver the new style of regulation.

Food business operators may also have vested interests in the existing system. For example food business operators that do not currently effectively control food safety may prefer the status quo which gives them an (unfair) advantage over competitors that do invest in safe food.

Consumers frequently mistake “many controls and licenses” for “effective guarantee of food safety,” and consumer associations or NGOs may for this reason strongly oppose the reform.

For these reasons, it is essential to properly map every important stakeholder, their position and vision, and to try and gather as much support as possible from all sides, by explaining the logic of the reform, and making the elaboration of the reform open and transparent. Partnering with others is essential (including of course the private sector).

Importance of realism in objectives and timeframes

Any reform effort needs to be realistic on what outcomes are possible in the timescales of a project. For example, what regulators are ready to change, how much change in regulators’ approach to control and attitudes is realistic, what the capacity and willingness of the private sector to engage in reforms and the readiness of consumers to change habits. This is a general issue that relates to all the points above. It is crucial to have a realistic assessment of the starting points for the country and of the possible outcomes in a project timeframe.

Snapshot 7.1 Italy: Reducing Bureaucratic Side of Food Safety Without Changing Regulations

Although food safety legislation for many EU member states proceeds essentially from EU directives and regulations (for example, it is the same in all member states, at least in its requirements, if not exactly similar in the way processes take place), some additional regulations and procedures may exist. Many of these are additional requirements or authorizations to open premises or start activities. Some food safety regulations may have been created recently, but most tend to be decades old.

Italy has a number of such examples, with approvals dating in some cases as far back as 1928 (regulation on meat trade) or 1954 (approvals for transhumant herds of animals). Since federalization has given responsibility of enforcing many regulations (including most of those related to health) to the regions, it is now up to each region to decide on what procedures to keep, or to reform.

In Italy, except for premises for which EU regulations mandate prior authorization (for example, slaughterhouses), all FBOs can start work through a simple declaration of start of productive activities given to the “single window” office.

These reforms show that, even with similar regulations, the actual implementation of these regulations (in terms of procedures, approvals, etc.) can be made simpler – or on the contrary, worsened. Simplifying the bureaucratic side of such procedures is an effective way to reduce administrative burden without negatively affecting safety, and without having to undertake a resource-intensive or politically difficult review of requirements themselves (which, in the EU, would anyway have to take place at the EU level, making it extremely difficult).
Measuring results

There are a number of ways to measure results that can have varying degrees of relevance depending on the country context, and be more or less difficult to measure.

A useful approach to developing measures for a project is called the outcomes and impacts modelling approach. A logical map of activities and the outcomes that follow from these activities is produced so that activities being carried out as part of the project can be clearly linked to the desired outcomes.

The model shows what resources and activities are planned and what you expect to happen (outputs, outcomes and impact). Using this logical approach is a good basis to design appropriate measures for the project as it enables the project team to see what was done as part of the project and what is intended to happen as a result of this. The steps to developing measures involve:

- thinking about how the key elements of the model could be measured. The aim of the step is to produce a long list of indicators that covers the whole pathway;
- mapping these potential indicators against known indicators, identify where relevant data is already being collected and by whom and map this against the model;
- prioritizing the measures so that they are available for the key areas by thinking about the relevance of the measure, and how easy it is to collect;
- determining if it measure a key outcome or impact that is of particular importance to the project;
- determining if it is a necessary indicator to achieve a balanced assessment;
- determining if the indicator already being measured;
- determining if it can be integrated in existing data gathering (for example, citizens’ survey);
- determining if it could be easily collected while performing the activities (for example, another tick box on an inspection protocol), and
- determining if it would require substantial primary data collection? (such as a complete new survey).

Outcomes measures

Often it is relatively easy to measure inputs (such as amount of money spent or number of staff hours), and activities and outputs (for example, legislation is introduced, new institutional structure is set up) but measuring outcomes can be more difficult.

Outcomes can be influenced by various factors beyond those being implemented in a reform project. For instance, an increase in export activity can increase standards as firms change to meet purchaser requirements. The logic modelling approach outlined above assists by putting the reform steps in context. It encourages measures that go from inputs/activities to outcomes.

Some examples of potentially relevant outcome measures are given below:

- **Burden reduction.** Compliance Cost Savings are in many countries of intervention a perfectly appropriate indicator, as excessively frequent and non-transparent inspections, as well as multiple permits, approvals, certificates etc, constitute a very heavy burden for businesses, without really bringing substantial benefits in terms of safety.
- **Exports.** In many cases, sector with high potential for growth (or for moving up the value chain) are shut out of the most important markets because the food safety regulatory system in the country is not credible, and thus importing countries (such as the EU) do not accept their products (in particular for foods of animal origin). Increasing the number of goods, which can be exported, or the number of establishments in the EU-approved list (for instance), can be a very valid objective, and indicator. The value of exports can also be an indicator, but attribution to the reform can be difficult in many cases.
- **Investments.** Foreign or national, in food processing facilities, or other important facilities such as refrigerated warehouses, can be indicators of the success of the reform in fostering increased confidence in the sector, enhanced access to foreign markets, and higher readiness of consumers to pay a premium for safer food. On the other hand, issues of attribution are problematic, as many other factors likely have more influence (or at least as much) on investment decisions.
- **Food Safety.** Any reform effort should have an effect on food safety. However, isolating the effects of a reform project can be difficult and should be measured over a number of years. Some potential measures include: instances of food-borne diseases, hospitalizations, and amount of related pharmaceuticals purchased. This data is usually available from the health ministry or for imported pharmaceuticals from the country’s trade data.
- **Businesses experiences of being regulated.** A survey of business experiences of being regulated can give useful information about the success of a reform process and about implementation by inspectors that can be used by the regulatory agencies to improve their performance.

Indicators can be tracked and objectives defined either for the entire food sector or for a specific sub-sector, if the project focuses on a particular supply chain.

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2 As above
Potential implementation risks from external events

Reform of the food safety system is highly dependent on the political will and capacity available in both the governmental and private sector.

<table>
<thead>
<tr>
<th>Political will may be influenced positively by the following factors:</th>
<th>Political will may be influenced negatively by the following factors:</th>
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<tbody>
<tr>
<td>• Trade requirements. If priorities for trade are countries that recognize international standards in food safety then adopting international standards will be important politically.</td>
<td>• Constant changing of the priority trade countries. For example, in 2009 Belarus decided to harmonize rules in dairy production with EU rules, which led to Russia banning imports of milk and dairy products from Belarus. After signing a treaty to enter the “Customs Union” with Russia and Kazakhstan, Belarus again implemented food safety standards aligned with Russian GOST standards.</td>
</tr>
<tr>
<td>• Possibility of joining WTO. In the accession phase the SPS agreement and its provisions can be a very strong driving force.</td>
<td>• Private interests overpowering public ones.</td>
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<td>• Accession to the regional trade unions. Countries that have a prospect of joining the EU or other regional trade unions will be required to harmonize their legislation and practices.</td>
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<tr>
<td>• Strong consumer demand regarding food safety. For example in the United States, a new food safety bill has been introduced as a result of pressure exerted by consumers on regulators.</td>
<td>• Corruption.</td>
</tr>
<tr>
<td>• Large direct foreign investment into agriculture and implementation of best practice technologies.</td>
<td>• Economic crisis. No funds available to be allocated for reforms and capacity building.</td>
</tr>
<tr>
<td>• A major food safety crisis can result in reform of the food safety sector. For example, after the BSE crisis in the EU when mandatory animal identification and recording of animal movement was introduced, and traceability system for animals and food of animal origin was developed.</td>
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In order to have an efficient food safety system, it is necessary to have capacity in both the governmental and private sectors.

In the governmental sector, lack of capacity can be the result of:

• underestimation of the importance of food safety and transfer of capacity and resources to other sectors;
• inadequate educational structure or experience for government officials and inspectors;
• New organization created without retaining previous expertise. For example, in Armenia food inspection was historically performed by the Ministry of Health Sanitary Service and when the Food Safety Inspection Service was created only a limited number of inspectors were transferred from the old service to the new agency;
• suspension of the food safety law and food safety inspection in Georgia, the whole food safety inspection was suspended in order to cure corruption and a new service is difficult to organize;
• After each election drastic change in the food safety policy, completely new teams, no historical memory;
• fear for its own positions/jobs (too old and reluctant to changes).

In the private sector, lack of capacity can be the result of:

• low economic status;
• monopoly on the market – protectionism, which prevents other players, both national or international, from entering the market;
• lack of legal requirements on the implementation of food safety systems and preventive measures;
• corruption in control bodies – no demand for the improvement of the food safety system;
• lack of access to information – usually the private sector has better access to information (from their trade partners) than the public sector; and
• Bad management practices.
Reforms of the food safety system can be efficient and profound, or superficial, more formal, and with no positive outcome. There are cases when the adoption of the food safety law and reforms were prolonged for several years due to resistance from parts of the private and governmental sectors (in Serbia, almost nine years were needed to adopt the new food safety law and divide responsibilities of control bodies).

Other factors may contribute to the unsuccessful reforms or no reforms at all:

• Lack of national policy – constant change, no planning or measuring of results of activities.
• Lack of strategy or prioritization of activities.
• Trend to avoid changes by insisting on the “special situation in the country,” which requires international standards to be adjusted to local circumstances.
• Inconsistent implementation of measures – relying on certification, which may not be based on the estimation of the efficacy of the system in place, but instead controlling only the formal side (documentation, paperwork).
• Adoption of regulations with no follow-up implementing measures – businesses may implement measures according to their own will and inconsistency is a problem.
• Lack of sustainability in measures – highly dependent on foreign experts and funds.
• Procurement problems/purchase of low-quality equipment for governmental agencies.
• Funds allocated for food safety reallocated to other sectors due to some emergencies or to a political decision.
• Lack of division of responsibilities, constant disputes and transferring of responsibilities from one agency to another.
• Lack of capacities in the national scientific community and no efforts to develop them.
• Lack of public awareness on the importance of food safety for public health.
• Manipulation information and depriving public the access to information.

The situation in the food safety area is dependent on international collaboration, access to scientifically sound data, constant development of resources, and participation of all stakeholders in the food safety system. Improvements should be made based on insight into real national needs and potentials. Lack of planning and recognition of potential bottlenecks postpones actions or even endangers some already achieved results.
Q1. Has capacity been built in for monitoring and evaluation?

Q2. Has sufficient focus been placed on implementation?

Q3. Is control performed across the food chain?

Q4. Is there overlap in food safety control between different agencies?

Q5. Have external implementation risks been considered?

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**Dairy sector example**

Q1. Monitoring and evaluation of interventions in the dairy sector will need to be considered in the context of the entire sector supply chain and not just focused in the high-risk aspects, such as processing.

Q2. Designing interventions is one thing, but implementing them is another matter, especially if multiple actors and drivers are being considered. Implementation in the dairy sector is likely to involve multiple agencies and players. Implementation support as well as oversight need to be considered.

Q3. Inputs and outcomes are not the same thing. The distinction between them must be well understood and dairy sector intervention designed with both in mind.

Q4. Measuring success is also very important and there are various tools already available to do this via the World Bank Group. Selecting a measurement tool to fit the dairy sector specific interventions is required so that measurements are accurate.

Q5. In any intervention scenario there will be risks posed to the success of the project by external issues. Political will, consumer demand, corruption and lack of capacity can be positive or negative influences that will need to be considered. (For all detail on external risks see module 7 of the Toolkit).
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
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
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

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Armenia

Challenges and limits of the ‘single agency’ approach

In December 2010, several services dealing with food safety were merged into a new State Food Safety Service (SFSS) by a Presidential Decree. The Veterinary Inspection and Phytosanitary Inspection from the Ministry of Agriculture were directly merged into the new service, and the functions pertaining to supervision of safety of food products were removed from the Sanitary and Epidemiological Service (SES) of the Ministry of Health and given to the new SFSS.

While staff from the veterinary and phytosanitary inspectorate was transferred to the new service, there was no systematic staff transfer from the SES. Instead, the SFSS hired some new staff to cover areas where existing veterinary and phytosanitary specialists may not be competent, and some of these new staff may have come from the SES. Relevant functions from the Metrology inspections were also transferred (when they related to food products), again without transfer of staff.

On this basis, the government largely considered that the food safety issue was solved, or at least its institutional aspect. The food safety law itself was amended in 2006, and the set-up of a new “single agency” was intended to complete the reform.

In fact, the “single agency” creation has shown that is was no such “silver bullet.” A number of issues remain unsolved, possibly because too much was expected from the merger itself, rather than seeing it as a first step in a long set of actions. Even though the SFSS is working hard at improvement and has potential to contribute positively to further changes, it is worth considering why it has so far been unable to fulfil expectations.
Lessons learned

• Insufficient preparation and issues with structures, competences and staffing. Even though the Armenian government clearly foresaw that much work would be needed to support the SFSS once set up, it did not fully envision how considerable the work would be to transform it into a modern food safety service. The “merger” work was also done without fully considering the competences previously vested into the SES of the Ministry of Health, and transferring relevant staff (contrary to, for instance, what was done in Lithuania or Latvia). As a result, there are some skill gaps, the relations with the SES are unclear, and it seems that in practice the SES is still checking some hygiene issues that, in FBOs, should be checked by the SFSS if it were to really be a “single food safety agency.”

• IT and planning. In order to really fulfill its functions, the SFSS needs to conduct risk-based planning of control activities (inspections etc.). It is currently not able to do it because of the lack of appropriate database and software. IFC has helped develop a methodology for risk-based inspections planning, but implementation is a problem not only because of IT issues, but also because of staff in the SFSS being slow to take up new approaches.

• Staff vision and problem analysis. The SFSS was not fully on board for a new approach to food safety regulation that would put more focus on the role of the private sector, and seek to minimize administrative burden while preserving and even strengthening effectiveness. Crucially, even though the SFSS has a strategy document for food safety reform, it is based on a somewhat generic goal of “getting closer” to EU regulations. What was needed was a proper stock taking of issues, gaps and problems to reach specific EU regulations. At the same time there was no clear understanding or agreement that the current system is both burdensome and of limited effectiveness. The interim result was a bifurcated scenario with a desire for improved safety but a reality where some stakeholders sought to introduce fees, fines and a heavier oversight process.

• Coordination. There is a risk that SFSS sees itself as a “single food agency”. However, for success it will need to coordinate closely with others (for examples, the health care system, SES etc.) At the same time the same stakeholders within the Government tend to think that the issue has been solved with the SFSS being set up.

In conclusion, there has been mixed success in Armenia with the single agency approach. The SFSS is still a young organization, and its management is showing signs of understanding the need for further change. The government is strongly supporting reform and ready to make the necessary commitments. On the other hand, however, it can be used as a strong reminder that setting up a “single agency” will, in and of itself, not solve any issue. It can be a useful tool if all the relevant steps are being taken. It can also in some circumstances act as a distraction, when it is thought that this merger will solve all issues and thus attention is being taken away from the real problems that need to be solved.

Canada

Regulatory reform following Listeria outbreak in 2008

Background and context

Canada is among the world’s largest countries, and its territory is second only to Russia. The Gross Domestic Product per capita in Canada was last reported at $25,588 US dollars in 2010, according to a report published by the World Bank. Canada’s GDP per capita is equivalent to 207 percent of the world’s average. Agriculture accounts for 3 percent of the nation’s GDP and 3 percent of its workforce.

During the summer of 2008, Canada experienced one of the worst outbreaks of Listeriosis. What initially began as an increased number of Listeriosis cases was soon to become a major public health concern. The source of the outbreak was traced back to cooked meats that had been contaminated with a pathogenic organism, L. monocytogenes. The cooked meats had been produced at Maple Leaf Foods in Ontario.

1 Retrieved on 4/07/12 from http://www.tradingeconomics.com/canada/gdp-per-capita
2 Source: http://www.indexmundi.com/canada/gdp_composition_by_sector.html
3 Source: http://www.thecanadianencyclopedia.com/articles/agriculture-and-food
The outbreak resulted in 57 confirmed cases and 23 deaths that were spread across seven provinces. The contaminated meat was primarily sent to hospitals and long-term care homes in catering sized packs. The majority of cases involved the elderly, who are known to be at greater risk of contracting Listeriosis.

Following the outbreak an independent investigation was set up by the Canadian federal government and presided over by Sheila Wetherill who was directly appointed by the Canadian prime minister.

Financial implications and cost areas

Maple Leaf Foods initially predicted that the financial burden would cost the company around $20 million. The outbreak eventually cost in excess of $37 million. The cost included collecting and destroying the recalled product of $17.6 million; and losses incurred on product dispositions directly related to the recall of $2.2 million. Closing down the site and implementing a full clean and sanitisation program cost $6.7 million; incremental media of $4.2 million; the cost of setting up a customer response call center of $1.2 million; and other related cost $5.6 million (Maple Leaf, 2008).

Sales of sliced cooked meats fell by 50 percent from the previous years’ sales. The company’s meat product adjusted earnings had declined from $94.1 million prior to the outbreak to $29.5 million throughout the duration of the outbreak and ensuing investigation estimated to be 9 months. The total group meat product sales had declined by 4.5 percent to $3.3 billion compared to $3.5 billion. The outbreak is estimated to have cost the economy $132 million, due to loss of earnings,

Box 8.1 Food Safety in Canada
medical costs, travel expenses, and increased surveillance and testing in dealing with the outbreak.

Class action lawsuits were filed against Maple Leaf foods at a cost of $27 million.

After the recommendations made by the Wetherill report, the Canadian Food Inspection Agency (CFIA) demonstrated commitment by increasing the budget to improve the food inspection service. $75 million was announced in September 2009 and the budget was to increase by $100 million over five years. The report of the independent investigator is estimated to have cost $2.7 million.

**Food safety regulatory responsibility and legislation**

Within government, three agencies have the responsibility for the Canadian food safety system – the Canadian Food Inspection Agency (CFIA), Health Canada, and The Public Health Agency of Canada. See Box 8.1 for details.

At the time of the outbreak, Maple Leaf Foods would have been regulated under the Meat Inspection Act. The Act requires companies to be federally registered and licensed. Companies must establish safety measures and controls at every step of the food production process to comply with the regulation (Weatherill, 2009). During the outbreak the 2004 Canadian Policy on L. monocytogenes in ready-to-eat foods was a published. Maple Leaf Foods was found to already be following this policy.

Prior to the outbreak a new system called the “Compliance Verification System” was being piloted (CVS). The system was designed by the CFIA, to consolidate all the inspection requirements that previously existed in different meat inspection programs. In April 2008, the CVS was introduced and CFIA inspectors are now required to conduct specific inspection activities at the registered federal meat plants.

**Lessons learned and changes to legislation**

The Weatherill Report made 57 recommendations. A void in leadership, a raft of systemic flaws, and a shortage of inspectors were just some of the criticisms levelled at Canada’s food safety regulatory system. There was a clear focus that both regulators and business should place safeguarding consumers at the center of their consciousness and collective actions.

The investigation identified four broad categories where improvements need to be made. There must be:

- more focus on food safety among senior officials in both the public and private sectors;
- better preparedness for dealing with a serious foodborne illness with more advance planning for an emergency response;
- a greater sense of urgency if another foodborne emergency occurs; and
- clearer communications with the Canadian public about Listeriosis and other foodborne illnesses, especially at-risk populations and health professionals.

The CFIA announced that they would be implementing the full 57 recommendations made from the report with a full review of all policy and legislation concerning food safety.

The 2004 Listeria policy has undergone a full review, taking into account the roles and responsibilities of industry, government, and consumers. It is based on Codex standards and provides guidance on definitions of ready-to-eat foods that may support the growth of Listeria.

In 2012, the new Safe Food for Canadians Act was introduced and will consolidate a lot of the specific acts, including the Meat Inspection Act. This followed from one of the recommendations made by the Weatherill report to “modernize and simplify federal legislation and regulations that significantly affect food safety.” The Act will impose tougher penalties for activities that put health and safety at risk, provide better control over imports, institute a more consistent inspection regime across all food commodities, and strengthen food traceability (CFIA, 2012).

**Conclusion**

The regulatory reform initiatives that came about following the Maple Leaf outbreak were based on an understanding of shared responsibility for food safety. It would have been easy for the government to place the entire burden of responsibility on the food business itself but it clearly recognized institutional failings in its own systems for assuring food safety. Key features of this regulatory reform are:

- better communication systems in the event of an outbreak;
- improved food safety education for consumers particularly those in high-risk groups;
- improved understanding of the potential demographic of at-risk groups based on an evaluation of available scientific data;
- a new regulatory requirement for FBOs to communicate trends in product and environmental contamination data;
- improved training for inspectors to ensure that they had product- and process- specific expertise – identification of a “scope” for inspectors; and
- better division of responsibility among federal agencies clarifying their role in the event of an outbreak.

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5 CFIA, 2011

6 Weatherill, S. (2009) Recommendations to Strengthen the Food Safety System, p. 15

7 Harrington, 2009

8 Weatherill, 2009

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Croatia

Reform of the food safety system

Croatia is a transitional South East European country and candidate to access the EU in 2013. Coming out from the centrally controlled economy in 1990’s and Balkan wars from 1991-95, it underwent the period of early market economy and managed to conduct necessary reforms and harmonize legislation and practices with the EU. The driving force for reforms were WTO membership and EU perspective.

Croatia joined the WTO in 2000, and until 2012, has reorganized completely the food safety area and built capacities of the competent authority - the Ministry of Agriculture. The capacities of regulators to perform harmonization and risk management were increased, along with the setup of functional Codex Alimentarius, OIE, IPPC, RASFF, WTO-SPS contact points.

Financial and technical support were provided through various donor projects, in the form of trainings, establishment of the animal identification system, prevention and eradication of animal and plant diseases, and also support of all related services (customs, laboratories, research institutes) and the private sector (training of farmers in GAP, producers in GHP, GMP, HACCP).

The state reorganized the inspection service, made one common State Inspectorate (composed of different inspectorates such as tax, fire, construction, mining, work safety, equipment under pressure) but control of food was left in the competence of the Ministry of Agriculture and partially of the Ministry of Health, according to the EU model. Control of food is performed by specialist inspectors split into veterinary and border veterinary, phytosanitary, agricultural, livestock, water management fishery and wine inspections.
The number of state veterinary inspectors is below optimal, but the veterinary practitioners were trained to perform food safety controls and for that service they are paid from the state budget. Risk-based control was introduced in all sectors, and guidelines, checklists, trainings for inspectors have been organized. Laboratories were specialized for testing of certain types of commodities, accredited according to the ISO 17025 (by Croatia’s accreditation body, which is a full member of the ILAC) and they are organized in such a manner that the whole territory is easily serviced.

Harmonization of legislation and practices is well advanced in the food and veterinary area, but implementation of measures is still behind schedule in the phytosanitary area.

Multiannual control plans were developed with technical assistance from the EU, which has a policy of supporting implementation of Reg EC 882/2004 in EU candidate countries.

Electronic databases exist in different inspectorates and need to be interconnected.

Regional trade (among eight countries of the CEFTA - Central European Free Trade Agreement zone: Albania, Bosnia and Herzegovina, Croatia, FRY Macedonia, Kosovo, Montenegro, Moldova, Serbia) represents a very important segment of trade in agricultural commodities. All countries decided to harmonize legislation and practices according to the EU model and are working actively on supporting a transparent manner of preparing new legislation and measures, with the CEFTA Secretariat as an active mediator and facilitator.

Benefits of the CEFTA agreement for the food safety sector include:

- identification of main regional export commodities and potential non-tariff trade barriers associated with them;
- harmonization of legislation and practices in line with EU practice for main export commodities in order to facilitate trade;
- sharing information about new laws and measures-transparency, through the CEFTA coordination body (CEFTA Secretariat);
- training in different food safety areas organized for whole region;
- bilateral collaboration (countries share their experiences through harmonization, and control bodies collaborate in setting up common practices in inland and border inspections);
- bilateral collaboration in laboratory testing (for example: Montenegro uses capacities of Serbian laboratories for official certification of geographical denomination for their certain vine types); and
- common projects in food safety area facilitated by the CEFTA Secretariat.

Lessons learned:

- Early identification of a main goal of the food safety reform process. In Croatia’s case it was harmonization with EU requirements in order to export to the EU and become a member state.
- Setting up strong contact points with international standard-setting organizations, information sharing, RASFF system in place and functioning.
- Fulfillment of all necessary requirements of the WTO-SPS helped reorganize and strengthen the food safety area.
- Access to EU funding for potential member countries was essential for financing extensive reforms.
- Clear division of responsibilities between inspections controlling food. Although they belong to different ministries, their collaboration and cooperation is functional and on a constant basis (monthly meetings, exchange of information, joint actions).
- Monitoring and eradication plans developed and enforced in line with OIE, IPPC, and relevant EU bodies (FVO) recommendations.
- Where there is a regional trade agreement, having one country that is more advanced in terms of international food safety requirements can become a strong driving force for other countries to reform their systems and practices.
Lithuania

Food safety reforms to join the European Union, and improve the business environment

Of the three Baltic states, Lithuania is the largest, and the one where agriculture contributes most to the national economy. Agriculture accounts for more than 12 percent of the country’s GDP, which is relatively high for an EU member state. Lithuania has a long agricultural tradition with strengths in dairy, cereals, fodder, and animal production for meat, in particular. A significant share of its production is exported to other EU members and to Russia.

Given the importance of agriculture and agribusiness for the country, improving its food safety system was a particularly salient as part of its EU accession process. In the second half of the 1990s, as candidate countries in Eastern Europe were regularly assessed, Lithuania was for a long time one of the “laggards.” It was long thought that it would not be able to join along with the batch of new entrants scheduled to join in 2004. Only through a considerable acceleration of reforms from the end of the 1990s was it able to eventually join along with others to form the (then) EU-25.

Prior to reforms, Lithuania’s food safety system was largely built on the former Soviet Union’s foundations. This meant a strong reliance on ex ante controls and certification of product types, many permits and approvals, and split responsibilities between veterinary, sanitary and trade inspections, with many overlaps and duplications.

In 2000, the State Veterinary Service with its subordinate institutions, the State Hygiene Inspection under the Ministry of Health and the State Quality Inspection were (for the most part) merged into a new institution – the State Food and Veterinary Service. The SFVS is in charge of food safety control in the whole chain in line with the EU concept “from stable to table” and “from field to fork.” Another institution established as a result of reform was the State Non Food Products Inspectorate under the Ministry of Economy, which took over controls on safety of non-food products.

The SFVS is responsible for risk analysis and for inspections and enforcement. For the most part, regulatory powers are clearly divided between ministries (Economy for labelling, Agriculture for rules concerning pri-
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mary production, and Health for residue levels, hygiene, and all other issues pertaining to human health). The SFVS is itself the regulatory institution for animal health and welfare. This was decided because the competence in this field is concentrated in this institution following the reform.

The goals of the reform, beyond the immediate purpose of EU accession, were:

• to decrease the administrative burden for business operators by decreasing the amount of mandatory approvals and certificates, and the burden of control for low-risk operators;
• to implement in Lithuania the EU market surveillance principles and give priority to ensuring food safety by means of official controls;
• to shift responsibility for food safety to producers/operators;
• to establish uniform food control according to the concept “from stable to table” and “from field to fork”;
• to form more favorable conditions for free movement within EU member states in parallel ensuring effective controls of imported products of animal origin; and
• to ensure further improvement of animal welfare and protection against contagious animal diseases.

The reform was financed from the state budget. However, since this was the pre-accession to the EU period for Lithuania, at the time and later on after accession to the EU, the country received additional substantial financial assistance from the EU for build up control infrastructure.

As a result of the reform:

• a single institution is responsible for safety in the whole food chain;
• a uniform control system was established;
• the administrative burden decreased; and
• clearer conditions and requirements were set for food business operators.

Lithuanian producers gained access to the EU market, and retained or increased their access to third markets (such as Russia). The safety situation in the country also improved. The reform promoted consolidation of producers, in order to be able to cope with the investments needed to comply with the new requirements. While this generally can be held to have had positive economic effects in the long run, there were nonetheless some downsides in the short term with decreases in primary production employment as the industry modernized.

The intergovernmental working group was established by decree of the prime minister in February 2000 to prepare the reform. The resolution that created the new institutions was adopted by the government in May 2000. They started functioning in July 2000. In other words, the initial step of the reform was implemented in record time. Full implementation of the reform, to get institutions working and improving their practices, took several years. To some extent, it is still going on, as the government has been implementing (since 2010) a comprehensive inspections reform program that covers food safety as well as all other issues. The aim is to make inspections more transparent, more risk based, and to help businesses comply through better information efforts.

Moldova

Leveraging competitive advantage through agribusiness related investment climate reforms

Moldova benefits from a favorable climate, soil, and topography. This combined with relatively low wages and its proximity to major consumer markets (the EU, Russia) to give it a potentially important comparative advantage in agro-based exports, particularly high-value agricultural products. In addition, Moldova enjoys preferential export quotas for most agricultural products under the EU-Moldova Autonomous Trade Preference Agreement of 2008.

In spite of these advantages, agriculture has lagged behind throughout the last decade: its share of real GDP value added halved between 2000 and 2008, and Moldova is unable to fulfill its EU preferential export quotas for most agricultural products.

One of the reasons for the decline of Moldova’s agricultural sector is that it suffers from an outdated food safety infrastructure and from other policy and regulatory constraints distorting the agricultural inputs markets and hampering the efficiency of transport, logistics, and export procedures.

Given this situation, the Government of Moldova sought to: (i) address regulatory constraints hampering the development of a competitive agribusiness industry, and (ii) attract investors in the high value agriculture subsector. Within this, building a credible, EU-compatible food safety system was identified as a key priority, as this is a binding constraint for high value exports development.
As a result, the government of Moldova adopted an integrated package of reforms for the agribusiness sector in the fall of 2011, including the following:

- Abolishing the list of food products subject to mandatory certification, a key step in removal of non-tariff barriers to trade (mandatory certification being not only in contradiction of WTO SPS, but also widely seen as ineffective to guarantee the safety of food) and important contribution to free trade negotiations with the EU.
- Adoption of the National Food Safety Strategy for 2011-2015 in line with EU approximation requirements, including the establishment of a single food safety agency.
- Piloting the adoption of the EU Common Catalogue for Seeds and Seedlings by allowing the import of all EU-registered varieties for a selected number of crops that are under-represented in the national catalogue.
- Transposition of several EU Directives on product safety and quality standards (95/16/CE, 2009/142/CE, 97/23/CE, 88/378/CEE, 2000/9/CE, 94/25/CE, 2009/105/CE) into national legislation, thus fast tracking the harmonization process with EU and internationally recognized standards of a significant number of manufacturing product categories, including agricultural equipment, thus making imports of modern machinery easier.

The high point of reforms so far has been the recent adoption of a new Law on Food Safety (voted by Parliament on May 18, 2012). This law continues the approximation process by setting forth rules on food safety that are directly taken from EU legislation. It also foresees the creation of a national food safety agency, with both regulatory, and inspections and enforcement powers. As such, it can be seen to constitute both a final step (to the series of legal changes on the food safety side) – and a starting point (for implementation work to make this new food safety approach a reality).

In spite of overall consolidation of functions in the NFSA, a certain number of areas of competence are reserved for the Ministry of Health. Given the law’s wording, it is likely that some areas of friction or duplication of control may arise over the control of food on the market (where MoH has competence over certain types of foods, and certain aspects, whereas the NFSA has general competence), or to its production (where MoH supervises the health and knowledge of workers, and the NFSA again has general competence).

Major efforts will be needed to implement the new law. They will need to set up the NFSA, prepare and adopt a considerable amount of secondary legislation, and develop new guidelines and processes. However, in only about two years, the country has managed to move from sever challenges in the food safety arena to a reality where outdated regulations (such as mandatory certification) have been abolished, and a new, coherent, EU-compatible food safety law has been adopted.
Mongolia

Challenges of developing food safety legislation

Mongolia presents an interesting case of the many challenges and contradictory pressures and demands that can arise when attempting to support the development of new food safety legislation. Since 2009, an IFC project has been working with the Government to improve at improving business inspections in Mongolia through legal reform and changes in structure and practices of the “State Inspectorate” (formerly called General Agency for Specialized Inspections, now being renamed Public Safety Agency) in charge of most inspections outside of tax, customs, and fire safety (its mandate is now being slightly narrowed down, but remains very broad, covering most safety issues).

As one of the Inspectorate’s major functions is to enforce regulations in food production, processing, and trade, and given the importance of food safety for the Mongolian economy (with its significant meat and dairy export potential, currently considerably hindered by low food safety reliability), the project logically focused an important part of its activities on the Inspectorate’s work in relation to food. This included:

- developing a methodology for risk-based planning of food business operators (FBOs);
- designing checklists for inspections of FBOs; and
- consolidating internal structure of the Inspectorate to have more coherence in supervision of FBOs (single “food safety” department being considered), as well as retraining of staff.

All these activities showed, however, that proper implementation of new tools and practices required sound, modern, and comprehensive food safety legislation to be in place. This was not the case, with some aspects regulated in an outdated way, some left uncovered, and overall an incoherent set of legal acts. As understanding grew in the country of the loss of competitiveness and market access for food exports due to the poor food safety framework, the project was approached by requests from members of parliament and the presi-
dential secretariat to assist with drafting a new food safety law.

This proved to be a challenging undertaking for a variety of reasons, many of which may be applicable to other countries and settings:

- A comprehensive food safety law needs to regulate a variety of issues, some of which may not exist in any other legislation in the country (such as recall of unsafe foods, recognition of third-party certifiers, and liability of producers). This may end up being problematic if other legislation (for example, on certification, producers’ liability) is missing, which forces the food safety law to become increasingly detailed and complex, or to leave out key issues.

- Attempting to refine the contents so as to have a “technically perfect” piece of legislation may run contrary to political agendas (which require things to happen quickly) and fail once the draft law becomes debated in parliamentary proceedings, where all kinds of changes may take place.

- Debates on the proper level of regulation vs. risk of undue burdens on the private sector, or on the adequacy of “imported” standards vs. real capacity in country, may be intense and cause significant delays. In Mongolia, this was the case regarding all regulations for slaughter (“informally” and that this is because most consumers trust “informal” meat more, how likely was it that regulations would be successful or which incentives to build in the legislation?) and regarding HACCP. Given that it was clear that mandating HACCP for all FBOs would be completely unrealistic and create massive burden and/or corruption opportunities, what incentives for HACCP adoption or “graded introduction” were possible?

As a result of these discussions, the final version of the law went for generally “good practice” or even “best practice” solutions (where applicable), but always staying realistic. Producers’ liability was introduced, as well as traceability, requirements allowing for product recalls, and requirements to ensure safety of the products at all stages. The law establishes a National Reference Laboratory, clarifies supervision powers and responsibilities, and mandates risk assessment and management. It does not, however, make HACCP mandatory, and foresees that clear and simple guidelines have to be issued to make implementation of new requirements easy for SMEs. Thus, it aims at supporting Mongolian businesses to improve.

On top of all this, the project had to deal with competing legislation, as the Ministry of Agriculture had in its action plan to prepare a new “Food Law” for 2012, and proceeded with it. The contents of this new draft law were mostly rather vague, and dealing with many issues not linked to food safety as such (mostly food supply and storage), but some sections of it clearly dealt with safety, creating a kind of “collision” with the concurrent draft food safety law. The team had to devote a lot of energy to support reconciliation of these two drafts and possible merger into one.

In the end, the new food safety law was adopted after some delay, due to parliamentary elections. The new coalition that came in power was even more strongly in favor of the reform and the food safety law entered into force in January 2013. This was the result of a very important part of the work that focused on building understanding of food safety issues and support for reform among policymakers, politicians, and the media. This was done thanks to a series of meetings, seminars, conferences etc., with participation of foreign experts, in particular from governments and regulatory agencies having already successfully conducted similar reforms (such as new member states of the EU).

The experience from Mongolia also gives an idea of the timeframe involved. Preliminary work with the inspectorate lasted over a year and half (from early 2010 to mid 2011) before it became clear, and agreed upon, that a new law was needed. Then actual drafting took close to a year, with intense communication around it. Support to adoption then took over six months, after which implementation was the next issue to worry about. This process took already a fair amount of time in Mongolia, a country where decision making is actually very fast, the parliament functions well, and all political parties are overall in favour of reform. Timescales may be far longer in other countries.
Ukraine

Food safety reform as a key to unlocking agribusiness potential and foreign markets access

Ukraine is not only the largest country in Europe after Russia, but also one with exceptional natural conditions for agriculture. Lands are particularly fertile (mostly so the chernozem, or “black earth” belt), the climate is relatively moderate, and rainfall is sufficiently abundant. Geographical location combines easy sea access for bulk exports and proximity to the EU and Russia, its two major markets. Agriculture employs 16 percent of the labor force, and agricultural production plus processing make up close to 16 percent of gross domestic product (GDP). Production is important both in cereals and staples, and meat and dairy. Overall, Ukraine has a particularly high agricultural and food export potential, but it has yet to realize its full potential. The country is mostly concentrated on relatively low-value-added segments, such as bulk cereals or vegetable oils.

The regulations provide inadequate guarantees of food safety, thus limiting foreign market access for local producers and processors, and also limiting their ability to differentiate their products on the local market, in particular for subsectors such as dairy. Even though there are significant dairy exports from Ukraine (mostly to the CIS and developing countries), they are in large part confined to the lower end of the value chain. Access to higher-value markets such as the EU is still closed.

Reform in Ukraine has often been made very difficult by political upheavals, gridlock, and vested interests. Not only have agribusiness and food safety not been an exception in this perspective, but they have been marked by particularly problematic reform. Even WTO accession in early 2008 failed to bring about the changes in food safety regulations that were agreed as part of the accession package (they were voted but not implemented). The perspective of free trade with the EU provided important incentives, but changes remained slow. In this context, the IFC IC intervention tried to bring about much-needed change by building on previous achievements.

1 See IFC Reforming Food Safety Regulation in Ukraine: Proposals for Policymakers - A Background Policy Paper, 2009 - http://www1.ifc.org/wps/wcm/connect/fc9b751b54db577a9ec56bf6eac26e1c2/food_safety_report_ENG.pdf?MOD=AJPERES&CACHEID=fc9b751b54db577a9ec56bf6eac26e1c2
Starting in the early 2000s, and with growing emphasis and resources from 2005, work had focused on promoting reform of permits and business inspections. It has had some important successes, such as the adoption of a Permits Law in 2005 and an Inspections Law in 2007, but also with some disappointments in the implementation of these reforms. Given the apparent need to concentrate resources and attention on a specific sector, priority was given to agribusiness and specifically food processing. The initial emphasis was on the dairy sector, which was one area where Ukraine was particularly far from reaching its potential, and where the EU had quite critically appraised the regulatory regime.

Ukraine’s food safety regulatory regime pre-reform was (and still is to a large extent) characterized by:

- Burdensome administrative procedures limiting business set up, growth, and product innovation, – with many mandatory prior approvals and permits, and mandatory standards and certificates (applying even to product recipes).
- Duplication and overlaps in control activities, with six agencies covering food safety from various perspectives, with little or no coordination.

Many aspects of the food safety system are (or were) a relic of the planned economy, in particular mandatory standards regulating the exact way in which products should be prepared, rather than focusing on safety parameters, and placing oversight of the food chain on several regulatory agencies with overlapping mandates. The existence of several uncoordinated technical agencies results in repetitive checks, themselves conducted against outdated requirements, at great cost to businesses. State agencies are not held accountable when unsafe products enter the market. Private food businesses bear little responsibility for food safety, and the capacity of supply chain systems to ensure food safety is not leveraged, contrary to what is the case in the EU. The focus is purely on meeting formal requirements (permits, certificates) and not really on ensuring that only safe products are on the market.

Results of the first phase of work (up to 2012) were significant, even though they only constitute a first step. The main changes were the cancellation of mandatory certification for food products (in line with WTO SPS and EU practice), which was adopted in December 2009 (even though full implementation of this decision took some time) and the merger of the Veterinary and Phytosanitary Agencies in May 2011. This merged service in theory has primary responsibility for food safety inspections, but in practice the Sanitary and Epidemiological Service still conducts a vast number of food-related inspections.

This reform work also resulted in the preparation of a draft new law on food safety, which was approved by the government and sent to Parliament, but saw its consideration delayed by the 2012 elections. This new law, when adopted, should form the basis for a new food safety system in line with international (and in particular European) best practice. It proposes traceability, HACCP, recall procedures, reinforcement of FBO liability, and also elimination of permits, approvals, and controls that are not strictly necessary.

Thus, by leveraging WTO accession requirements, EU free trade perspective, the projects were able to support key steps that had long been mooted, but never pushed through. In particular, the cancellation of mandatory certification removes a very important source of administrative burden, which also has acted for a long time as a brake on innovation in the food sector in Ukraine. The merger of the veterinary and phytosanitary agencies is more a foundation stone for further work, to help this agency become really a modern food safety body, risk-focused and intent on promoting compliance. The draft law development is also a crucial foundation for further work.

The experience of this work showed the benefits that can be reaped from focusing advisory services efforts on a specific sector. It also taught lessons on the need to plan carefully the responsibilities and actions when two projects are involved, and to have full agreement on the goals and steps before starting work, as coordination is never easy. Finally, it showed the relevance of an approach that strongly emphasizes private sector involvement, as the private sector ultimately has to implement reformed regulations, and is the main driver of food safety in practice. Working with large retailers, in particular, proved to be particularly important.
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<tr>
<td>APLAC</td>
<td>Asia Pacific Accreditation cooperation</td>
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<td>BAP</td>
<td>Best Aquaculture Practice</td>
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<td>BRC</td>
<td>British Retail Consortium</td>
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<td>CAC</td>
<td>Codex Alimentarius Commission</td>
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<td>CAS</td>
<td>Country Assistance Strategy</td>
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<td>CFIA</td>
<td>Canadian Food Inspection Agency</td>
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<td>CPS</td>
<td>Country Partnership Strategy</td>
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<td>EAL</td>
<td>European Cooperation for Accreditation of Laboratories</td>
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<td>EC</td>
<td>European Commission</td>
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<td>East African Community</td>
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<td>Food business operators</td>
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<td>GDP</td>
<td>Goss Domestic Product</td>
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<td>GAP</td>
<td>Good agricultural practices</td>
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<td>GMO</td>
<td>Genetically modified organisms</td>
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<td>GMP</td>
<td>Good management practices</td>
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<td>GRMS</td>
<td>Global Red Meat Standard</td>
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<td>HACCP</td>
<td>Hazard Analysis Critical Control Point System</td>
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<td>ILAC</td>
<td>International Laboratory Accreditation Cooperation</td>
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<td>ILAC</td>
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<td>IPC</td>
<td>International Plant Protection Convention</td>
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<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
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<td>QF</td>
<td>World Organization for Animal Health</td>
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<td>PCB</td>
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JUSTIFICATION AND SCOPE OF WORLD BANK GROUP INVOLVEMENT

Food safety is key for growth in the food-processing sector because it allows development of the local market as well as provides access to export markets. It thus has direct benefits for the private sector, in addition to its role in ensuring growth more broadly by reducing the burden of food-borne diseases. It is an important area where the International Finance Corporation and the Investment Climate Department of the World Bank Group have a specific role to play to improve the regulatory environment, which often acts as a barrier to development, access to markets, and investment. Demand for food safety regulatory reform can come from many quarters: domestic businesses, would-be exporters, retailers, foreign investors, etc. It is part of a broader set of changes as regulation is only one piece of the food safety puzzle. Many changes are simultaneously needed on the private sector side (how businesses actually work), as well as changes of behavior among consumers.

Before getting involved in starting a food safety reform project, the Investment Climate Department of the World Bank Group has to clarify:

- whether the proposed intervention fits with the World Bank Group mandate and strategy for the country and region;
- that needs and demand for the intervention are sufficiently evidenced, and that there is real added value for intervention by the Investment Climate Department of the World Bank Group; and
- what the realistic limitations are on the scope of the project.

On the first point, this is a crowded space with many international organizations and donors. Therefore, the Investment Climate Department of the World Bank Group needs to play to its strengths. It needs to collaborate rather than compete with the other players and that means there has to be a strong private sector development reason for becoming involved. Although there are many technicalities in the field of food safety regulation, it is also fundamentally about developing markets and supporting the growth of the private sector. That is what projects of the Investment Climate Department of the World Bank Group should focus on. Food safety regulation aims at “healthy markets” in addition to healthy people.

It is also essential to know what the project will precisely focus on and aim to achieve. The field is too vast to just start a “food safety regulation” project without a clear objective. In parallel with defining the focus, it is also important to consider how a project will add value to that of others or will in some other way complement the projects of others. It is also absolutely essential to check that there is a real demand for the project from policymakers and key institutions, and that there is a good chance of the project being successful even if there are changes in important personnel in the government.
In terms of scope, the following main options should be considered, generally in some combination as framework and implementation should be seen as complementary:

- Revision of legislative framework – is this a critical pre-condition for further work, and does this involve only limited changes to roughly adequate legislation, or fundamental rewriting? If there is a need for fundamental rewriting, it is important to think through what will be needed in terms of implementation support.

- Institutional reform – because food cuts across so many issues of government there is often confusion and overlap across both ministries and agencies. On this point reform can be limited reform (clarifying some problematic issues) or fundamental reform (setting up a whole new institutional framework). This has implications at the implementation level.

- Process reform (changing how regulators organize and conduct their work) and implementation support – this is an essential part that can come as “stand alone” (if framework is generally right) or in complement to framework reform. The Investment Climate Department of the World Bank Group has expertise and a track record in inspections and licensing reforms, and other regulatory reform tools that are relevant to food safety reform implementation.

Once the decision has been made for involvement by the Investment Climate Department of the World Bank Group, and the scope of the intervention is determined, a certain degree of training for World Bank Group staff would be helpful, particularly in supporting productive relations with collaborators who are experts in the food safety, such as the World Health Organization and Food and Agriculture Organization.
Role of the Investment Climate Department of the World Bank Group in food safety

The involvement of the Investment Climate Department of the World Bank Group in food safety is relatively recent, and limited in geographical scope, reach, and breadth of issues addressed. In some cases, this involvement can be seen as intruding on the legitimate sphere of other institutions, which have been active for a longer time in food safety, and for which it is part of their core mandate. It is thus crucial to understand which institutions are involved, what their roles are, and where the Investment Climate Department of the World Bank Group can fit in and add value.

In the food safety area, the leading international institutions are the Food and Agriculture Organization (FAO), from the food production angle, and the World Health Organization (WHO), from the human health perspective. The FAO and WHO are linked through the Codex Alimentarius Commission (CAC). The CAC was established by the FAO and WHO, and develops harmonized international food standards, guidelines, and codes of practice. CAC standards and guidelines form the basis of modern internationally accepted good food safety practices.

FAO and WHO are the institutions that set the direction in the food safety sphere, and coordination with them is essential. Other international organizations, particularly the OIE (World Organization for Animal Health – in the veterinary health sphere) and IPPC (International Plant Protection Convention – for plant health) set important parameters for primary production, which contribute to the continuum of safety along the food chain. The WTO has incorporated most of the norms elaborated by these institutions as part of its SPS rules.

These international institutions set best practice that should be incorporated into national regulations. They also provide codes of practice and guidelines for implementation. The FAO and the CAC, in particular, have developed sets of guidance documents that are very helpful, and should be used in addition to this toolkit to provide further guidance and insights. When helping countries with the development of food safety regulations, it is thus essential that the staff of the Investment Climate Department of the World Bank Group pays attention to practices through which regulations are implemented and enforced (in particular inspections, testing, etc.) and support adjustment of practices in line with international organizations’ recommendations. Additional details on these institutions’ activities are provided under section “Coordination”.

Inside the World Bank Group, much of the work related to strengthening and developing food safety systems has generally been (and still is) done by the World Bank’s agricultural or health teams (Sustainable Development Network), while other departments (for example, Financial and Private Sector Development) may also be involved from a regulatory and quality infrastructure perspective. Projects sometimes focus on specific sectors (for example, animal production), or can aim at the whole food safety system (for example, with a view to achieving access to international markets, EU accession or pre-accession). In most cases, these are not only advisory projects, but mainly investment projects (for example, in laboratory networks, and other infrastructure), supported by advisory activities. In many instances, these projects can be usefully complemented

Risk-based food inspection manual is at: http://www.fao.org/docrep/010/a1391e/a1391e00.htm
Codex guide on import/export inspection/verification at: http://www.fao.org/docrep/010/a1391e/a1391e00.htm

2 Countries, which seek admission to or association with the EU, or a Free Trade Agreement with it, need to follow (or get as close as possible to, if only free-trade is sought, and not membership or quasi-membership) the EU official guidelines on Food Safety controls, which are contained in EC Regulation 882/2004, available at: http://ec.europa.eu/food/food/controls/index_en.htm (along with relevant guidance documents etc.).
by interventions by the Investment Climate Department of the World Bank Group, but it is essential to first map correctly what is being planned or implemented by the different departments of the World Bank, as these investment projects usually have a longer life-cycle, and a complex governance structure, meaning they are very difficult to change or steer in another direction. Depending on the area of the world, regional institutions and bilateral or other multilateral donors also play a key role. In particular, the EU has been supporting approximation of food safety regulations and regulatory systems in countries that try and deepen their commercial ties to the EU (in particular in Eastern Europe and the former Soviet Union). Countries that seek accession to the EU have to entirely adopt the EU approach to food safety regulation and regulatory enforcement. The U.S. Agency for International Development (USAID) is also frequently active in this sphere, similarly with an important trade aspect to its work (WTO accession context). Those donors often support projects that are larger than those implemented by IFC or Investment Climate Department of the World Bank Group, and can include significant components of investment in equipment and infrastructure needed to establish an effective food safety system. Like World Bank investment projects, they tend to have longer life-cycles and to be difficult to amend. Therefore, it is very important for staff of IFC and Investment Climate Department of the World Bank Group to be fully aware of existing or planned projects by bilateral or multilateral donors, even if they have not been fully subjected to such criticism inside the EU and should not necessarily all be adopted without consideration. Excessive burden can also arise because these norms are being imposed without the necessary transition times and flexibility in implementation and enforcement. One example is the case of mandating a HACCP-based approach, which is discussed in more detail in Module 7.

Of all these institutions and actors, outside of the FAO and WHO, the EU is probably the most influential in the food safety sphere, for two reasons:

- The size of the EU makes it the main actor in international food trade, and thus a key target market for existing exporters of agricultural and food products, and for businesses trying to start such exports (“would-be exporters”).
- As a multinational grouping, the EU has had to devote considerable attention and efforts to developing a regulatory regime for food products that ensures a high level of safety and consumer confidence, allows flexibility, and facilitates international trade. These characteristics make it in some ways the “reference” example for many countries trying to reform their own system.

Although there are an important number of actors that have prior presence in food safety regulation, there is an important role for the Investment Climate teams of the World Bank Group to play in countries of intervention. Indeed, Investment Climate projects of the World Bank Group have a certain number of specific strengths that are unique and constitute a major complement and addition to the other donors’ and institutions’ programs.

The following subsections discuss the specific “space” of the Investment Climate Department of the World Bank Group in the food safety regulation sphere.

Focus on private sector development and growth

Rather than a more “technical” food safety focus (as in WHO and FAO work), or an international trade angle (for the EU or USAID), the primary goal of the Investment Climate Department of the World Bank Group is private sector development, and this is the perspective from which they design and implement food safety regulations projects.

Advice and recommendations coming from projects with a strict “food safety” focus tend to not fully look at the cost/benefit aspect of changes, and to promote adoption of rules, regulations, and methods that are either excessively burdensome for local businesses, or not necessary to food safety improvements, or unrealistic given the country’s development level (or any combination thereof). Similarly, trade-focused projects can recommend wholesale adoption of regulations conforming to those in use in larger trade groupings (for example, the EU), without consideration of whether they are fully appropriate for the country, or what their cost may be for the local private sector.

There are indeed several ways in which what some hold as “gold standard” of food safety regulations may end up being more like “gold plating” (that is, excessive regulation that “looks good” but does not provide real benefits commensurate to its costs).

Mandating standards that are highly burdensome (in administrative terms) and costly to comply with or to implement for businesses, without commensurate expected benefits is a major form of such “gold plating.” These standards can be excessively burdensome because they are taken directly from countries that are members of the Organisation for Economic Co-operation and Development (OECD) or the EU, without consideration that they have not been fully subjected to such scrutiny in those countries. For example (many food safety rules from the 2004 EU “Hygiene Package” are not exempt of such criticism inside the EU and should not necessarily all be adopted without consideration. Excessive burden can also arise because these norms are being imposed without the necessary transition times and flexibility in implementation and enforcement. One example is the case of mandating a HACCP-based approach, which is discussed in more detail in Module 7.

Given that Investment Climate Department of the World Bank Group usually intervenes in countries where regulatory inspections and enforcement tend to be highly rigid and “punishment oriented,” lack of appropriate guidance for businesses and flexibility in understanding the new requirements is to be expected. Often, this fails to be taken into account by projects with a narrower food safety or trade focus.

Imposing requirements that are not adapted to a country’s stage of development is also a frequent, and major, problem. This means foreseeing a system that is simply not realistic in terms of compliance, and where most actors will fail to comply (with enforcement being either absent, or becoming a source of corruption, as non-compliance is near universal).

This can happen in several ways, for example, by ignoring the extent to which a country relies on informal channels and assuming that imposing new regulations and requirements will change things. In many countries, meat and dairy products come mostly from informal channels. Even if the long-term aim is to change this situation and get most meat to go through formal channels, designing appropriate regulations requires taking the starting context into account and adopting a phased-in, gradual approach, to make sure that new regulations do not just become a source of rent-seeking for inspectors. Another related issue can be trying to impose recent reforms from developed countries before essential prerequisites are in place (for example, mandating HACCP, which only became mandatory in the EU in 2006 before requiring Good Hygiene Practices). Doing this can distract the food business operators and regulators from focusing on putting the basis in place. They are instead pushed to focus on process-management approaches that, though good in theory, can only work once the fundamental elements are in place (which itself can take quite a few years).

Against this background, the Investment Climate Department of the World Bank Group can bring a different perspective to the reform process, one that takes into account:

- economic impact (on growth, employment, incomes, poverty);
- feasibility (in terms of reaching broad compliance with regulations); and
- risks (of disregard for the new regulations, corruption).

See Annex 1 for more details on the EU “Hygiene Package”.

Annexes 1: Justification and Scope of World Bank Group Involvement

11
Flexibility to use a variety of approaches, rather than “one size fits all”

This may be one of the most crucial advantages and specificities of interventions by the Investment Climate Department of the World Bank Group in comparison with EU-funded projects. Projects supported by the EU have an inherent goal to reach more approximation between local legislation and regulatory practices and the EU. The Investment Climate Department of the World Bank Group can adapt its messages and recommendations to local country-specific conditions, without necessarily promoting a single model. Such flexibility means that recommendations can be tailored to the development level and capacity (in the public and private sector) of the country; to the trade potential of its different agri-business sectors (depending which countries are the real targets for their exports, different regulatory models may be more or less appropriate); and to regional integration issues. While the EU approach may remain a “reference point” and a very good model in many ways, it is not the only possible one. The ability to pick and choose makes sense for the country of intervention, and what does not, is an important strength of the Investment Climate Department of the World Bank Group.

‘On the ground’ presence and ‘hands on’ advice

The Investment Climate Department of the World Bank Group has a variety of intervention models in different countries, regions, and situations. In a number of cases, their projects are based on having a team of specialists permanently in country, with a mix of profiles and expertise. Compared to typical EU funded projects, the Investment Climate Department of the World Bank Group employs a stronger share of local specialists, which gives them a better ability to understand the specifics of each country, and to convey their messages to decision makers. The fact that the core team is composed of employees of the Investment Climate Department of the World Bank Group also gives them greater legitimacy and access when delivering recommendations to client governments. All this can give, in specific situations, a better ability to achieve deep policy changes compared to other project delivery models.

Complementarities with other work of the Investment Climate Department of the World Bank Group and the Sustainable Business Advisory Business Line

Specific Investment Climate work on food safety regulations usually builds on, or is accompanied with, other activities on the Investment Climate Department of the World Bank Group and on the Sustainable Business Advisory (SBA) sides.

SBA work focuses on developing capacity and uptake in the private sector to implement best practice, internationally recognized approaches to food safety in processing operations. Sectors of intervention are selected based on country priorities and potential, and specific businesses are chosen based on their capacity and readiness to invest significant resources in this work. Other activities, depending on countries and contexts, may include public outreach to build understanding of food safety issues, and support to policy changes.

IC interventions in areas such as business licensing and inspections (combined under Business Regulation) may prepare the ground for similar work specifically in relation to food safety and agribusiness. Alternatively, a broad intervention aimed at improving licensing or inspections of private businesses in general (regardless of sector/type) may be complemented by deeper, more focused, sector-specific work on food-safety-related regulations, licenses, and inspections.

As a result, IC interventions focused on food safety can generally:

- build on broader IC work that to a large extent prepares the ground for more specific reforms; and
- get better “buy in” and support from the business community, thanks to SBA interventions.

These are crucial advantages when it comes to promoting such complex and politically difficult reforms. This being said, it is important to be nonetheless cautious about potential pitfalls.

On the Investment Climate side, a food safety intervention should not limit itself to being an extension of licensing or inspections work. There may be many other areas that need to be tackled (actual regulations and standards, certification and standardization procedures, and the work may need to go significantly deeper (requiring specific expertise).

Relative to the SBA side, the priorities should be complementary but not necessarily always identical. For example, while SBA projects are mostly promoting adoption and implementation of HACCP practices (along with other major standards, such as those promoted by the GFSI) by target businesses, the Investment Climate food safety work should only view HACCP as one of the many tools available. Similarly, clients of the SBA food safety work can be important sources of information on current practices and potential changes, and should be among the stakeholders that are consulted and involved in the reform process. But they should not have a larger say than other business groups.

These different specificities constitute a set of specific strengths for food safety work of the Investment Climate Department of the World Bank Group. They may not be all applicable in each and every country, and their importance will vary, but they build up the case for involvement by the Investment Climate Department of the World Bank Group in this space. At the same time, it is a key priority to ensure that intervention by the Investment Climate department of the World Bank Group intervention is not seen as an intrusion or a disruption. It is also essential to make sure recommendations are technically sound and aligned with good international practices, but also take into consideration specifics of each country.
When to intervene and with which objectives

The key preconditions are demand from the client government or the private sector and additionality — that is, that the intervention would genuinely fill a gap, and not just come on top of existing or planned interventions by development partners for whom food safety is closer to their core mandate.

In terms of relevance, the essential parameters to consider are the need for food safety regulations reform from the perspective of economic development and business growth, and strategic fit with priorities defined by the International Finance Corporation and the World Bank Group for the country, region, and sector.

Preconditions – Demand

It is impossible for a project in this area to succeed or even be justified if there is a lack of clear and solid demand. But, as often with business regulation reforms, the question can be: from whom? Indeed, demand can (and should) come from the government, but also from businesses. Very often, it can happen that businesses (or at least some sections of the business population) have a much stronger perception of the burden created by existing regulations (which can be a primary cause for reforms) and of the limitations to their export potential. Inside the government, views can differ strongly, depending on which ministry or structure is being considered. Ministries in charge of economy, business development, and trade, are often far more likely to be aware of problems with existing regulations, and supportive of changes, than the ministries and agencies that administer the regulatory system (for example, agriculture, health, standards).

It is thus important to distinguish initial request for support from demand in the sense of real support for reform by key policymakers. This support can come from the private sector, and/or from various parts of the government, and can be addressed through various means — local Investment Climate teams of the World Bank Group, World Bank office, etc. “Demand” in this sense can be gradually developed through initial interactions with Investment Climate teams of the World Bank Group public or private discussions involving the private sector, foreign experts, or different ministries. It does not need to always mean that the regulatory agencies themselves are very supportive of reform because it may well happen that they have in some ways a “vested interest” in the current system (and anyway, institutional resistance to change is very widespread). It is crucial to have sufficient (and stable) support from key sections of political decision-making systems, depending on countries, constitutions, and political systems. This can mean the prime minister or president and/or their offices, key ministries, or key players in Parliament.

Preconditions – Additionality

Whether involvement by the Investment Climate Department of the World Bank Group in food safety reform will really bring “additionality” is relatively easy to define in theory, but may be harder in practice. Indeed, this is not only about whether other actors are present or not. There may be other interventions existing (or planned), but they may not be covering the whole field — or they may be missing some key issues, which are essential from the private sector perspective.

A less clear-cut situation may arise in cases where on paper existing interventions are supposed to be addressing the relevant issues, but in fact these interventions have an approach that disregards key private sector concerns, or harms the private sector (because it increases regulatory burden without consideration to cost/benefit issues, for instance). Or the existing interventions may be failing at achieving real changes, because of resistance by entrenched vested interests (a case that has frequently been observed).

In other words, additionality may be evidenced in different ways depending on the context:

• Food safety regulations are a critical issue for business growth in the country, and no project is currently addressing it — nor is one being planned or developed in the near future.
• Some projects exist, but cover only a fraction of the food safety reforms that are needed. They do not really tackle the most critical points for private sector and economic development.
• Existing projects are failing to reach results because they lack the type of “convincing power” or the stature for policy dialogue that the World Bank Group may have.
• Approaches taken for reform are overly one-sided (emphasizing regulation at any cost), and threaten to actually harm economic/business growth.

Relevance – Need

The need for food safety reform has to be defined, in the case of involvement of the Investment Climate Department of the World Bank Group, not from a strict human health perspective, but from the perspective of economic and business development. It may be that, in a given country, food safety is a very serious public health problem, but has no major impact on economic growth other than that working days and lives due to sickness will always have an effect on the economy. For instance, if in that country food safety regulations do not create any significant burden for business, or if there is no serious existing or potential export opportunities which could be harmed by poor food safety.

The need for food safety reform can be defined from at least two angles: burden and export potential. Depending on the country, both or only one of these might be present. Justification for intervention by the Investment Climate Department of the World Bank Group will only be present if at least one of these is significant.

Such regulations often pose a burden and barrier to innovation and growth. Existing regulations impose a major administrative cost to businesses (often without being really effective), be it in terms of licenses and permits, certificates, or inspections. They also make starting a new business, launching new food products, or using new technologies very difficult.

Justifications for intervention by the Investment Climate Department of the World Bank Group

Before the Investment Climate Department of the World Bank Group intervenes in a country’s food safety regulatory system, certain preconditions have to be met, and issues have to be relevant to its mandate and strategy. Any proposed intervention targeting the food safety regulatory system has to be justified in two ways: preconditions have to be met, and issues have to be directly relevant to their mandate and strategy for the country and region being considered.

Given the above, it is clear that the Investment Climate Department of the World Bank Group does not have a mandate to intervene in the food safety regulations sphere everywhere and always. Its mandate is not to improve food safety or human health as such, but to focus on economic development through strengthening of the private sector. This can, in some countries and contexts, mean addressing growth bottlenecks created by inadequate food safety regulation. It is essential, therefore, to define precisely which issues can justify intervention by the Investment Climate Department of the World Bank Group in this area, and which pre-conditions need to be met.

It is important to clearly define, before inception, what the intervention by the Investment Climate Department of the World Bank Group is expected to achieve, and what its scope will be. The food safety regulations field is very broad, and Investment Climate projects of the World Bank Group can only cover a limited portion of it. Because the exact breadth of issues to be addressed varies in each country, some guidelines are needed on what is possible, and how to determine the scope and limits of new projects.
Export of key products (from agricultural or animal origin) to essential markets is impossible, or very difficult. Alternatively, export is possible but only to low-margin markets, or of low-margin products (raw products, lowest grade). In other words, the full export potential cannot be realized because the highest-margin markets consider the food safety system of the country to be unsatisfactory.

Relevance – Strategic fit and complementarities of interventions

Overall, interventions by Investment Climate teams of the World Bank Group in the food safety regulations sphere fit with the their strategies that put a strong emphasis on developing the agricultural and agribusiness sectors, which present major opportunities for growth and job creation in many parts of the world, in particular among “frontier” countries and regions. This is the justification for food safety policy reform work to be an integral part of the “product offering” of the Investment Climate Department of the World Bank Group – but is not sufficient to form the basis for intervening in a particular country. The fit between the potential project and the country- and region-specific strategies first needs to be evidenced, as well as the complementarity (if any) with other World Bank Group interventions.

There are several strategic documents that should be reviewed to check the relevance of a proposed project: World Bank Group Country Strategy (usually Country Partnership Strategy, CPS – in some instances Country Assistance Strategy, CAS), International Finance Corporation Country Strategy, International Finance Corporation Advisory Services and Investment Regional Strategies – as well as strategic directions for the development of the Industry Specific Investment Climate product line.

The point is not to take a “tick box” approach but to really design projects that effectively support these strategies (which themselves are essentially aligned and present different levels of details and emphasis). Food safety policy reform, if it is relevant to the World Bank Group strategy in a country, can be either developed as a stand-alone project, or embedded in a broader intervention (Investment Climate Department of the World Bank Group or Sustainable Business Advisory at IFC experimented as a pilot component, pursued at the national or local level, or only in a given subsector. Decisions on how to precisely structure a project should be taken based on the strategic priorities (and of course the demand and starting situation – see above).

In conclusion, interventions by the Investment Climate Department of the World Bank Group in food safety policy have to be carefully considered and justified in terms of need, demand, additionality, and strategic fit. In many cases, it may be appropriate to start by a limited and narrowly focused pilot, and expand it if demand is confirmed and experience shows that success is possible.

Scope of activities of the Investment Climate Department of the World Bank Group

It is not sufficient, as already suggested above, to ascertain that an intervention by the Investment Climate Department of the World Bank Group is justified (from the perspective of need, demand, additionality, and strategic fit) – it is also necessary to determine the scope of this intervention.

Indeed, the food safety policy field is very broad, and the range of issues that can be addressed considerable. The degree to which specific points may be changed and reformed can also vary greatly. All these may also evolve over time, from a pilot phase, which, if successful, can lead to a broader, more ambitious program.

Objectives depend on the context: starting situation, potential in terms of growth and exports, other sources of assistance, government and private sector capacity etc. In particular, the reform work can focus on one sector (if demand, need, capacity and/or strategic fit are stronger in this sector), or on one segment of the regulatory “chain” (the most important, or the “low hanging fruit”).

Scope in relation to sectors and regulators

Projects can be designed to either:

- support reform covering the whole food safety sphere, including all food types and production/processing sectors, and all regulatory agencies (typically through framework legislation);
- focus on a specific food supply chain or sector (such as dairy) and target all regulatory steps and actors affecting it; or
- target only one regulatory process or regulatory agency, possibly combined with a focus on only one sector.

The decision on scope is likely to affect the choice on depth (see below), as limited resources will be available in any case, and will have to be spread thinner if the scope is wider. The main factors in this choice are, however, not primarily resources (these will come as a limiting factor, and a secondary decision factor, of course) but needs and strategic priorities.

If problems, such as regulatory burden or lack of access to foreign markets, cannot effectively be solved without reforming the overall legislative framework for food safety, and there is real demand and support for this, then the project will best be planned with a broad scope and the objective to change the general legislation.
On the other hand, if the potential for exports or the burden for growth primarily affects only one sector or supply chain, or this sector is a major strategic priority for the country and the World Bank Group, and meaningful reforms can be achieved without changing the overall framework, and with a narrower focus, then the project can pick this sector as a focus for activity. Similarly, if a single regulator is seen as a major bottleneck, it may make sense to focus on this agency.

These different approaches may be combined to different extents. For instance if legislation is seen as a major problem but there is little demand/support for broad reforms, then it may be appropriate to take a narrower focused or sectoral approach. It may be that initial success in a narrower scope project can build up support for broader action in the future. It is also possible that both components progress in parallel: broad reform limited to the top legislative level, and more specific work for example on implementing regulations or procedures) concentrated on a specific sector, supply-chain and/or agency.

Depth – from legislation to processes and institutional capacity

Reforming food safety issues can mean intervening on a variety of levels – from the framework legislation (be it one law on food safety or several laws or legislative acts) and reform of institutional structures (which agency or agencies are in charge of what) through regulatory procedures and processes (such as licenses, inspections, certificates) and safety requirements themselves (maximum residue levels, hygiene standards) to strengthening of regulators’ capacity (staff training etc.). Projects can work on one, some, or all these levels, depending on needs, demand, priorities and presence (or absence) of other development partners – and, of course, availability of resources.

The levels of intervention can once again be phased, starting with some targeted, lower level intervention and “escalating” if more support or resources are available and of course combined (interacting at different levels simultaneously). Agency-level interventions need not target all regulators involved in food safety, and can focus on the most important ones in terms of objectives of the Investment Climate Department of the World Bank Group, or on the most ready to reform.

Some of the activities that may be implemented at the different levels include supporting:

- revision of existing laws(s) or development of new laws(s) on food safety – in order to create foundations for a system in line with international practices, for example, through introduction or strengthening of FBO liability for safety, planning of controls based on risk, clarification of mandates of different regulators, and traceability;
- changes in institutional structures, such as consolidation of several agencies, clarification of respective roles of different regulators, establishment of a coordination and information sharing system between agencies, and consolidation of laboratories;
- reform of specific procedures or processes, such as simplification/abolition of licenses or permits that are not in line with international practices and create undue burden, development of risk-based frameworks for inspections planning, and checklists for inspections; and
- implementation of reform procedures, through development of revised internal processes, design of new information systems, training for staff, guidelines/ procedures for samples taking, and laboratory testing.

In most cases, the specific role of the Investment Climate Department of the World Bank Group may limit the depth of involvement at least on the fourth item. But the need to achieve real, concrete results that change the situation in practice for businesses means that if the client clearly cannot handle this without assistance, and no other is forthcoming apart from the Investment Climate Department of the World Bank Group, it may be appropriate to include such points in the project. This should be seen as a general “menu” where teams will take specific elements depending on objectives, initial conditions, needs and constraints that all have to be clearly identified and stated.

In practice, most projects will be a combination of some elements of the above, and not always easy to categorize fully in one or the other. This, however, gives an idea of the range of possible level of engagements and areas of focus.

In order to properly assess the situation in a particular country, a checklist is annexed to this toolkit to help define objectives and extent of actions needed. This will incorporate instruments already created by the FAO and OIE, as well as the Investment Climate Department of the World Bank Group experience.

The limitations of World Bank Group interventions

Just as important as defining when an intervention by the Investment Climate Department of the World Bank Group is legitimate and appropriate, and what it should consist of, is to know where it should stop – limits that should be foreseen from the start, so as not to create excessive expectations among clients, stakeholders, and development partners.

First, the sheer scope, variety, and complexity of elements of the food safety regulatory system essentially rule out any intervention or project being really able to address all issues.

Second, there are inherent limitations linked first to budget and human resources issues, and also to the core competence and mandate of the Investment Climate Department of the World Bank Group. While this has partly been described above (Sections 4 and 5), it is useful to specify these limitations a bit more precisely.

Resource limitations

Supporting the reform and improvement of the whole food safety regulations system would mean working with all relevant agencies at all levels, from the legislation down to the training of staff, and working throughout the country. However, project size, budget, and duration are always limited, and it is in practice impossible to have any project that would have such a comprehensive approach.

It is important to make a choice between the range of potential points of intervention, and identify, together with the clients and all stakeholders, the most critical, binding constraints that prevent the reform from moving forward, unduly burden business development, and prevent full integration in international trade. The project should be designed so that it effectively focuses on these issues, and can have real impact, even if not all elements of the broader food safety system get reformed at the same time or pace.

Teams should conduct careful project planning to estimate what financial and human resources will be needed for each component and activity, and ensure that they make realistic commitments. If resources are insufficient for a component, and neither the client nor other development partners can take it up, the team should consider whether the project objectives can still be achieved whether the reform will work without this component being completed, whether it makes more sense to drop the component entirely, or whether initiating work on it still makes sense because it can act to encourage further reforms.

Need for coordination

Resource limitations mean that it is crucial to understand which other donors may support components of the reform that the Investment Climate Department of the World Bank Group cannot take care of, or which donors may continue work initiated by the Investment Climate Department of the World Bank Group.

The first requirement is to understand each of the other development partners’ mandate and core competence, as well as potential resources. While the available budgets will of course be country specific, with some organizations having a stronger focus on some types of countries or regions (based on income level, political priorities, or geography), a quick typology is nonetheless possible:

World Bank – (investment operations – mostly Sustainable Development network but also Financial and Private Sector Development, both investment and advisory operations). The focus can be on different issues, such as laboratories, supply chain improvement, overall regulatory and quality infrastructure (technical and food safety regulations, standards) or building the capacity of the entire food safety control system. Breadth and depth differ. Common characteristics are...
potentially important funds available for equipment (laboratories, Information technologies), staff training and similar resource-intensive activities, long project preparation times (complex approval process), and delivery through Project Management Units embedded in the government structures. Amounts available for advisory and technical assistance vary significantly. Stand-alone advisory projects can exist if donor funding is available. The “anchor” (headquarter teams supporting operations throughout the world) has significant expertise on food safety regulatory systems.

Regional development banks (investment operations) – Depending on the region, the bank can be the Asian Development Bank, African Development Bank, or the Inter-American Development. Through investment operations, banks may be able to provide significant support to equipment upgrades (laboratories, information technology), and staff training.

European Commission (EC) – There are different instruments available depending on region and country. Budget support may be allocated for certain countries, in which case if the government puts food safety as a priority, and this is agreed with the EC delegation, important resources may be available for equipment, staff training and similar expenses. Technical assistance, if present, is usually conducted primarily through EU consultants, which deliver high-level advice (reports), or targeted recommendations (for example, on a specific legal document). Overall, the focus in technical assistance is on approximation of legislation and regulatory systems with those of the EU. Typical projects will focus not only on food safety but on approximation of trade-related laws and practices in general. Twinning projects are a specific resource, in which case one or several EU-member states’ institutions are “twinned” with a host country institution, such as a veterinary or standardization agency. In this case, mostly advice is provided (through resident experts, visits and study tours) but also some limited equipment. The advice is then targeted (and can be targeted specifically at food safety), and can cover legislation and regulations but mostly focuses on capacity building of the “twinned” institution. The limitation is that the project can then work nearly only with and through this institution.

USAID – The agency’s projects tend to be increasingly large and incorporate a variety of components. Food safety will rarely be addressed as a stand-alone project, but will be an element of trade facilitation or business development projects. As such, usually only a relatively narrow set of issues is addressed. Projects funds are usually allocated to a mix of technical advice and equipment purchases.

FAO – The agency is responsible for food and agriculture and jointly leading Codex Alimentarius with the WHO. Its expertise is in the area on food safety regulatory systems and control systems. Small team in headquarters specializing on these issues can be a source of expertise. But most operations are handled by regional offices. There may be small offices in country on a permanent basis. In some countries, FAO may implement rather significant projects focusing on food safety, mostly technical assistance (with possibly very limited equipment), with different sources of ad hoc funding. It can be a very important complement to the work of the Investment Climate Department of the World Bank Group, or a basis on which to build further work as the FAO mostly deals with the setting up of the right framework, such as country food safety strategy and general legislation.

WHO – The agency is responsible for human health issues and jointly leading Codex Alimentarius work with the FAO. It has considerable expertise in setting up effective food safety systems, often supporting the development of country or regional strategies to this effect, which can form a very useful basis for further work. It often has a representative office in country, which can provide specific input, and participate in high-level discussions. It sometimes may implement larger projects based on ad hoc donor funding. Operations are essentially managed at regional level.

OIE – Its focus is on veterinary issues, such as animal health at the breeding stage (epizootic control, etc), up to slaughter level. It mostly implements diagnostic projects with high-level recommendations. It provides authoritative advice on animal health issues, but has limited resources for projects.

IPPC – This is a reference organization on plant protection. It does not normally implement projects, but issues guidelines. Annual Commission on Phytosanitary Measures (CPM) issues recommendations and guidelines.

Focusing on core mandate and competences of the Investment Climate Department of the World Bank Group

As clearly shown, the Investment Climate Department of the World Bank Group cannot cover every aspect of food safety policy reforms, nor should they try to. In addition to selecting priorities based on the needs and potential in the country, and thus designing the project so as to address successfully the most critical problems for the private sector, it is important to understand what the Investment Climate Department of the World Bank Group is most competent in, and what its key strengths are in terms of experience and technical expertise.

Building on the track record over several years and various projects, and on the inherent strengths of the World Bank Group, these areas of specialization can be summarized as follows:

- Development or revision of framework legislation on food safety
- Introduction of risk-based planning of inspections
- Improvements of inspection methods
- Review and reform of licensing and permitting requirements
- Review of spheres of competence of different institutions (institutional reform)
- Development of strategic documents and action programs

To a lesser extent, the Investment Climate Department of the World Bank Group can also be working on:

- transformation of internal processes and organization of agencies in charge of food safety regulation;
- introduction of information systems for food safety regulation;
- training and capacity building of regulators’ staff.

In all areas, the specific Investment Climate Department of the World Bank Group value added should be to bring the private sector perspective (or rather perspectives, as different types of businesses have different interests and concerns in such a reform) to the discussion and actions.

In conclusion, there are limits inherent in what the Investment Climate Department of the World Bank Group can focus on. Supporting the drafting of all substantive food safety requirements is more appropriate for organizations with far more of a technical focus on food safety like the FAO or WHO. The Investment Climate Department of the World Bank Group can however, and should, point to general directions of how these requirements can be developed or changed (including, as suggested, translating the Codex Alimentarius) and link clients with other organizations, more suited to supporting this type of work. The Investment Climate Department of the World Bank Group can also support work at the “business end” of things, such as the development of checklists and guidelines for FBOs on how to comply with regulations.

It is also essential to understand that what the Investment Climate Department of the World Bank Group can do and support will in most cases not be enough on their own to achieve deep and lasting changes. It can help initiate such changes but, to ensure real impact for the private sector and sustainability of changes, it is needed to embed such actions in a broader context of government programs, private sector involvement, and assistance by other development partners.
Q1. Does proposed intervention fit World Bank Group Strategy for country and region?

Q2. Does evidence exist that needs demand for intervention exist?

Q2.1 Does evidence need to be obtained?

Q3. Is there a real ‘additionality’ for IFC / World Bank Group intervention?

Q4. Would IFC / World Bank need to collaborate with others?

Q5. Is there a high chance of failure?

Dairy sector example

Q1. Are we looking at the dairy sector as important and instrumental to supporting growth? If we have a strategy for the region, is dairy identified as part of it?

Q2. What is the economic data around the dairy sector from farm to fork? Is it primary production, that is, milk production as well as added value production such as milk, cheese, yoghurt, and other dairy derivative reliant products such as infant formula. Data should show annual outputs for the sector, national consumption requirements, and export potential. Is added value being lost to other countries, that is, is the milk produced being converted into other products in country or is this being done elsewhere? What other evidence do we need to justify intervention in the dairy sector? What are the comparable markets and how do they differ? What interventions in this sector have been successful? How much capacity is needed to meet a growth in demand?

Q3. What is World Bank Group bringing to the table in the dairy sector that others cannot? What expertise do we have in this sector and what other successes have we had in dairy added value products?

Q4. Who do we need to collaborate with? Should it be WHO, FAO, or central and local governments, academia, businesses, and consumers? Dairy trade associations or agriculture expertise? Food production and processing technologists – international associations such as IuFOS?

Q5. Dairy sector demand may be high both nationally and internationally, but how sustainable is supply and can it meet demand? Is reform across the entire dairy supply chain required, that is, primary production right through to added value? Could we focus on one aspect of the sector, such as milk production, and still achieve success or do we need to succeed across the entire dairy sector supply chain?
Q1. Is revision of legislative framework a critical precondition for further work?

Q2. Is there institutional overlap currently?

Q3. Is limited reform required?

Q4. Is process reform required?

Dairy sector example

Q1. Is there existing legislation that applies to this sector? Does it cover a farm-to-fork approach? How rigorously is it enforced and by whom? What are the correlations between national legislation and International legislation? Codex dairy standards need to be considered as well as anything governing animal health and animal feed. Added value products derived from dairy will also require appropriate legislation and enforcement, such as milk, cheese, yoghurt, ready-to-eat foods with dairy derivatives, and infant formula. If the regulatory framework is sound, the focus should be on a risk-based approach to dairy sector revisions. If the regulatory framework for this sector is weak or non existent, or does not cover the entire dairy food chain, then fundamental reform is required.

Q2. Which ministries have regulatory responsibility for dairy? Does it overlap with food and animal health? How is legislation implemented and monitored? Have there been any dairy related outbreaks?

Q3. If only limited reform is required, then problems need to be clarified in the context of the entire supply chain for dairy products to ensure cohesion and shared responsibility.

Q4. If process reform is required, then organizing and conducting regulatory delivery is key. Animal health inspection needs to be considered in the context of dairy products production and distribution. Production and processing hazards should be identified and risks should be managed. There is a dearth of internationally agreed standards on this that can be used as a basis to understand what needs to be done. Control measures for food safety hazards in dairy, such as pasteurisation, are well understood around the world.
Annex 2:

**EUROPEAN LEGISLATION ON FOOD SAFETY**

Food safety policy in the EU is defined as a key priority in the White Paper on Food Safety. The key elements of the EU food safety policy are:

- use a risk-based approach;
- use scientifically based international standards;
- cover all steps in the food chain;
- secure the same level of protection and control across the entire EU community;
- inform the public about risks and ways to prevent and combat them; and
- present requirements to trade partners outside the EU.

Regulation (EC) 178/2002 lays down these principles and outlines a model to be followed when developing a food safety law in the EU member states. Those principles are:

- high level of protection of human health, consumers’ interests and, where necessary, animal and plant health and the environment;
- implementation of international standards whenever they exist, and use of other standards only when no international standards exist and until they are developed;
- “Farm-to-fork” regulations and measures to cover all stages of food production, processing, transportation, retail, and catering;
- Risk analysis – a three-tier system to be introduced and implemented by official bodies in policymaking and enforcement;
- “Precautionary principle” when there is a risk of harmful effect on human health, animal, or plant health. Management of that risk can be performed by ad hoc measures only if scientifically based measures do not exist for that risk. Such measures should be replaced with scientifically based ones, as soon as they are developed, or remain in force if proved to be scientifically sound and effective;
- food and feed imported into the EU market from third countries shall have the equivalent food safety characteristics as food produced in EU member states. If there is a specific agreement between a third country and EU member state, than food must comply with provisions stated in that agreement;
- transparency is important when developing food laws and measures, and when estimating their impacts. Involvement of all stakeholders (authorities, private sector, associations of producers, scientific community, NGOs, chambers of commerce, international trading partners, trade organizations) is recommended;
- primary responsibility of food business operators for safety of food they place on the market;
- food business operators are responsible for fulfilling all regulatory requirements concerning food and feed;
- implementation of the preventive approach to control of hazards is at all levels of food and feed production, circulation and use;
- presentation of food and feed that does not mislead consumers; and
- Securing traceability along the food chain at least as "one step down-one step up."

In addition, a “hygiene package” group of regulations aiming to produce consistency in the food chain was developed, namely:

- General hygiene: Regulation (EC) 852/2004 on the hygiene of foodstuffs2 (including its updates and regulations that are developed later dealing with particular operations)3, which states that:
  - primary responsibility for food safety rests with the food business operator;
  - food safety should be ensured from primary production to end consumer;
  - cold chain must be respected and food kept at the temperature needed for that type of food;
  - GMP and GMP need to be implemented in order to reinforce food business operator’s responsibility and to create a solid basis for a functional food safety system;
  - food safety systems based on HACCP principles should be considered for export oriented companies and/or major food producers;
  - microbiological criteria and temperature requirements (for specific technological operations) must be based on up-to-date solid scientific grounds; and
  - imported food shall be of the same hygiene level or higher than that produced in the country of import.
- Food of animal origin: Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin,4 such as:
  - detailed requirements for qualifying FBOs in particular with respect to traceability and recall, and most significantly HACCP;
  - prerequisite requirement specifics;
  - requirements for inspectors enforcing the provisions to have specialist knowledge and training; and
  - list of product categories to which this regulation relates: minced meat, meat preparations, mechanically separated meat, meat products, live bivalve molluscs (shellfish), fishery products, dairy products, eggs (not primary production)/egg products, frogs’ legs/snails, rendered animal fats and greaves, treated stomachs, bladders and intestines, gelatine, collagen.

Regulation (EC) 852/2004 laying down specific rules for the organization of official controls on products of animal origin intended for human consumption, namely:

- specific requirements on approval of establishments from which food can be traded in the EU market;
- list of issues to be controlled within one establishment;
- how control of hazards should be performed with specific interest in the HACCP system in place;
- how verification of control is performed;
- risk-based control principles;
- specifics of control of: fresh meat, live bivalve molluscs, fishery products, raw milk and dairy products; and
- list of third countries and their establishments from which export to the EU is allowed.

Regulation (EC) 882/2004 on official controls performed to ensure verification of compliance with feed and food law. Animal health and animal welfare rules regulate:

- general obligations of control bodies;
- capacities to be in place in so called “competent authorities” (control bodies) and their operational criteria;
- delegation of specific tasks to different control bodies;
- requirements related to control body’s staff;
- principles of transparency and confidentiality;
- procedures needed for efficient control and verification;
- sampling and analysis in officially designated laboratories, reference laboratories;
- crisis management;
- principles of control of food and feed coming from countries third countries;
- principles upon which control plans should be made;
- how certificates on animal health should be issued; and
- reporting and financing.

The implementation of the “hygiene package” was supported then with:

- microbiological criteria for food stuffs: Regulation (EC) 2073/2005—a regulation laying down principles for representative sampling, types of microbes to look for as signs of safety of food, methods according to which microbes should be tested, places in the food chain to look for microbes according to type of products/technology used;
- implementing measures for certain products under Regulations (EC) 852, 853, 854, 882 and transitional measures until the “hygiene package” was not fully in force;
- legislation on animal welfare—setting the rules on keeping animals according to best practices; and
- National legislation of EU member states: It is important to emphasize that Regulation (EC) 852/2004 and Regulation (EC) 853/2004 grant exemptions to certain specified activities if they are regulated by national rules in such a way that they ensure the achievement of the objectives of the EU regulations (for example, Ireland: slaughtering outside licensed slaughterhouses, some activities in butcher shops; Bulgaria: small and medium sized milk producers; Germany: regulations on feed, regulations on meat and poultry).

There are also EU guidance notes on certain provisions in regulations belonging to the “hygiene package” and other pieces of regulation dealing with specific problems. A list of such regulations in food safety, veterinary, and phytosanitary areas is given below.


implementing acts:

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2 Consolidated version 2004R852 – EN — 20 04 2009 — 002.001 — 1
3 Example: although pasteurization of milk was regulated by the Regulation EC 852/2004, updated rules are given in the Regulation EC 605/2010
4 Consolidated version 2004R853 — EN — 11 03 2011 — 008.001 — 1

amended by:

implementing acts:


implementing acts:


16. 2009/821/EC: Commission Decision of September 28, 2009, drawing up a list of approved border inspection posts, laying down certain rules on the inspections carried out by Commission veterinary experts and laying down the veterinary units in TRACES.


36. Council Directive 2000/39/EC of May 8, 2000, on protective measures against the introduction into the community of organisms harmful to plants or plant products and against their spread within the community.


47. Council Regulation (Euratom) No 3954/87 of December 22, 1987, laying down maximum permitted levels of radioactive contamination of foodstuffs and of feeding stuffs following a nuclear accident or any other case of radiological emergency.
54. Commission Regulation (EU) No 206/2010 of March 12, 2010, laying down lists of third countries, territories or parts thereof authorised for the introduction into the EU of certain animals and fresh meat and the veterinary certification requirements.


105. Commission Regulation (EC) No 450/2009 of May 29, 2009, on active and intelligent materials and articles intended to come into contact with food.


108. Commission Regulation (EC) No 1895/2005 of November 18, 2005, on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.


111. Council Regulation (EC) No 2219/89 of July 18, 1989, on the special conditions for exporting foodstuffs and feedingstuffs following a nuclear accident or any other case of radiological emergency.


Annex 3:

GUIDANCE NOTES

III. Guidance notes on Regulation (EC) 852/2004:
   • Commission staff working document on the understanding of certain provisions on flexibility provided in the Hygiene package - Guidelines for the competent authorities
   • Commission staff working document on the understanding of certain provisions on flexibility provided in the Hygiene package (Frequently Asked Questions - Guidelines for food business operators)
   • Guidance document on the implementation of certain provisions of Regulation (EC) No 852/2004 on the hygiene of foodstuffs
   • Guidance document on the implementation of procedures based on the HACCP principles, and facilitation of the implementation of the HACCP principles in certain food businesses

IV. Guidance notes on certain provisions of Regulation (EC) No 853/2004 published by the European Commission:
   • Commission staff working document on the understanding of certain provisions on flexibility provided in the hygiene package - Guidelines for the competent authorities

V. Guidance document on the implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of food of animal origin

VI. Guidance document on the implementation of procedures based on the HACCP principles, and facilitation of the implementation of the HACCP principles in certain food businesses

Guidelines for the development of community guides to good practice for hygiene or for the application of the HACCP principles in accordance with Article 9 of Regulations (EC) No 852/2004 on the Hygiene of Foodstuffs and Article 22 of Regulation (EC) No 183/2005 laying down requirements for feed hygiene

Annex 4:

SUGGESTED LIST OF TOPICS TO BE COVERED BY TRAINING AND WORKSHOPS

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<td>Laboratories (official, private, from food producing facilities)</td>
<td>Modern microbiological methods, Regulation EC 2073/2005, quick methods for detection of pathogens and quick tests on hygiene</td>
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<td>Chemical residues in food of animal and plant origin</td>
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<td>Series of training on control and eradication of animal diseases (general and specific topics)</td>
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<tr>
<td>Regulators, inspectors, private sector, academia</td>
<td>Series of training on control and eradication of plant diseases and pests (general and specific topics)</td>
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<td>Animal welfare</td>
</tr>
<tr>
<td>Regulators, inspectors, practicing veterinarians</td>
<td>Animal identification and registration</td>
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<tr>
<td>Regulators, inspectors, practicing veterinarians</td>
<td>Veterinary medicinal products</td>
</tr>
<tr>
<td>Regulators, inspectors, plant protection extension service</td>
<td>Principles of application and control of pesticides and fertilizers</td>
</tr>
<tr>
<td>Laboratories, inspectors</td>
<td>National Residues Monitoring Program in animals, animal products and animal feed</td>
</tr>
<tr>
<td>Laboratories</td>
<td>Accreditation of methods, certification of laboratories according to ISO 17025</td>
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<tr>
<td>Regulators, inspectors, private sector</td>
<td>WTO requirements – SPS and TBT</td>
</tr>
<tr>
<td>Inspectors, private sector</td>
<td>Requirements for export of food – depending on the market</td>
</tr>
<tr>
<td>Private sectors, regulators, inspectors, retail sector</td>
<td>Traceability</td>
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</table>
Annex 5: Checklists

The aim of checklists is to access the most important aspects of prerequisite programs Good Hygiene Practices and Good Manufacturing Practices (GHP and GMP) in a structured way and to help identify potential places or operations where hazards for safety of food occur. Once hazards are identified, their control or eradication is enabled.

Checklists should be used by inspectors to ensure the objectivity of their work. Also, they should be used by food handlers to access the situation in their facility and to understand requirements set by inspectors.

Checklists should cover the following issues:

### GOOD HYGIENE PRACTICE AND GOOD MANUFACTURING PRACTICE

1. Establishment design and facilities
   - Description of the factory site (fenced, vast, and domestic animals)
   - Surrounding area (countryside: woodland, lake, river, agriculture), industrial area (such as chemical industry), city
   - Outside the factory building (for example, green areas)
   - Hygiene status of the access routes (sandy pathways, soft pathways, muddy)
   - Separation of the hygiene zones into hygienically clean and non-clean areas
   - Regulations governing flow of persons and materials
   - Design of the work areas (rooms, walls, ceilings, windows, doors, loading-bay doors)
   - Hygiene status of the plant, machines, apparatus, work surfaces
   - Pallets (for example, wood, plastic)
   - Hygiene in the non-production areas (receipt of goods area, stores)
   - Wood, glass, plastic and other materials in production areas
   - Machines (appropriateness for the type of work, material from which they are made, maintenance)

2. Control of operation
   - Protection of the raw materials, inputs, packaging (including process materials) from contamination and cross-contamination (keep closed, short standing times, rotation)
   - Adherence to the necessary temperatures and humidity (for example, cold chain)
   - Traceability of goods received and dispatched
   - Handling rework
   - Keeping surfaces that come into contact with the foods in hygienically flawless state (without residues)
   - Using interim storage areas
   - Separating clean and non-clean areas
   - Hygienic conditions for transport within the operation
   - Hygiene of rooms, protection of pests
   - Hygiene of equipment and tools
   - Separate tools for separate processes
   - Organizing modern processing methods
   - Light conditions, ventilation and the number of micro-organisms in the air (if needed)

### 3. Maintenance and sanitation

- Use of suitable and tested products that are approved for use in food areas
- Obtaining and labeling of equipment and objects for the different factory areas
- Planning and implementing maintenance of equipment
- Storage of cleaning and disinfection products separately from foods
- Labeling of containers with disinfectants as protection against mistakes
- Separation of waste and labeling of the containers
- Keep container closed, with lid
- Have waste containers that can be opened with the foot
- Store waste separately from hygienically clean work areas
- Disposal conditions – store until collected (frequency)

### 4. Personal hygiene

- Access regulations (for employees, visiting workmen, visitors)
- Work clothing (safety, trousers, head covering)
- Gloves, mouth protection, beard cover
- Prohibition of jewelry (for example, wristwatch, chain, earrings, bangles, visible piercing, rings) and mobile phones
- Designation of places for eating, drinking, smoking aside from production areas
- Avoidance of the spread of disease pathogens
- Prohibition of certain activities and tasks in cases of illness
- Hygienic treatment of infections on the hands
- Regulations for “acute sic” or “permanent sources” of disease pathogens
- Behavior in the event of illness
- Reporting obligation in the event of signs of illness
- Visitors reporting of illness, rules of conducts

### 5. Working with hazardous substances

- Training employees in handling hazardous substances
- Labeling containers, such as for cleaning products and disinfectants, dissolvent
- Observing the storage conditions
- Keeping separate storage areas
- Actions in case of emergencies

### 6. Packaging and labelling

- Appropriate packaging for the type of products
- Fulfillment of labeling requirements (identification of product)

### 7. Storage

- Hygiene, light, ventilation, protection of pests
- Ensuring the required temperatures for the storage of semi-finished and finished products
- Storing raw materials and finished goods separately
- Preventing direct contact with the floor and wall surface
- Labelling opened containers
- Keeping rooms closed
- Rotation of products (FIFO: first-in-first-out principle)
- Respecting shelf life of products
- Following traceability procedures – controlling and recording lots of final products in the storage and realized from the storage
- Recalled products visibly labeled and stored separately from products intended to the market

### 8. Transportation

- Fulfillment of special transport conditions
- Adherence to hygienic loading procedures
- Ensuring required transport temperatures
- Using means of transport that are suitable for foods
- Checking that vehicles are clean and vehicle surfaces have been cleaned
- Observation of hygienic behavior on the part of the driver
Food waste, inedible by-products and other waste:

- must be removed as soon as possible from areas in which foods are handled, so that accumulation of this waste is avoided, and
- must be stored in closable containers unless the company can prove to the relevant authority that other types of container or other disposal systems are appropriate. These containers must be appropriately constructed, kept in perfect condition, be easy to clean, and if necessary, easy to disinfect.

Persons who work in an area in which foods are handled must keep to a high standard of personal cleanliness. They must wear suitable and clean work clothing, and if necessary, protective clothing.

Persons with a disease that can be transmitted through foods, or carriers of such a disease, and persons with infected wounds, skin infections or lesions, or diarrhoea are generally forbidden to handle foods or enter areas in which foods are handled if there is the possibility of direct or indirect contamination. Such persons who work in a food company who may come into contact with foods must inform their employer without delay of illnesses and symptoms, and, if possible, their cause.

Annex 6:

LIST OF FOOD SAFETY WEBSITES

Alimentation, Environment, Travail (ANSES); French Agency for Food, Environment, and Occupational Health and Safety

Danish Ministry of Food, Agriculture and Fisheries

Finnish Food Safety Authority (EvIRA)

Food Safety Standards Australia New Zealand - Bi-national Government Agency

Austrian Federal Office of Food Safety

31. http://www.ble.de/EN/00_Home/homepage_node.html
German Federal Office for Agriculture and Food

Food and Agriculture Organisation

International Food Safety Authorities Partnership

Food Standards Australia New Zealand - Bi-national Government Agency

New Zealand Food Safety Authority

Russian Federal Ministry of Agriculture

New Zealand Ministry of Agriculture and Food

New Zealand Food Safety Authority

Food Safety Standards Australia New Zealand

European Commission website on Food Safety and Health

Bibliography – further reading

Justification and scope
1. United Nations

2. Food and Agriculture Organisation
http://www.fao.org/foodstandards/foodstandardscode.cfm

3. Global Food Safety Partnership

4. International Food Safety Authorities Partnership
http://www.foodstandards.govt.nz/foodstandards/foodstandardscode.cfm

5. OIE
http://www.oie.int/

6. IPPC
http://www.foodstandards.govt.nz/

Guiding Principles
7. Global Food Safety Resource

8. Barriers to HACCP Implementation
http://www.foodsafety.govt.nz/foodstandards/foodstandardscode.cfm

9. The relationship of food safety standards
http://www.foodstandards.govt.nz/foodstandards/foodstandardscode.cfm

Legislative Reform
1. EFTA
http://www.efta.int/

2. NAFTA
http://www.naftanow.org/

3. CEFTA
http://www.ceftatreadeportal.com/

4. EAC
http://www.eac.int/

5. Perspectives and guidelines on food legislation, with a new model food law
http://www.foodstandards.govt.nz/foodstandards/foodstandardscode.cfm

6. Codex Sampling Guidelines
www.codexalimentarius.org/index.html/.../standards/10141/CKG_050e.pdf

Institutional Structure
7. Joint FAO/WHO PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR NATIONAL FOOD CONTROL SYSTEMS,
Risk Assessment
1. WHO/FAO 2008; Risk characterization of Microbiological Hazards in Food, Microbiological Risk Assessment Series 17, WHO/FAO 2009
http://www.who.int/foodsafetypublications/microMRA17.pdf
2. WTO /SPS applicability
http://centers.law.nyu.edu/jeanmonnet/archive/papers/04/040201.pdf
3. Preparing for effective enforcement
delta?contentType=&itemId=/content/chapter/gov.glance-2011-52-en&containerItemId=/content/
serial/22214399&accessItemId=/content/book/gov.glance-2011-en&simpleType=text/html

Principles of Food Safety Management
1. HACCP
http://www.who.int/foodsafety/fs_management/haccp/en/
2. Introducing HACCP
http://www.who.int/foodsafety/fs_management/haccp_intro/en/
3. Guidance on HACCP implementation in small businesses
4. Codex HACCP
http://www.fao.org/docrep/W8088E/w8088e05.htm
5. Codex prerequisites
www.codesalimentarius.org/input/download/.../23/CXP_001e.pdf

ACRONYMS

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<th>Acronym</th>
<th>Description</th>
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<tr>
<td>APLAC</td>
<td>Asia Pacific Accreditation cooperation</td>
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<td>BAP</td>
<td>Best Aquaculture Practice</td>
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<td>BRC</td>
<td>British Retail Consortium</td>
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<tr>
<td>CAC</td>
<td>Codex Alimentarius Commission</td>
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<td>CAS</td>
<td>Country Assistance Strategy</td>
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<td>CFIA</td>
<td>Canadian Food Inspection Agency</td>
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<td>CPS</td>
<td>Country Partnership Strategy</td>
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<td>HACCP</td>
<td>Hazard Analysis Critical Control Point System</td>
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