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INVESTMENT CLIMATE



Food Safety Toolkit Case Studies: Armenia, Canada, Croatia, Lithuania, Moldova, Mongolia, Ukraine

Investment Climate | World Bank Group



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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 it 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 in fact be checked by the SFSS if it were to really be a “single food safety agency.”
- IT and planning. In order to really fulfil 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 some 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.¹ The GDP per capita in Canada 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.

GDP by sector: Agriculture: 2.2 percent, Industry: 26.3 percent, Services: 71.5 percent (2010 est.)²

A large proportion of Canada's pork, beef, and live animal exports are to the United States, which is Canada's largest export market for farm products. Most grain and oilseed exports, which are dominated by wheat and canola are sent to other markets. In recent years, Japan, EU, Mexico, and China have become major export markets for Canada.³

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 8.1⁶ Food Safety in Canada

ACHIEVING FOOD SAFETY

INDUSTRY

- Established and conduct food safety program in accordance with regulatory requirements and industry practices
- Verifies effectiveness of food safety systems and ensures safe production and distribution of food

CONSUMER

- Clean, Washes hands with soap
- Handles, prepares and cooks food safety
- Consumes foods with caution

LOCAL PUBLIC HEALTH / REGIONAL PUBLIC HEALTH AUTHORITIES

- Inspect food establishment
- Educate regarding food safety practices
- Report confirmed cases of foodborne illnesses to province/territory
- Investigate foodborne illness outbreaks; collect food samples; send samples to labs
- Conduct analyses of findings

PROVINCIAL / TERRITORIAL GOVERNMENTS

- Regulate food processing within their jurisdiction
- Implement food safety program
- Lead outbreak investigations within their jurisdiction
- Communicate food safety messages to public

FEDERAL GOVERNMENT

CANADIAN FOOD INSPECTION AGENCY (CFIA)

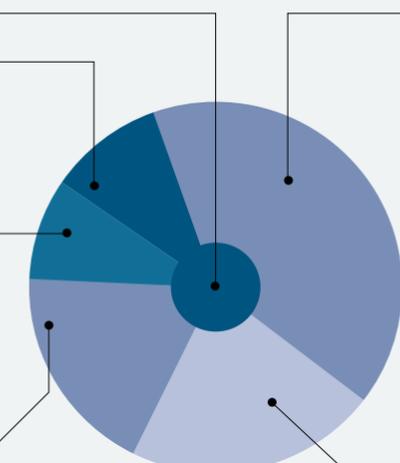
- Enforce all federal laws and regulations dealing with food
- Ensures industry compliance with food safety regulations through inspection/compliance verification of food producers
- Investigates food responsible for foodborne illness outbreaks with food safety partners
- Initiates food recalls (with industry)

HEALTH CANADA (HC)

- Sets food safety standard/policies
- Makes health risk assessment decisions re food on market
- Communicates to public on food safety issues

PUBLIC HEALTH AGENCY OF CANADA (PHAC)

- Acts as first point of contact for federal government for human health impact of foodborne outbreaks
- Conduct public health surveillance
- Lead epidemiological investigations when investigation is in more than one province





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.⁴ 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 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.⁶ There was a clear focus that both regulators and business should place safeguarding consumers at the center of their consciousness and collective actions.⁷

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.

⁴ Wetherill Report into the maple Leaf outbreak in 2008. The full report can be viewed at http://www.cpha.ca/uploads/history/achievements/09-lirs-rpt_e.pdf

⁵ CFIA, 2011
⁶ Weatherill, S. (2009) Recommendations to Strengthen the Food safety System’ P.15
⁷ Harrington, 2009
⁸ Weatherill, 2009





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.

GAP, GHP and GMP are mandatory, according to Reg EC 852/2004 and Reg EC 853/2004, which were transposed into national legislation. HACCP became mandatory in 2006. It was first introduced into export facilities, then in production of food of animal origin, and by 2015, there is a plan to have all facilities in line with HACCP requirements.

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.
- Fulfilment 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-





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 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.

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.

Moldova

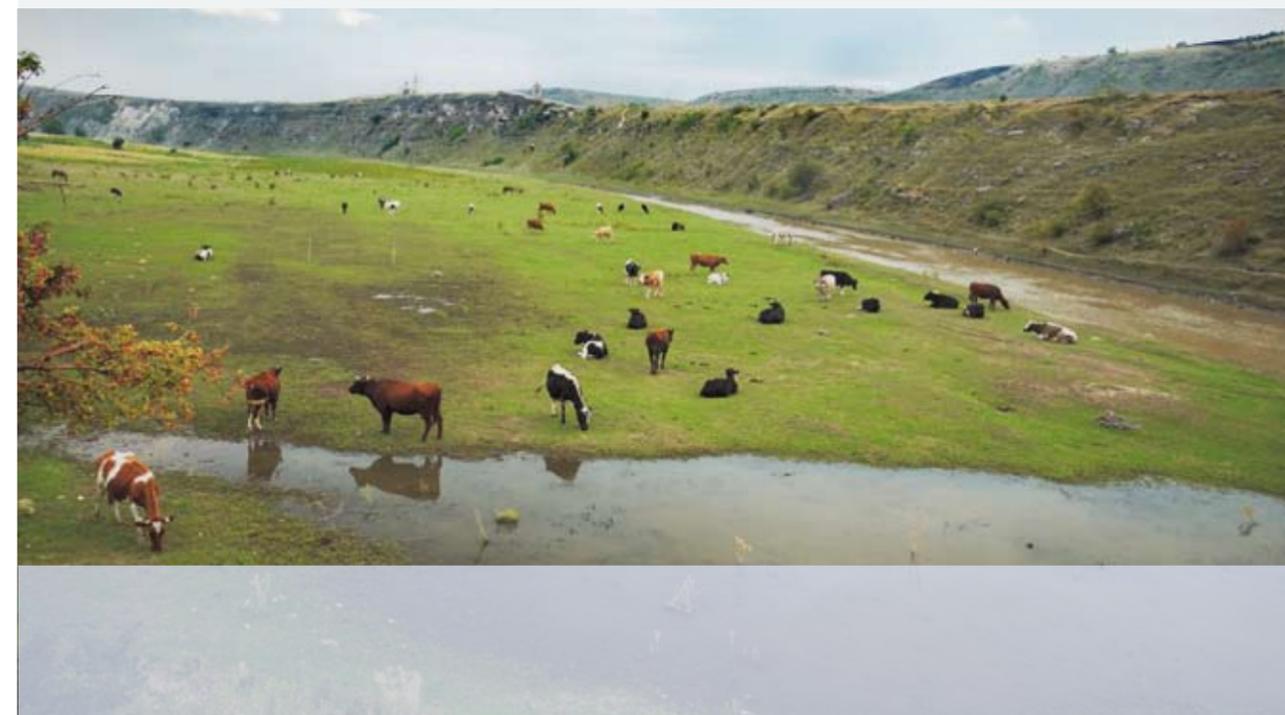
Leveraging competitive advantage through agribusiness related investment climate reforms

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 fulfil 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 severe 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 (knowing that most meat sold in Mongolia is slaughtered "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 time-frame 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.¹¹

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.

¹¹ See IFC Reforming Food Safety Regulation in Ukraine: Proposals for Policymakers - A Background Policy Paper, 2009 - http://www1.ifc.org/wps/wcm/connect/fc9b75804b5f7acd9ec6bf6eac26e1c2/Food_safety_report_ENG.pdf?MOD=AJPERES&CACHEID=fc9b75804b5f7acd9ec6bf6eac26e1c2



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.



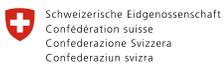
ACRONYMS

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

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