

# Food Safety Inspections: Lessons Learned From Other Countries



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December 2010

In partnership with



**IFC**

**International  
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## Foreword and Acknowledgements

The International Finance Corporation (IFC), with the support of the Austrian Ministry of Finance, presents this analytical report “Food Safety Inspections: Lessons Learned from Other Countries”. The report was prepared by IFC’s Ukraine Investment Climate and Food Safety Projects and includes findings of a study, undertaken by Prof. Gordana Ristic, Professor of Belgrade Institute of Hygiene, and directed by Florentin Blanc, an IFC state inspections reform expert, as part of the Business Entry and Operation project.

The objective of this study was to assess existing inspection systems in five most successful European countries and offer specific recommendations for inspections reform to government officials and policymakers in Ukraine.

The study is based on data collected from various sources, including country reports made by the FVO (the European Food and Veterinary Office), DG Sanco, FAO (the Food and Agriculture Organization of the United Nations), and WHO (World Health Organization); official data on food and laboratory inspections available on official web sites; and material and data provided directly by officials, consulting companies or consultants working in the field of food safety. In most cases we use data from 2007 since these were more widely available at the time of writing (2009). Where possible, data from 2008 are presented.

IFC sincerely thanks the experts that contributed generously to the preparation and review of this report, including, in IFC Advisory Services in Eastern Europe and Central Asia: Alberto Criscuolo, Kateryna Onul, Eugeniu Osmochescu, Sarah Ockman and Denis Torkhov. Lars Grava, World Bank Group Investment Climate Advisory Services, also provided valuable input.

Kyiv, December 2010

## List of Abbreviations

CIS	—	Commonwealth of Independent States
DG SANCO	—	Health and Consumer Protection Directorate General of the EU
EC	—	European Commission
EFSA	—	European Food Safety Authority
EU	—	European Union
FAO	—	Food and Agriculture Organization of the United Nations
FVO	—	Food and Veterinary Office
GAP	—	Good Agricultural Practices
GDP	—	Gross Domestic Product
GHP	—	Good Hygienic Practices
GMP	—	Good Manufacturing Practices
HACCP	—	Hazard Analysis and Critical Control Points, the internationally-recognized food safety management system
RASFF	—	Rapid Alert System for Food and Feed
WHO	—	World Health Organization
WTO	—	World Trade Organization

# Executive Summary

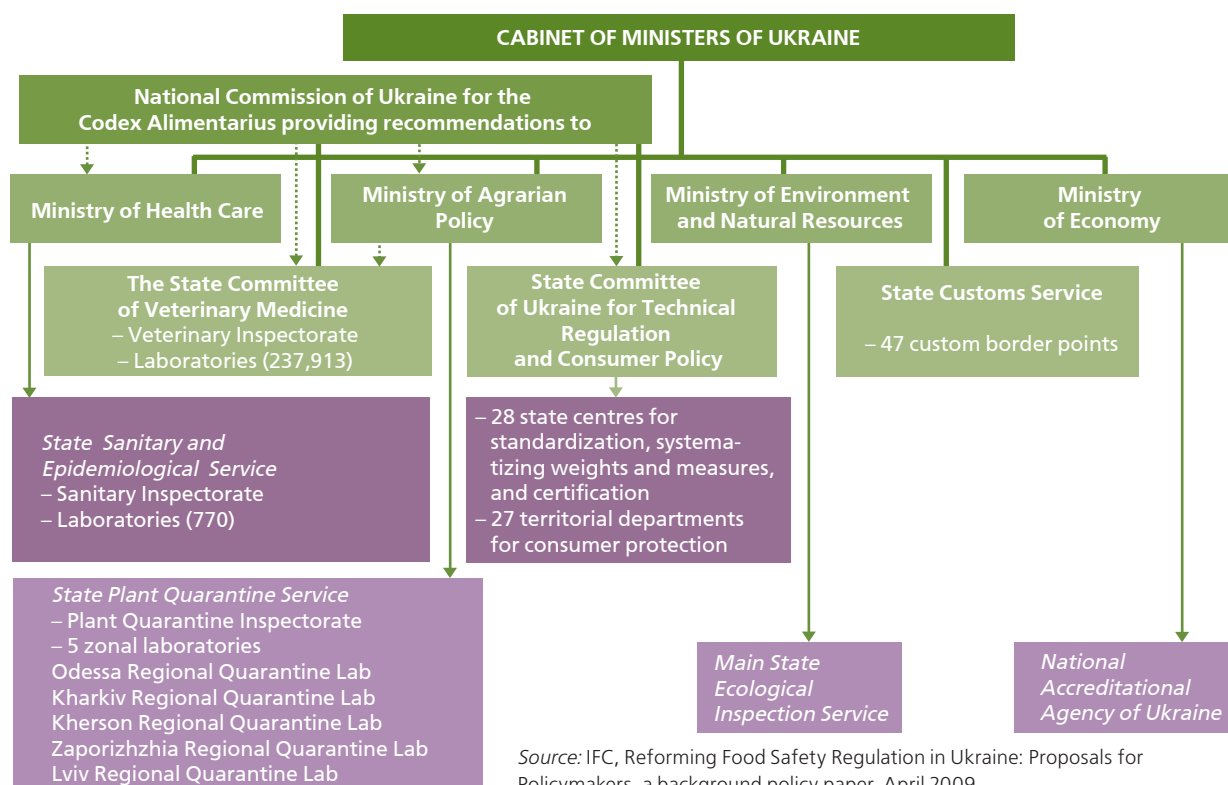
It is no secret that Ukraine has significant competitive advantages in agribusiness. Much has been said about Ukraine's unrealized potential in this sector over the years and many experts have highlighted challenges in infrastructure, access to finance, and inadequate legislation as barriers to growth in the sector. Many have also pointed to Ukraine's potential productivity increase as a way to help alleviate global food security issues. With adequate access to finance and infrastructure, Ukraine should in theory be a top exporting country in all agricultural sectors, not just in low-margin sectors like grains.

The potential also exists for Ukraine to be a top exporter of high-margin products like meat, dairy and fruit/vegetable processing. In order to realize this potential, however, stronger food safety control needs to be in place to export to markets like the EU.

By facilitating access to these markets, Ukrainian food companies could increase sales and profits, since these products enjoy higher margins than traditional Ukrainian export products like grain. Furthermore, some would argue that the neighboring EU market has reached its maximum yield for these high-margin products and will increasingly look to countries like Ukraine for processed milk, meat, fruits, and vegetables. With increased growth in the sector, more jobs will quickly follow and the Ukrainian economy will become more competitive.

In Ukraine, food safety inspection practices are still based on experiences from the late 1980s. Companies face constant pressure from the global crisis, market competition from importing companies, pricing pressure from retailers, and seemingly endless inspections from government bodies. In fact, there are three state agencies (State Sanitary Epidemiological Service, State Committee on Veterinary Medicine, State Committee on Technical Regulation and Consumer Policy) that regularly inspect food companies, often performing the same functions and loading these already cash-strapped enterprises with unneeded administrative burden.

## Structure of Government bodies, involved in food safety system of Ukraine (before the administrative reform 2010)



Furthermore, these inspections are not 100 percent risk-based and do not guarantee the safety of the food produced. Food safety legislation is weak in that the legislative framework is vague and imposes unneeded financial charges on businesses. Unfortunately, the legislation fails to guarantee the safety of food products for Ukrainian consumers and hinders companies from expanding their client base.

In this context, IFC endeavored to survey best practices from nine different countries throughout the globe in order to find experiences and lessons that could guide Ukrainian policymakers. IFC then put together nine case studies that differ in terms of the history of food safety systems, economic strength, cultural and political heritage and present state of participation in the global food trade. Each case study goes into great detail on the following criteria of host countries:

- Agency structure, and how this impacts the quality of food safety control in the selected country;
- Existence of a Register of food businesses, and whether this helps inspectors provide more effective service;
- Frequency of fees and inspections;
- Quality control of inspection performance;
- Sampling;
- Training; and
- Transparency.



Based on these findings of the nine surveyed countries, IFC highlighted five nations as having the lessons of most interest for Ukraine. These five cases in turn are split into two categories: as good examples of the single agency approach, Denmark and Sweden, and as examples of a coordinated system of several agencies, as in Poland, Croatia and Slovenia. Despite this paper's recommendation to follow the single agency approach, data from post-Soviet area countries might be interesting for Ukraine as they show peculiarities of food safety control systems in transition.

Indeed, some system elements, such as the frequency of fees and inspections in Poland, or the transparency of inspections in Croatia, might also be considered when developing a single agency approach. Inspections data from these countries could help reform a national food safety system as they show the allocation of state resources determined by the number of food business operators, state inspectors, duration of inspections, etc. These five case studies are included in this report.

Based on the findings from this research, IFC has summarized the best practices from these countries thus:

- 1. A single inspection agency is the most effective way to deliver transparent, consistent inspections based on food safety and consumer protection.** In countries with the most effective food safety control, roles and responsibilities are clear from the top to the bottom of the inspection agency and information is shared consistently throughout the agency. In the ideal scenario, roles and responsibilities for risk assessment, risk management and risk communication are separate and clearly defined. In a fully functioning agency, an adequate budget is allocated and inspectors are well paid.
- 2. Training of all inspectors is continuous and in accordance with clearly defined regulations to ensure risk-based inspections at all times.** Training is an essential tool for creating a "risk-based culture" in an agency. When appropriate, specific training should be tailored to the type of inspections performed; for example, inspectors at import border posts for high-risk commodities will have different requirements than sanitary doctors for routine visits in low-risk enterprises. In the most effective food safety agencies, these inspectors provide concrete advice to the food enterprises on ways to improve future audits and, therefore, the level of food safety at the enterprise. Inspectors are also trained on available tools, such as industry checklists, which are proven methods for enhancing objectivity.
- 3. A central register of food business operators promotes transparency.** A central register provides a repository for internationally recognized data. Inspection reports on specific companies are available to all appropriate inspectors to prevent duplication of effort and unnecessary burdens to food businesses. The registration also provides data that allows the agency to evaluate the quality and quantity of inspections per enterprise and on an aggregate level, allowing the agency to adjust the number of inspections based on risk assessment. Registration procedures should be mandatory, simple, and preferably online.

4. **Certificates issued by authorities are in accordance with WTO requirements and internationally accepted practices.** In these cases, well-performing companies with effective food safety management systems are hindered by trade quotas and export permit procedures. Inspections from one country are recognized by another' because there is an inherent trust in the country's system — both are based on the same internationally recognized principles.
5. **Sampling of imported and domestic goods is performed according to regulations with defined “triggers”.** Examples of triggers for sampling in the most effective agencies include: non-conformities observed in documentation; previous violations or concerns with the same importer/producer; or notification on food safety risks associated with a certain product placed through the international Rapid Alert System or some other regional system.

Based on these findings, it is clear that Ukraine must reform its food safety inspection system in order to protect its consumers, facilitate trade, and ensure growth in a strategic industry. There are many steps that can be made to improve the system, but IFC believes the following steps are of the utmost priority in order to secure the nation's public health and economic expansion:

1. **Reform the current system of state food safety control by creating a single agency, while streamlining laboratory services.**
2. **Harmonize national food safety legislation with EU standards and use the horizontal approach when adopting national legislation on food safety.**
3. **Develop a national program for training state food safety inspectors.**

# Introduction

The food processing industry in Ukraine is among the fastest growing sectors of the economy and has been highly resilient to the recent economic crisis. In the last decade the food processing industry represented 7-8 percent of value-added production and about 8 percent of exports. This sector also proved to be highly resilient to the output drop of 2009. The leading exporter is the sunflower oil sub-sector. The highest pace of output growth over the last years was experienced by sub-sectors such as preserved vegetables and canned fruits and beverages. Fruit juices alone represented roughly 50 percent of processed food exports in 2009.<sup>1</sup>

However, according to a World Bank study published in June 2008<sup>2</sup>, Ukrainian agriculture is operating significantly below capacity, producing only 22 percent of its total potential output. The industry has witnessed a significant decline in recent years, with total agricultural output in 2008 at only 72.3 percent of the levels recorded in 1990.<sup>3</sup>

Overall the agri-sector has demonstrated a solid potential for growth: despite the recent crisis, profitability in Ukrainian agri-sector in 2009 increased by 5.4 percent, with average growth of 120 percent year-on-year.

Exports of agricultural and food products in Ukraine represent the fourth largest sector (18 percent of total volume), \$4.25 billion in January-July 2010, with the following distribution:

- Non-animal products – 36.6 percent
- Oils and fats – 27.9 percent
- Processed food products – 26.6 percent
- Dairy – 7.3 percent
- Meat and fish products – 1.3 percent
- Other products — 0.3 percent.

Exports to the European Union and other advanced economies, however, accounted for only 11.6 percent of dairy exports in 2009.<sup>4</sup> Food products (including both unprocessed and processed goods) constituted only 23.9 percent of total exports in 2009, with high value-added products constituting only 5.3 percent of total export volumes<sup>5</sup>.

<sup>1</sup>Ukraine – Country Economic Memorandum for Ukraine: strategic choices to accelerate and sustain growth. World Bank, 2010.

<sup>2</sup>World Bank, Europe and Central Asia Region, Sustainable Development Unit, "Report. Agricultural Competitiveness. Ukraine. June 2008.

<sup>3</sup>The State Statistics Committee of Ukraine.

<sup>4</sup>International Finance Corporation (2009), "Reforming Food Safety Regulation in Ukraine: Proposals for Policymakers. A background policy paper." <http://www.ifc.org>.

<sup>5</sup>The State Statistics Committee of Ukraine. Data refers to the period of January– November, 2009.

Poland is comparable to Ukraine with its geographical and climate conditions, size of land, and population.

Agriculture alone (food processing excluded) contributes some four percent of GDP, while 17.4 percent of the total workforce is employed in agriculture.

Since 2003, Poland has been a net exporter of agri-food products, especially processed fruit and vegetables, meat, and dairy products.

In 2005, Poland's food and agricultural market was worth approximately \$40 billion, with 85 percent of goods being supplied by domestic producers, whereas in 2005 Ukraine became a net importer of food products: the country showed a trade deficit of agricultural products with the EU equal to \$86.5 million in 2005, while rebounding to a \$59.4-million trade surplus in 2006 and a \$231.8-million surplus in 2007.

The main market for Polish food and agricultural products is the EU (80 percent of exports). This contrasts with Ukraine, which ships most of its agricultural and food exports to CIS countries<sup>6</sup>.

The agribusiness sector officially employs over 4.2 million people, or close to 20 percent of the workforce. To fully realize the growth potential and create more jobs, the level of Ukrainian food safety and official control system should be improved; without reform, a lack of food safety will remain one of the main barriers to high-margin exports to the EU and other developed markets.

The current regulatory framework deters entry, increases operational costs, limits competition, and harms export diversification and growth, which is particularly true for the agri-sector at large and the food processing industry specifically<sup>7</sup>. State policy and regulation in the agro-food sector is outdated, fragmented, complex, burdensome, and plagued by governance shortcomings. Over the years, the government developed specific regulations for sugar, baked goods, oilseeds, alcoholic beverages, dairy products, and baby food, among others. Different sets of rules often exist for different subsectors.

In some cases, a single factory produces foods in several subsectors and must meet a plethora of complex and sometimes contradictory regulatory requirements. The legislation and regulation of product standards, including sanitary and phyto-sanitary (SPS) measures, are outdated and do not correspond to standards in the European Union and other high-end markets. Most state laboratories lack modern equipment and fail to satisfy international standards, thus making safety certificates expensive or impossible to obtain domestically. As a result, the majority of enterprises in the food sector export predominately to former CIS countries.

<sup>6</sup>Agriculture and Food Economy in Poland. Ministry of Agriculture and Rural Development. Warsaw, 2009.

<sup>7</sup>More on that can be found in Investment Climate in Ukraine as Seen by Private Businesses. IFC, 2009. Chapter 4: Food Safety Regulations.

Improvement of the national food safety system requires not only structural changes, but also serious work on national food safety legislation to bring it in line with WTO requirements and international standards. For example, mandatory certification of food products has long posed a barrier to national food producers' ability to provide the necessary level of safety for certified food products. Ukrainian legislation violated WTO accession commitments, but national authorities defended the obsolete norms, despite the outdated regulations impeding the competitiveness of local producers and discouraging innovation.

Finally, in October 2010, mandatory certification of food products was cancelled. It is expected that cancellation of this inefficient mechanism will free food production companies of the costs incurred complying with mandatory certification, and will allow new products to be introduced to the market more easily and at lower cost. As an indication, the Ukrainian Scientific-Research and Training Center for Certification, Standardization and Quality Problems (just one of the number of certification bodies) estimates the annual income from such certification services at approximately 40 million Ukrainian hryvnias (approximately \$5 million).<sup>8</sup> This is only one example of how an old legal norm hindered improvement of the food industry. Revisions are also required to a number of other obligatory permitting documents, inspection methods and other practices that impede the country's access to EU and other developed markets.

The lack of relevant statistics is another problem that inhibits state officials from beginning full-scale food safety reform in Ukraine. Unfortunately, the indicators that the Ministry of Health uses for food safety in Ukraine do not show the full picture. For example, there is no information on the number of food-borne diseases; instead one can find data on the number of food poisoning cases and acute intestinal infections, or the number of mushroom poisoning cases. However, the data do not portray the whole spectrum of human health issues related to food safety.

EU countries in 2007 established a special task force to provide the general public with statistically reliable data on the health status of the EU population in relation to food safety. The task force developed nine criteria in order to identify the «Top-20» food safety related diseases. Today each EU country provides data on each disease from the list, with required details. This example might be of interest to Ukraine.

<sup>8</sup>Information on this organization is available at: [http:// www.ukrndnc.org.ua/eng/](http://www.ukrndnc.org.ua/eng/). A (Russian-language) analysis of the costs of compliance may be found at <http://delo.ua>. Delo magazine (2010), "«Золотой» сертификат, или Как бизнес победил Госпотреб-стандарт," June 8.

Statistical problems concern not only health issues related to food safety, but also require new approaches to registering food business operators. Ukraine today has a unified state register of all enterprises and organizations, with limited public access. However, there is no unified register of food business operators. On the website of the State Committee of Veterinary medicine one can also find a list of enterprises under state veterinary control. However, this list is far from exhaustive. Specifically, it overlooks food business operators that do not work with foods of animal origin, restaurants, catering companies, grocery stores, etc.

Therefore, the system could be improved by taking into account the best practices in Europe. The Danish example is informative, as the Danish approach to registering food business operators gives relevant authorities details on facilities producing food of animal origin for export and local consumption, the total number of all such premises, the total number of food and feed-producing establishments, and the number of registered shops and restaurants. Such detailed information enables state authorities to plan inspections and organize control of food business operators in an effective and efficient way.

**Table 1. Comparison of number of inspectors and average number of inspection visits in five countries**

Country	No of food business operators per full time employed veterinary inspector	No of food business operators per full time Ministry of Health inspector	No of food business operators per full time phytosanitary inspector	Annual No of inspection visits per premise
<b>Denmark</b>	37	1:117.5	0.35 – 0.5	
<b>Sweden</b>		2,75 <sup>9</sup> 73,4 <sup>10</sup> – 163 <sup>11</sup>		0.65
<b>Poland</b>	5	46.6	66	1.9
<b>Croatia</b>	12.7	205		1 – 1.2
<b>Slovenia</b>	1.6	236	33	0,35 – 1.6

<sup>9</sup>In counties number of veterinarians who also perform inspection varies from 0.5 to 4 per country, National Food Administration (NFA) of Sweden.

<sup>10</sup>Without primary producers.

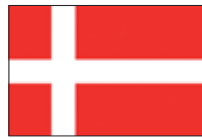
<sup>11</sup>With primary producers.

Data on the number of food business operators per inspector show that veterinary inspection in these five countries benefits from an adequate number of state inspectors or a combination of private and state inspection services. Inspections within ministries of health in all countries, except Denmark, suffer from a lack of trained inspectors and a high number of food business operators per inspector. This situation is due to ministries of health mostly being responsible for small and medium-sized producers and the retail and catering sector, thus the high number of such food business operators in the selected countries.

On the other hand, veterinary inspection deals with a lower number of enterprises and therefore inspectors handle a smaller list of facilities. Data from Denmark show a high number of facilities per inspector, but this is only relative to the shortage of inspectors, since producers perform self-inspection and inspectors mostly perform audits of the food safety system documentation, provide guidance in development of HACCP plans, and rarely have to visit plants.

In phytosanitary inspection, due to the high number of smaller producers, a single inspector has to take care of 33 (Slovenia), 66 (Poland) or even up to 117 (Denmark) producers. Note that in such lower risk areas it is manageable to organize the inspection with a smaller number of inspectors. In Denmark, where self-inspection is common, one inspector can be responsible for a large number of producers, while in countries where self-inspection is rare, the number of food business operators per inspector must be lower.

# Country Reports



Data from the report show that the most functional model is the Danish risk-based food safety system with the centralized inspection model.



The Swedish model reveals the particularities of decentralized systems, with good coverage at the central level and gaps at the local level. This country, on the other hand, has a very good food safety agency, which effectively gathers and implements development expertise. It is a good example of regional collaboration in matters of food safety.



Poland, Croatia and Slovenia emerged from the same model of the food safety system and transformed their systems according to the EU model. Croatia and Slovenia are good examples of transitional countries still remodeling inspection, even as Croatia is moving towards a single inspection agency. These three countries are good examples of food safety system reform in CIS countries, since their historical background is similar.



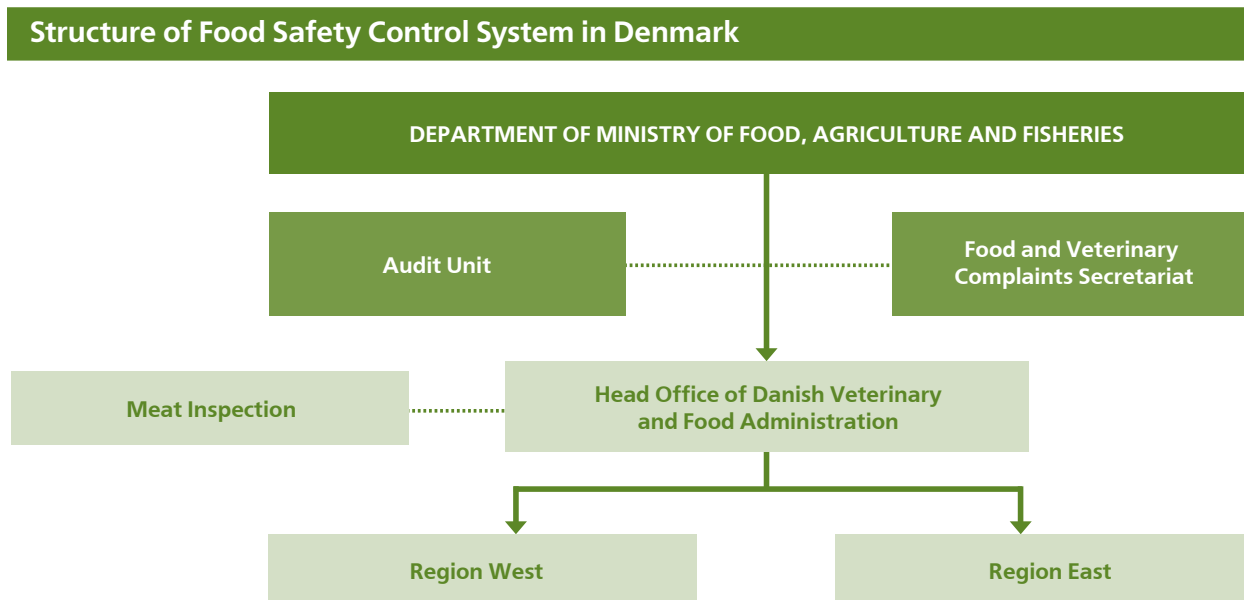
# A Single Control Agency System

## Denmark

### **Institutional structure**

The reform of Denmark's food safety system started in 1997 and resulted in centralization. A new agency – The Danish Veterinary and Food Administration (DVFA) – consolidated all food safety functions, including inspections in the control of food of animal origin. Previously, inspection functions were distributed among the Ministry of Health and the Ministry of Fisheries and Municipalities. The main purpose of the reform was to improve the system and make it less burdensome by reducing overlaps in responsibilities. Before the reform, municipal inspectors were part of a small system. Thus, to foster acceptance of the new approach and reinforce the new agency's mission, the Danish Veterinary and Food Administration moved employees to centralized locations and held monthly meetings on the new system.

The current Danish food system has the following structure:



Source: Ministry of Food Agriculture and Fisheries of Denmark, Danish Veterinary and Food Administration, <http://www.uk.foedevarestyrelsen.dk/Aboutus/Organization/forside.htm>

**I. The Ministry of Food, Agriculture and Fisheries** is the main body responsible for regulation and control of food safety. In Denmark the hierarchy in implementation of food regulations is conducted from the top to the local level. The Ministry itself and the permanent Secretary are responsible for determining policy in agriculture, fisheries and food production and developing the food safety policy. The so-called Department is divided into four separate bodies, or Directorates. They are: the Veterinary and Food Administration, the Plant Directorate, the Danish Food Industry Agency, and the Directorate for Fisheries. Within the Directorates there are laboratories and other entities responsible for a variety of research and analysis.

The Department's responsibility is to cover the whole food chain "from farm to table" and ensure implementation of the basic food law (Danish Food Act). It executes its authority through four agencies, all of which have both administrative and control functions:

*A. The Danish Veterinary and Food Administration* has a mission to promote safety, health and quality. It is responsible for: animal health, animal welfare, hooknoses protection, the safety of food of animal origin, promoting healthy eating habits among the population, food quality residue control, and organic food control. The Danish Veterinary and Food Administration is responsible for issuing regulations, food inspection, feed inspection, provision of information and advice in the primary and secondary production of food. The Danish Food Act establishes one national food and veterinary inspection authority. Within the 12 divisions of the head office, eight deal with food safety, animal health and welfare, and feed safety. The Administration's controlling activity is decentralized; it is performed through two regional centers and their 10 regional branches. The Regional Veterinary and Food Authorities are important for the organization of the national policy from top to bottom. The Regional Authorities are knowledge centers that provide information and guidance concerning legislation, practices and information through the veterinary and food area. They handle the inspection of food and veterinary matters from farm to table.

The Administration employs about 540 full-time employees, while the 10 Regional Authorities each employ an average of 1,370 full-time employees. Two specialist research institutions are also connected to the agency: the National Veterinary Laboratory and the National Institute for Virus Research. Their main role is veterinary emergency service. The National Veterinary Laboratory's mission is to prevent and combat both livestock disease and food-borne human diseases originating in primary livestock production (zoonoses). The National Institute for Virus Research prevents and combats viral infections in mammals, including (exotic) viral infections originating outside Denmark. These institutions serve both the government and the private sector. Each institution has a reference laboratory that instructs local private control laboratories in methods and problem-solving techniques. In collaboration with the accrediting authority, the The Danish Veterinary and Food Administration evaluates the quality of the control laboratory's work.

The Administration's "travel teams" cooperate with the inspection office, jointly checking accounts and other internal documents. Based in the eastern region, the "travel teams" operate throughout the nation.<sup>12</sup> The official control and inspection of food and animals in Denmark is based on the principle that companies and primary producers are responsible for ensuring that regulations are observed and followed. The companies and producers must have self-inspection programs with systematic action plans that ensure – at a minimum – that statutory requirements regarding the handling and treatment of foodstuffs are respected (general food safety requirements, food additives, packaging and labeling) and that the foodstuffs do not pose a risk to human health under normal use. The self-inspection program must be organized in accordance with the principles of the HACCP system. The self-inspection programs of individual companies must be approved and registered by the authorities. It is important to differentiate between government control and self-inspection programs<sup>13</sup>.

Food industry companies and companies handling non-food animal products are required to implement self-inspection programs in accordance with EU-legislation, national legislation, and possible legislation from third parties (other countries). Primary producers and companies that transport livestock must have a self-inspection program in place to ensure compliance with the regulations on animal welfare, animal care, and livestock health.

<sup>12</sup>For more details on the Danish Veterinary and Food Administration organizational structure please, visit website: <http://www.uk.foedevarestyrelsen.dk>.

<sup>13</sup>[http://www.uk.foedevarestyrelsen.dk/Inspection/Own\\_checks\\_in\\_food\\_establishments/forside.htm](http://www.uk.foedevarestyrelsen.dk/Inspection/Own_checks_in_food_establishments/forside.htm).

**Roles of the inspection authority:**

- Providing information to producers on how to implement regulations
- Registering of food business operators and assessment of the company by inspection of preconditions for the production unit (authorization, approval or registration must be performed prior to production or selling of food products)
- Sampling (determined by the inspection authority or at the central level; for example the residue monitoring scheme or monitoring of certain pathogens at the national level)
- Performing risk-based inspections on the basis of need
- Tracing the source of the problem along the production line
- Levying sanctions sufficient to enable the respect of regulations
- Ensuring uniformity at the national and sector level.

The Administration is moreover required to co-ordinate the control process – such as by harmonizing professional assessments and techniques and ensuring compliance with guidelines for the prioritization, reporting, and frequency of inspections. The Administration conducts annual visits to each region in order to be acquainted with their work and sometimes takes part in the inspection in an effort to harmonize national inspection work.

The activities of the control and enforcement offices include the following:

- Registration, approval and authorization of herds, food enterprises, non-food enterprises and transporters
- Inspection, including inspection for approval, inspection of herds, food enterprises and non-food enterprises, and the inspection of labeling and traceability of live animals
- Meat inspection at abattoirs and meat product enterprises
- Border control of imports/exports of live animals, foodstuffs and non-food products of animal origin at 15 border posts
- Sampling for analytical control
- Follow-up on confirmed violations
- Case processing relating to registration, labeling and traceability of live animals
- Issuing of certificates, e.g. in connection with export, and sealing of trucks
- Nutritional information under the “All about Diet” mobile team.

*B. The Danish Plant Directorate* is responsible for inspections of companies and farms. It also controls: seeds, animal feed production and safety, health and quality control of plants, production of fruit and vegetables, organic farming, and EU agricultural schemes.

*C. The Danish Food Industry Agency*, established on April 1, 2000 by merger of the Danish Development Agency and the Danish EU Affairs Agency, implements agricultural policy and administers EU subsidy payments to support farmers, fruit and vegetable growers and fisheries.

*D. The Danish Directorate for Fisheries* is responsible for hygiene inspections at sea and in fresh water (all vessels except freezing and cooking vessels), where fish are landed, at auctions, and on the premises of the first buyer.

**II. The Environmental Protection Agency** is responsible for control of nitrosamines and their release to the environment.

**III. Danish Tax and Customs Administration** manages the register of food, feed and plant importers to Denmark. It also performs a check of documents regarding organic food and feedstuffs.

**Table 2. Division of inspections**

Area	Inspection authority
<b>Animal health</b>	Regional Veterinary Food Authority
<b>Food of animal origin</b>	Regional Veterinary Food Authority
<b>Import of animals and food of animal origin</b>	Regional Veterinary Food Authority & Customs Services
<b>Feed and animal nutrition</b>	Plant Directorate
<b>Animal byproducts</b>	Regional Veterinary Food Authority
<b>Veterinary medicines authorization and distribution</b>	Danish Veterinary and Food Administration and Regional Veterinary Food Authority
<b>Veterinary medicines residues</b>	Regional Veterinary Food Authority
<b>Food and Food hygiene</b>	Regional Veterinary Food Authority
<b>Genetically modified organisms</b>	Regional Veterinary Food Authority Plant Directorate Danish Environmental Protection Agency
<b>Imports of food of plant origin</b>	Regional Veterinary Food Authority
<b>Plant protection products' authorization and sale</b>	Regional Veterinary Food Authority Plant Directorate Danish Environmental Protection Agency
<b>Plant protection products' residues</b>	Regional Veterinary Food Authority
<b>Animal welfare</b>	Regional Veterinary Food Authority
<b>Plant health</b>	Plant Directorate
<b>Restaurants, shops</b>	Regional Veterinary Food Authority

## Register of food business operators

There is a detailed register of the 4,400 facilities that produce food of animal origin for export and local consumption. The total number of food and feed producing establishments is 49,600. As of January 2008, there are 69,730 registered shops and restaurants.

## Frequency of control and fees

The Danish Veterinary and Food Administration ensures that all food sellers comply with the law, in order to protect consumer health and eliminate inaccuracies and dishonesty in food labels and descriptions. The monitoring of food in Denmark is the task of three regional food authorities. Their regular inspection visits are typically unannounced. In certain cases, the regional monitoring authorities may warn of the inspection in advance. Regardless, the company must be prepared to cooperate with the inspectors. During their visit, the inspectors will often take samples of raw materials, semi-finished goods, packaging, or additives<sup>14</sup>.

There are no standard prescribed values for fees and fines. Fines are often determined by the fine values set during similar prior cases. There are four sanction instruments: warnings (no legal status but important for risk ranking), enforcement notice (ban, required correction, training, and consultancy), administrative fine (prescribed when it is the first time and not a serious problem), and reporting to police for prosecution (complicated or repeated frauds).

Facilities are inspected according to the level of risk. Inspection frequency drops as the level of risk decreases or if after four visits within the same year there have been no hygiene or safety problems. Such establishments are called “elite” and receive fewer inspections. One third of all food and feed producing establishments have “elite” status.

In DVFA’s scheme for determining a facility’s general risk level, each facility is classified in one of six risk groups, based on seven risk factors (microbiological and chemical). Depending on classification, retailers are visited by an inspector anywhere from three times per year to once every five years, while wholesalers are inspected from seven times per year to once every two years. Inspectors apply the so-called “four item approach” which means they check:

- 1) the display of the inspection report with the “Smiley” sign, which illustrates whether the premises is excellent, good, moderate or bad<sup>15</sup>
- 2) hygiene (of premises and equipment)
- 3) whether the premises practices self-inspections
- 4) the last item can vary (labeling, additives, composition of food, etc).

<sup>14</sup>[http://www.uk.foedevarestyrelsen.dk/Inspection/Inspection\\_of\\_food\\_establishments/forside.htm](http://www.uk.foedevarestyrelsen.dk/Inspection/Inspection_of_food_establishments/forside.htm)

<sup>15</sup>[http://www.webreg.dk/magnoliaPublic/UNB/Ansoeger\\_NY/Selv-studie\\_UK/Fodevarelovgivning/SmileyOrdningen.html](http://www.webreg.dk/magnoliaPublic/UNB/Ansoeger_NY/Selv-studie_UK/Fodevarelovgivning/SmileyOrdningen.html)

The “*Smiley approach*” was introduced in Denmark in 2001 and has become one of the most well-known public schemes. Now smiley reports are to be posted in all supermarkets, groceries, bakeries, butchers, greengrocers, kiosks, restaurants, hospital kitchens and elderly homes. Even the outdoor hot-dog stands have them. The inspection report includes all results and the inspectors’ remarks and the general rating of the facilities. There are four different Smileys, symbolizing that the inspector either:



had no remarks



emphasized that certain rules must be obeyed



issued an injunction order or a prohibition



issued an Administrative Fine, reported the Company to the Police or withdrew an approval.



The elite-smiley is awarded to enterprises that have received the happy smile on the last four inspection reports and zero remarks during the last 12 months.

At each inspection a number of control areas are checked. The Smiley given by the inspector equals the result for the worst area. In Denmark inspections are carried out on a need-oriented basis. Thus, the areas controlled may vary from inspection to inspection and from shop to shop<sup>16</sup>.

Animal feed is controlled by Danish Plant Directorate twice a year in production establishments and once a year on farms that have implemented HACCP. The focus is on control of:

- HACCP/GAP implemented
- Traceability
- End products
- Storage, separation, transport
- Cleaning.

Import feed is controlled only if arriving from a source that has proven historically unsafe. Otherwise only a check of documents is performed. The Directorate controls seeds and planting material in inland production and in export/import. Usually, they visit each food business operator they control once per year.

<sup>16</sup>«Smileys keep food safety high in Denmark», <http://www.findsmiley.dk/en-US/Forside.htm>

**Table 3. Data on inspection (2007):**

Total No. of inspectors	<b>2220<sup>17</sup></b>
No. of inspectors at Danish Veterinary and Food Administration	<b>1,617</b>
No. of inspectors at Danish Plant Directorate	<b>428</b>
No. of inspectors at Directorate for Fisheries	<b>175</b>
No. of food business operators for veterinary inspection	<b>4,400</b>
No. of food business operators registered at Danish Veterinary and Food Administration	<b>49,700</b>
No. of food business operators for inspection of Directorate for Fisheries	<b>502</b>
No. of food business operators registered by Danish Veterinary and Food Administration	<b>50,302</b>
Annual No. of inspection visits by Danish Veterinary and Food Administration	<b>61,434</b>
No. of visits per one inspector of Danish Veterinary and Food Administration	<b>38</b>
Average annual No. of Danish Veterinary and Food Administration inspection visits per premise	<b>0.5</b>
Annual No. of inspection visits to food business operators by Danish Plant Directorate	<b>16,050</b>
Annual No. of inspections per one inspector of Danish Plant Directorate	<b>37,5</b>
Annual No. of Danish Plant Directorate inspections per food business operator	<b>1.0</b>
No. of fishery inspectors per food business operator	<b>0.35</b>
No. of inspection audits conducted as a percentage of Audit Plan (percent)	<b>Over 95 percent</b>
Percentage of audits with registered nonconformities	<b>7.5 percent</b>
Annual No. of inspection reports (all inspections)	<b>42,000</b>
Percentage of follow up visits per year	<b>18 percent</b>
Annual No. of appeals	<b>Not available</b>
Annual No. of recalls of domestic products	<b>Not available</b>
Annual No. of confinements at border inspected by Danish Veterinary and Food Administration and Danish Plant Directorate	<b>13,000</b>
Annual No. of recalls- import	<b>100</b>
Annual No of samples (food and meat at slaughtering) according to the National sampling plan	<b>2119 + 250 000 samples BSE ta TSE<sup>18</sup></b>

<sup>17</sup>Employed on a full-time basis.

<sup>18</sup>[http://www.uk.foedevarestyrelsen.dk/Inspection/The\\_monitoring\\_of\\_food/forside.htm](http://www.uk.foedevarestyrelsen.dk/Inspection/The_monitoring_of_food/forside.htm), BSE – bovine spongiform encephalopathy, TSE – transmissible spongiform encephalopathies.



## Quality control of inspection performance

Inspection activities include monitoring, sampling, auditing, and actions in case of non-compliance. There are internal audit systems for control of quality of inspection work in all directorates. Regional offices monitor inspector effectiveness and accuracy by checking samples of their reports, with an eye toward clarity, uniformity of approach, and accuracy of legal requirements.

The Regional Veterinary and Food Control Authority is responsible for the hiring, training and payment of inspectors. Veterinarians receive classroom training in veterinary public health and food inspection as part of their veterinary degree course of study. When applying for the inspection job, veterinarians receive on-the-job training at the establishment level. Veterinary technicians, who often have experience as slaughterhouse workers, are educated at the Danish Meat Trade College. Their course consists of 14 weeks of theoretical training and seven weeks of practical training. Ongoing training needs are determined and scheduled by the official veterinarian or the head veterinarian through consultation with the Regional Veterinary and Food Control Authority. Special emphasis is placed on HACCP, Sanitation Standard Operating Procedures and supervisory training.

A yearly performance conference for each Danish Veterinary and Food Administration employee is required by Danish law. Written guidelines outline the conduct of these conferences, which are documented and the files retained by the employee's supervisor<sup>19</sup>.

## Sampling

During inspection visits, inspectors take samples of raw material, additives and semi-finished material and send them to laboratories affiliated to the Administration in order to check if the company is observing the regulations. Sampling can be a part of the national plan – which is created at the central level with suggestions from the regional level. The multi-annual control plan for 2007-2010 was approved by the EC. The sampling plan for each year is prepared in consideration of the projected annual production of food stuffs to be sampled. It must also take into consideration new pathogens and threats from known pathogens.

In 2007 the Administration took 56,252 samples of various contaminants and components, with 22,000 taken at the regional level. Some 370 samples were taken on genetically modified organism analysis. Also, 600-700 samples of feed are taken annually by the Danish Plant Directorate. Eight laboratories carry out the national plan for control of residues: three in Denmark and five in the EU.

<sup>19</sup><http://www.fsis.usda.gov/OPPDE/FAR/Denmark/Denmark2008.pdf>.

## Training

The training of veterinary inspectors and those controlling food of animal origin and feed is obligatory according to EC Regulation EC 854/2004. In the 2009-2010 period all Administration food inspectors are to be trained on general control issues and on other specific needs based on competence. The Danish Plant Directorate also has a training scheme for all inspectors in this authority. The Administration also coordinates and carries out in-service training programs in dialogue with the regions and organizes “Exchange Meetings” among inspection personnel in different regions.

## Transparency

Information is available online about the status of inspection reports and the general public is informed at various retail points about the results of the “Smiley” campaign. The European food and feed recall site offers a monthly report and information based on the Rapid Alert System can be found at the website of the Danish Ministry for Food, Agriculture, and Fisheries.

## Summary

A new, consolidated food safety system in Denmark reveals several benefits, including:

- **A reduction in inspection overlap.** Before the reform, one inspection was performed by several inspectors from different agencies. Today one inspector is able to complete the inspection of a single food processing facility.
- **The frequency of inspection is now based on an individual food product’s safety risk and an individual company’s food safety record.** This reduces the number of necessary inspections and makes more resources available for inspections of higher risk companies and foods. As a result, the new “Smiley approach” was introduced, and it *has proven highly effective in raising food safety and food safety awareness.*
- **The enforcement of food safety regulations is more consistent,** which improves the food safety system’s effectiveness.
- The reform also **streamlined communications,** defined responsibilities more clearly, and improved service delivery as a result of having a single contact.
- Finally, the **reform emphasized the practice of self-inspection,** wherever it has been approved by the relevant food safety bodies.

Being one of the biggest exporters of food in the EU, Denmark is implementing all principles and practices required by the EU legislation. Further, remarks from the EU control missions are seen as guidelines on how to harmonize current EU food safety legislation and the ground reality in Denmark. The government and the private sector collaborate closely as shown in the case of the eradication of zoonosis, wherein the government initiated a process that was followed up by actions from the private sector, which realized the importance of food safety for their businesses.

# Sweden

## Institutional structure

The system in Sweden has three levels: the national (ministries and authorities), regional (21 counties), and local levels (290 municipalities). The government allocates responsibilities at the general level, but municipalities autonomously implement these national regulations and determine fees for controls and other charges. Laws are issued by the Parliament and regulations by the responsible authorities.

Sweden's food system has the following structure:

### At the central level:

**I. The Ministry of Agriculture** which has overall responsibility for the agricultural sector, animal health and welfare, plant health, food and feed production, and fisheries. The Ministry gives the policy orientation and proposes a budget according to annual reports received from authorities under its jurisdiction. The Ministry has four departments dealing with food safety and four administrative units. Also, the Ministry provides general oversight of a number of state agencies directly involved in food safety, specifically: the National Food Administration, the Swedish Board of Agriculture, the National Veterinary Institute and The Swedish Board of Fisheries<sup>21</sup>.

*A. The National Food Administration* is an autonomous state agency that deals with issues related to food products and potable water. The Administration acts in the interests of consumers and pursues three main goals:

- Safe and high quality food products;
- Fair trade with food products;
- Healthy eating habits.

The Administration consists of five departments responsible for risk assessment and development (1), the regulatory framework (2), control (3), nutritional value of food products (4) and management (5). The Administration has a staff of 530, with one third employed by a regional organization in charge of supervising the meat industry<sup>22</sup>.

*B. The Swedish Board of Agriculture* is responsible for animal and plant health, control of contagious diseases, feed and animal by-products. The District Veterinarian Department has 430 veterinarians in its headquarters and District Veterinary Stations. They are responsible for direct control of animal health, the import of live animals and control of the veterinary residues, and also provide services to farmers.

The Crop Production Department has 100 employees, of which 21 are plant protection inspectors. This department controls genetically modified organisms, organic production, and seed.

*C. The National Veterinary Institute* is the expert veterinary body, responsible for the prevention of outbreaks of animal diseases and zoonosis, the production of vaccines, and the control of contaminants in food and feed. It is the largest veterinary laboratory in Sweden.

*D. Swedish Board of Fisheries*

<sup>20</sup>For more details on the Ministry of Agriculture organization structure, please visit: <http://www.sweden.gov.se/sb/d/2064/a/19928>.

<sup>21</sup>For more details on these state agencies, please visit: <http://www.sweden.gov.se/sb/d/2064/a/20020>.

<sup>22</sup>For more details on the National Food Administration, please visit: [http://www.slv.se/upload/nfa/documents/about\\_us/org\\_nfa.pdf](http://www.slv.se/upload/nfa/documents/about_us/org_nfa.pdf).

## II. Ministry of Health and Social Affairs

*A. Medical Products Agency*

*B. Swedish Institute of Infectious Disease Control*

**III. Ministry of Finance** is responsible for monitoring the collection of fees from municipalities and municipal regulations regarding fees. Control over the import/export is performed through:

*A. Customs Service*

## IV. Ministry of Environment<sup>23</sup>

*A. Swedish Chemical Agency*

*B. Swedish Environment Protection Agency*

*C. Swedish Coast Guard*

### Regional level:

*County Administration Boards (21 counties)* – perform official control of animal health and welfare, food and feed hygiene in primary production, animal health, animal identification, audits of municipality performance in control of food safety, and training for municipality inspectors. They also manage appeals to the decisions of municipality control and report annually to the National Food Administration, Swedish Board of Agriculture, and Ministry of Finance.

### Local level:

1. *Municipality Administration Boards (290 boards)* control food, hygiene and environment. They control establishments dealing with food of animal (small establishments) and plant origin. If one municipality does not have the necessary capacity it may collaborate with a neighboring municipality.
2. *Municipality Public Health Offices (290 offices)* control food of plant origin.

<sup>23</sup>Before the structural reform of November 2010.

Table 4. **Division of inspections**

Area	Inspection authority
<b>Animal health</b>	Swedish Board of Agriculture County Administration Boards
<b>Food of animal origin</b>	National Food Administration County Administration Boards
<b>Import of animals and food of animal origin</b>	Swedish Board of Agriculture National Food Administration
<b>Feed stuffs and animal nutrition</b>	Swedish Board of Agriculture
<b>Animal byproducts</b>	Swedish Board of Agriculture, Regional & District Veterinary Food Authority
<b>Veterinary medicines authorization and distribution</b>	Medical Products Agency
<b>Veterinary medicines residues</b>	National Food Administration
<b>Food and food hygiene</b>	National Food Administration County Administration Boards
<b>Genetically modified organisms</b>	Swedish Board of Agriculture
<b>Import of food of plant origin</b>	National Food Administration
<b>Plant protection products authorization and sale</b>	Swedish Chemical Agency
<b>Plant protection products residues</b>	National Food Administration
<b>Animal welfare</b>	Swedish Board of Agriculture County Administration Boards
<b>Plant health</b>	Swedish Board of Agriculture
<b>Restaurants, shops</b>	Self control

## Register of food business operators

There is no national register of food business operators. Rather, establishment approvals are performed by different authorities, as per the new hygiene legislation (EC Reg 882/2004). All establishments had to be approved by the end of 2009. The total number of food business operators for 2007/2008 was 65,715, with 80,000 additional primary producers. The National Food Administration controls about 500 establishments.

## Frequency of control and fees (for food and feed)

According to the annual control plan, premises are visited at 0.2 - 12 times each year. Both frequency and fees to be paid by the food business operator are determined by the risk level of the type of business and according to previous hygienic status. The authority thus estimates the number of hours the inspector will need for that establishment, then multiplies that number by the hourly rate. For businesses controlled by municipalities, the municipality council defines the hourly rate.

For the primary production an annual tax is paid to the County Administration Boards. Sanctions in cases of nonconformity are prescribed by the National Food Administration, but municipality officials may decide on their own how to implement those sanctions. In general, detection of non-compliance intensifies the control, and more follow-up controls may be a part of the annual control plan.<sup>24</sup>

**Table 5. Data on inspection 2007–2008<sup>25</sup>**

Total No. of inspectors	<b>1,195</b>
No. of plant protection inspectors	<b>21</b>
No. of inspectors at National Food Administration	<b>300</b>
No. of food business operators controlled by National Food Administration	<b>550</b>
No. of veterinary inspectors in National Food Administration	<b>200</b>
Country Administration Board veterinary inspectors	<b>43</b>
No. of inspectors in municipalities (total)	<b>847</b>
No. of food business operators	<b>65,715 + 80,000 primary producers</b>
Annual No. of inspection audits to food business operators	<b>42,485</b>
Average No. of visits per food business operator	<b>0.65</b>
Annual No. of audits per inspector	<b>35.4</b>
No. of National Food Administration veterinary inspectors per large & medium size food business operator	<b>1,7</b>
Percentage of audits with registered nonconformities	<b>49 percent</b>
Annual No. of Follow up visits – (percent) of all audits	<b>Not available</b>
Annual No. of appeals	<b>197</b>
Annual No. of recalls- domestic products	<b>44</b>

<sup>24</sup>DG Sanco Country profile 7705/2008.

<sup>25</sup><http://www.slv.se/en-gb/Group3/Publications>

Table 6. Number of inspectors

Authority	Number of inspectors
<b>National Food Administration</b>	250 (200 full time employees)
<b>Swedish Board of Agriculture</b>	36 veterinary inspectors
<b>National Veterinary Institute</b>	198
<b>County Administration Boards</b>	43 (36 full time employees)
<b>Municipality Administration Boards</b>	847 (529 full time employees) food control
<b>Total</b>	1,374

A lack of capacity equivalent to 180 full-time employees exists in the municipalities. The recruitment and training of new inspectors began in 2006 and is expected to reach the optimal level by the end of 2009. Additionally, some jurisdictions like animal welfare and hygiene are to be transferred to County Administration Boards.

## Quality control of inspection performance

The National Food Administration has prepared guidelines for municipalities on how to perform control, which are available at the Administration web site. The Administration has also created checklists for different types of food producing operations. These checklists are supported by the computer program that stores data from inspection visits. Over 70 percent of municipalities have already implemented these computer-based programs. This is a good way to examine an inspector's performance.

There is an internal audit system, whereby the National Food Administration and Swedish Board of Agriculture audit the performance of each county administrative board and every County Administration Board makes audits on every municipality in their region. They perform audits using data that each municipality must send electronically to County Administration Board, which then be forward to the Administration. Three groups of parameters are used for assessing performance: microbiological, chemical contaminants, and labeling. The Swedish Board of Agriculture performs audits on border post inspection according to the same parameters.

## Sampling

The Annual Control Plan is the obligation of every EU country according to EC Regulation 882/2004. The sampling plan for border inspection (microbiological, chemical control) is made according to EC Regulation 134/2004. Official control on residues requires about 5,500 samples each year for veterinary medicines and hormones in food. The National Food Administration itself analyzes 6,000 samples of all food products, of which 693 (in 2007) came from sampling imported agricultural and food products during border inspection. Some 130 samples are analyzed annually on the presence of genetically modified organisms.

## Training

The Administration trains food inspectors on a variety of regulations, including HACCP principles, as well as veterinarians. It organizes regular training activities and carries out standardization inspections and visits to municipalities. The aim is to develop the skills of food inspectors and thus improve food controls.

## Transparency

Authorities are obliged to publish annual reports, disseminate them to their superiors and make them available on official web sites. Consumers can also find information on food contaminants online, as well as a “black list” of products and countries of origin.<sup>26</sup>

## Summary

The Swedish food safety system is functioning as a single agency model. However, from the administrative point of view it is divided at the central, regional, and local (municipality) level. The National Food Administration provides legislation, guidelines, checklists, laboratory testing, proficiency testing for laboratories and a connection with the European Food Safety Authority. The centralization of the inspection services may be a good solution for the Swedish food safety system (it was advocated by expert consultants in Sweden), but it has not yet been officially recognized. In the meantime, the risk-based inspection approach is applied in 70 percent of municipalities and their inspections are connected on-line with the National Food Administration. Thus, data from inspections are available to officials at the central level.

<sup>26</sup><http://www.slv.se/en-gb/Group2/Food-Control/The-National-Food-Administrations-Black-list/>



## B

# Coordinated System of Several Agencies

## Poland

Poland's National Strategic Plan for 2007-2013 seeks to enhance the competitiveness of the Polish food industry and implement preventive measures in the food chain. Also, it supports full harmonization of Polish legislation with the EU. According to acting legislation, the HACCP system is mandatory in all EU countries by January 1, 2010<sup>27</sup>.

### Institutional structure

**Authorities responsible for the food safety system:**

**I. The Ministry of Agriculture and Rural Development** cooperates with the Ministry of Health at the central, regional and district levels. The Department of Food Safety and Veterinary Matters issues regulations. Control function is implemented through three central authorities – inspectorates:

*A. The General Veterinary Inspectorate* is in charge of animal health and welfare, foodstuff hygiene of animal origin, animal feed, pharmaceuticals, rendering. The inspectorate has 10 border inspectorates, 16 regional (Voivodship) inspectorates and 304 district (Poviat) inspectorates. General Veterinary Inspectorates prepare annual plans, guidelines and instructions for regional and district inspectorates, and collect and analyze reports on their work. The network of official laboratories supports this system. There are 2,107 veterinary inspectors: 44 in the Inspectorate, 215 in regions, 1,476 in districts, 68 in border inspectorates and 304 feed inspectors. Besides full-time employees, there are 5,200 practicing veterinarians who perform ante- and post-mortem inspection in slaughterhouses, supervise certain establishments, issue veterinary health certificates, take samples, and take care of animal health.

<sup>27</sup><http://www.un.org/esa/agenda21/natlinfo/countr/poland/agriculture.pdf>

*B. The Main Inspectorate of State Plant Health and Seeds Protection Inspection* at the central level is responsible for control of plant health and use of pesticides, preparing control plans, training, guidelines, and instructions for lower levels. There are 16 regional, 269 district and 12 border inspection posts. Some 1,600 inspectors are employed in control at all levels. In each region there is an official laboratory that tests samples taken from inspectors and samples from the monitoring plan. At boarder stations there are 12 diagnostic units.

*C. The Main Inspectorate of Agricultural and Food Quality Inspection* ensures quality and labeling of genetically modified organisms (control of traceability) with 17 inspectors (one at the central level and 16 in regions).

*D. The Agency for Restructuring and Modernization of Agriculture* keeps a central official register of food business operators and agricultural holdings.

**II. Ministry of Health** prepares legislation and control in areas of food hygiene, pesticide residues, contaminants and import control of food of non-animal origin.

*A. The Chief Sanitary Inspectorate of the State Sanitary Inspection* - control of import of food of non-animal origin, materials that come into contact with food, food additives, genetically modified organisms in food, food supplements, and novel food. Sanitary Inspection also has responsibility for overseeing food processing. It prepares the annual plan, guidelines, and training for lower levels of inspection and collects their reports. There are 16 regional Sanitary Epidemiological Stations with 1,000 inspectors, 318 district with 2,500 inspectors and 10 border stations. In each region (16) there is an official laboratory with samples taken from inspectors and samples from the monitoring plan. There are three institutes nominated by the Ministry of Health to analyze official samples.

*B. The Main Pharmaceutical Inspectorate* has 15 inspectors who control the authorization and import of veterinary drugs.

**III. Customs** controls import of food and plants with responsible inspections from the Ministry of Agriculture and the Ministry of Health.

**IV. Road Transport Inspection** controls animal welfare during transportation (checks vehicles for transport).

Table 7. Division of inspections

Area	Inspection authority
<b>Animal health</b>	Regional and District Veterinary Inspectorate
<b>Meat production</b>	Regional and District Veterinary Inspectorate
<b>Food of animal origin</b>	Regional and District Veterinary Inspectorate Regional and District State Sanitary Inspection
<b>Import of animals and food of animal origin</b>	Regional, District and Border Veterinary Inspectorate Customs
<b>Feed stuffs and animal nutrition</b>	Regional, district and Border Veterinary Inspectorate Customs
<b>Animal byproducts</b>	Central, Regional and District Veterinary Inspectorate Regional and district State Sanitary Inspection
<b>Veterinary medicine authorization and distribution</b>	Pharmaceutical inspectorate
<b>Veterinary medicine residues</b>	Regional and District Veterinary Inspectorate
<b>Food and Food hygiene</b>	Regional and District State Sanitary Inspection
<b>Genetically modified organisms</b>	Agricultural and Quality Inspection State Sanitary Inspection
<b>Import of food of plant origin</b>	Regional and Border State Sanitary Inspection Customs
<b>Plant protection products authorization and sale</b>	Regional Plant Protection Inspection
<b>Plant protection products residues</b>	Regional, District and Border State Sanitary Inspection
<b>Animal welfare</b>	Regional, District and Border Veterinary Inspectorate Road Transport Inspection
<b>Plant health</b>	Regional Plant Protection Inspection
<b>Cold stores, catering</b>	Regional and District Veterinary Inspectorate Regional and District State Sanitary Inspection
<b>Production of infant formula Baby food production</b>	Central Veterinary Inspectorate
<b>Distribution and sales of infant formula and baby food</b>	Central Sanitary Inspection
<b>Retail (both meat and plant products)</b>	District State Sanitary Inspection

## Register of food business operators

According to regulatory requirements, all food business operators must be registered. Both the Veterinary Inspectorate and State Sanitary Inspection keep their own registers. The total number of food business operators in 2008, according to the register, was 33,000 – of which almost 20,000 were small operators (employing less than nine workers).<sup>28</sup> This register is not accurate since almost 30 percent of these enterprises either stopped work or never started. According to the same bulletin there were 6,428 food business operators controlled by the Veterinary Inspectorate.

The State Sanitary Inspection does not have a centralized register (district Inspectorates are registering food business operators and creating a register now). According to data in the official statistical bulletin in 2007, there were 11,200 industrial food producers and nearly 150,000 manufacturers (small producers).

A significant number of food processing facilities still operate in poor sanitary conditions, leading to serious concern about their future. By January 2010, producers given the clean-up grace period had to adjust their facilities and procedures according to EU hygienic requirements or be forced to cease operations.

## Frequency of control and fees

*Veterinary Inspection:* According to risk analysis and relevant EC Regulations (852/2004, 853/2004 and 178/2002), the official control plan is made with checklists for inspection visits. Traceability in meat production and the production of food of animal origin is controlled by veterinary inspection, while traceability of animal products in retail is controlled by Sanitary Inspection. Feed producers are inspected twice a year, traders of feed once per year, and five percent of farmers who keep food producing animals are controlled once per year. Food processors still struggle with poor conditions in many facilities, and some 1/4 of dairies and 1/3 of poultry processing facilities are in poor hygienic condition. This influences the frequency of inspection visits.

*Sanitary inspection:* Sanitary inspection frequency is determined not by risk (the risk-based system is under development), but rather by specific instructions and ordinances. The sanitary inspector approves food business operators self-inspection reports and guidelines for implementation of GHP and HACCP.

<sup>28</sup>Statistical yearbook of agriculture and rural areas 2008. [http://www.stat.gov.pl/bdren\\_n/app/strona.indeks](http://www.stat.gov.pl/bdren_n/app/strona.indeks)

**Table 8. Data on inspection in 2007–2008<sup>29</sup>**

Total No. of inspectors (veterinary + sanitary)	<b>5,505</b>
Total No. of food business operators	<b>Approx. 19,000</b>
No. of veterinary inspectors/Veterinary Inspection (domestic control) <sup>30</sup>	<b>2,005 + 700 private veterinarians authorized to perform inspection</b>
No. of food business operators for Veterinary Inspection	<b>6,428 industrial facilities + 3,500 manufacturers</b>
No. of food business operators per state Veterinary Inspection	<b>5</b>
Annual No. of inspection visits of Veterinary Inspection to food business operators	<b>5,200</b>
No. of follow up visits Veterinary Inspection	<b>2.7</b>
Samples taken by Veterinary Inspection annual sampling plan	<b>27,425</b>
Total No. of samples taken by all Veterinary Inspections	<b>Approx. 200,000</b>
Percent of samples with nonconformities	<b>3–4 percent</b>
No. of veterinarians participating in the annual sampling plan	<b>4,268</b>
No. samples taken by Veterinary Inspection (state and private veterinarians) per annual sampling plan	<b>6.5</b>
No. of food business operators for sanitary inspection	<b>About 12,500 industrial and almost 150,000 manufacturers</b>
No. sanitary inspectors (domestic control)	<b>3,500</b>
No. of food business operators/sanitary inspector	<b>3.57 industrial + 43 small manufacturers</b>
Annual No. of sanitary inspector visits to food business operator	<b>11,000 industrial + 110,000 manufacturers</b>
Total annual No. of samples, taken by sanitary inspectors	<b>16,254</b>
Percent of samples with nonconformities	<b>5.8</b>
No. of plant protection inspectors	<b>1,600</b>
No. of plant protection inspectors controls	<b>105,000</b>
Average annual No. of controls/ plant protection inspectors	<b>66</b>
Annual No. of samples per monitoring plan	<b>2,419</b>
Percentage of audits with registered nonconformities – Veterinary Inspection	<b>Example: 25.4 percent dairies</b>
No. of inspections conducted, as a percentage of Audit Plan - Veterinary Inspection (percent)	<b>Almost 100%</b>
Average No. of follow up visits – Veterinary Inspection	<b>2.5</b>
Percentage of audits with registered nonconformities- Sanitary Inspection	<b>0.5 percent fruit and vegetable processing. 3.8 percent bakeries</b>

<sup>29</sup>EC FVO: Final country profile on food and feed safety, animal health, animal welfare and plant health: Poland, 2008.

<sup>30</sup><http://www.wetgiw.gov.pl/>

**Table 8. Data on inspection in 2007–2008**

Annual No. of recalls - domestic products	<b>2.4 percent</b>
Fines collected from unfit products (incorrect labeling and low quality)	<b>\$125,000.00</b>

## Quality control of inspection performance

In the State Sanitary Inspection, the ISO 9001 system<sup>31</sup> is implemented and the annual work quality control assessment is performed. Guidelines for inspection performance are published by the State Sanitary Inspection and the performance is assessed according to adherence to these guidelines. There is an online inventory of satisfaction of the public with Inspection's services.

Internal controls of veterinary inspection work at each level is performed at least once per year, including overall quality checks and specific performance checks. In monthly field office meetings, requests are communicated from the central level to the regional and local levels.

## Sampling

The EU Food and Veterinary Office has authorized a multi-annual sampling plan that calls for regional and district veterinary inspectors and practicing veterinarians to take samples. In 2007, a total of 27,425 samples were analyzed with 124 found to be non-compliant. Plant Protection Inspectors took 209 samples on genetically modified organisms, 410 samples of pesticides (to control the quality of pesticides, combat fraud) and 1,800 samples of plants for pesticide monitoring.

## Training

There is an annual training plan for each inspection. Training in traceability is organized continuously. Training for chosen Regional and District veterinary inspectors is performed in a cascading fashion, with knowledge transmitted down to the lower level. Training is financed from the budget of the ministry.

## Transparency

Data on inspection controls, the status of inspection visit statements and the number of recalls are shared between inspectors but not publicly accessible. An IT system stores the inspection visit reports in the Veterinary Inspectorate. Results of the annual monitoring plan are regularly published by the EC Food and Veterinary Office.

## Summary

Polish legislation is mostly harmonized with the EU model. Though frequency and scope of inspections are still not based on the risk analysis approach, such a system is under development. Two ministries are obliged to share information on inspection results, but stronger cooperation and one single register of data would be beneficial. The HACCP system implementation is obligatory according to legislation, but comments from the EU Food and Veterinary Office and the U.S. Food Safety and Inspection Service indicate that the situation with food safety, GHP and GMP in facilities differs among those facilities allowed to export to the EU and others producing solely for the national market. The timeline for implementing the HACCP in all facilities is set for three years after accession to the EU. The epidemiological data indicate the triple incidence of food pathogens compared to the EU, thus signaling that food safety practices must be strengthened according to the best international models.

<sup>31</sup>ISO 9001 specifies the basic requirements for a quality management system.

# Croatia

## Institutional structure

Since 1990, Croatia has made many changes in food safety inspection: from the end-point checking prescribed by the ex-Yugoslav legislation to process control in food of animal origin export facilities and facilities that have HACCP. The process of negotiations with the EU has improved coordination between different institutions in the way of more frequent meetings and discussions of a control plan.

The Ministry of Agriculture has responsibility for food of animal origin and the Ministry of Health has responsibility for food of plant origin. The mandate of the Croatian Food Agency relates mainly to risk assessment and risk communication.

**I. Ministry of Agriculture, Fisheries and Rural Development** - according to the Food Act, is the central authority and national contact point in the field of food safety. Since 2004 Croatia is included in the Rapid Alert System for Food and Feed (RASFF) of the FAO and the contact point is the Ministry.

There are three Directorates involved in Food Safety:

*A. The Veterinary Directorate* - responsible for regulation, within which the Veterinary Inspection Directorate is responsible for control of animal health, welfare, safety and hygiene of production of food of animal origin as well as the disposal of animal by-products. Inspection covers border and inland inspection with state veterinary inspectors, border veterinary inspectors, 20 county offices and the Zagreb (the capital) city office. The total number of veterinary state inspectors is 164<sup>32</sup>. It is planned that the number of state inspectors should decrease to 96 and that 180 authorized private veterinarians should receive inspection training (authorization would be valid through the 5-year period).

*B. The Agricultural Directorate* – in charge of regulation, and, within it, the Division of Agriculture and Phytosanitary Inspections controls plant protection products in primary production and plant health at the border and inland.

*C. The Food Industry Directorate* – in charge of regulation of food quality, labeling, wine regulations, traditional food products, natural mineral, and table water.

## II. Ministry of Health and Social Welfare

*A. The Directorate for Sanitary Inspection* is responsible for regulation and control of food safety for products of non-animal origin, novel and dietetic products in food production. Control is exercised in production, retail and import. The total number of sanitary inspectors in the country is 205<sup>33</sup>. They are Units at the county level.

<sup>32</sup><http://www.mps.hr>.

<sup>33</sup><http://www.mzss.hr>.

**III. Ministry of Ecology** - responsible for regulation and inspection of waste (solid and water).

**IV. Croatian Food Agency** was founded in 2004. The main tasks of the agency are risk assessment and risk communication. It is organized according to the European Food Safety Agency model, with eight scientific boards covering different issues from animal and plant safety and animal welfare to food safety and residues in food and feed. They provide scientific opinion and risk assessment to regulators and the public. Collaboration among inspection services occurs through their monthly meetings and through the Croatian Food Safety Agency. The agency follows the model of similar agencies in the region, for example the Bosnia and Herzegovina Food Safety Agency.

**Table 9. Division of inspections**

Area	Inspection authority
<b>Animal health</b>	State veterinary officers and authorized veterinarians in counties
<b>Food of animal origin</b>	State veterinary officers Sanitary inspectors
<b>Import of animals and food of animal origin</b>	Border state veterinary inspectors
<b>Feed stuffs and animal nutrition- import</b>	Border state veterinary inspectors Phytosanitary inspectors, Customs office
<b>Feed stuffs and animal nutrition- production</b>	State veterinary officers Phytosanitary inspectors,
<b>Animal byproducts</b>	State and county veterinary inspectors
<b>Veterinary medicines authorization and distribution</b>	Veterinary inspection
<b>Veterinary medicines residues</b>	State veterinary inspection, Sanitary inspection
<b>Food and Food hygiene</b>	State and county veterinary inspection, Agriculture inspection, Sanitary inspection
<b>Genetically modified organisms</b>	Agriculture inspection Sanitary inspection Ecological inspection
<b>Import of food of plant origin</b>	Agriculture inspection, Sanitary inspection MHSW, Customs authorities, Phytosanitary inspection
<b>Plant protection products' authorization and sale</b>	Phytosanitary inspection, Sanitary inspection
<b>Plant protection products' residues</b>	Sanitary inspection, Veterinary inspection, Phytosanitary inspection
<b>Animal welfare</b>	State veterinary inspectors and authorized county veterinarians
<b>Plant health</b>	Phytosanitary inspection
<b>Restaurants, shops</b>	Sanitary inspection, Agriculture inspection



## Register of food business operators

There is no central register of Food business operators; each ministry has its own register. Croatia maintains no coordinated control plan or coordinated monitoring plan and inspection is not yet done on a risk basis. According to obligations Croatia assumed in the process of association to the EU, monitoring plans have to be coordinated in order to identify the real threats for food safety. Until the new Law on Sanitary Inspection (2009) was issued, both sanitary and veterinary inspections were controlling areas of production of food of animal origin.

## Frequency of control and fees

Both ministries have their annual inspection plans; the annual monitoring plan for residues in food of animal origin is performed by the Food and Veterinary Office. Inspectors visit each food business operator at least once a year and if non-compliances with regulations are identified additional inspection visits may follow (1-2). Inspection visits last from 0.3 to 3 days, depending on the type of inspection (inspectors spend 60-70 percent of their working time performing field work, according to the 2007 official report on control activities). Veterinary inspectors are always present at the slaughtering line (on slaughtering days).

Coordination between inspections is performed through the State Inspectorate and Croatian Food Agency, but also directly, through the monthly coordination meetings of sanitary and veterinary inspectors at the regional level. Food safety inspection at the Ministry of Health is financed from the central and county budgets, according to the Framework Plan of Food Inspection.

The Ministry of Agriculture sets fees for veterinary-sanitary checks, health protection and the issuing of animal health certificates. Out of that money, some 15 to 30 percent remains in the central ministry budget, while the rest is returned to the regional office that performed the service. Income from these fees represents 39.3 percent of the ministry's annual budget. All veterinary inspectors are civil servants employed in the Ministry of Agriculture and inspection services are paid directly from the budget of the ministry.

**Table 10. Data on inspection in 2008<sup>34</sup>**

Total No. of inspectors (veterinary + sanitary)	<b>369</b>
No. of food business operators in sanitary inspection register	<b>45,700</b>
No. of food business operators in veterinary inspection register	<b>1,380</b>
No. of veterinary inspectors	<b>164</b>
No. of food business operators per veterinary inspector	<b>12.7</b>
Average No. of veterinary inspector visits per food business operator	<b>1.2</b>
No. of inspection visits as percent of Audit Plan percent	<b>97 percent</b>
No. of sanitary inspectors	<b>205</b>
No. of food business operators per sanitary inspector	<b>210</b>
Average No. of sanitary inspector visits per food business operator	<b>1.5</b>
Percentage of visits with registered nonconformities	<b>Not available</b>
Annual No. of follow-up visits (percent of all audits )	<b>20–30 percent</b>
Annual No. of appeals	<b>Not available</b>
Annual No. of recalls	<b>5.81 percent</b>

## Quality control of food inspections

One of the roles of the State Inspectorate is to control the performance of inspections according to legal requirements and financial output. Quality assurance systems in inspections dealing with food safety have to be implemented and regularly assessed to obtain the highest level of objectivity in inspection work and provide a basis for further improvements.

## Sampling

Sampling is performed by veterinary and sanitary inspectors. Importers pay for the cost of laboratory analysis of samples taken by inspectors in import control. The testing of samples in production and retail, on the other hand, is paid for by the respective ministry, with exemptions when samples fail to conform to regulations, in which case producers or retailers pay the laboratory fees. Samples tested for purposes of the annual monitoring plan are financed from the budget of the ministry (either agriculture or health, depending on which took the samples).

Sampling overlap by two ministries existed until the most recent version of the Law on Sanitary Inspection was issued in 2008. The Food Act had not been in accordance with the previous Law on Sanitary Inspection (1999), which allowed sanitary inspection to control all types of food business operators.

<sup>34</sup>Information obtained from interviews with civil servants and from official websites.

## Training

Annual inspection training is the responsibility of each inspection unit, according to the Croatia Food Act. Sources of funding are taken from the EU pre-accession funds. These same funds also financed the capacity building and training of the Sanitary Inspection in the period 2002-2006, as well as capacity building in the prevention of zoonosis and control over pesticide residues.

Separate training on HACCP was organized for inspectors and manufacturers. Since HACCP is mandatory for manufacturing of animal products from 1999, numerous facilities have significantly improved the quality of their output, enabling export to the EU. However, a great many food business operators still fall short of the EU requirements<sup>35</sup>. Training on implementation of checklists for classification of businesses was conducted in 2005, and currently the checklists are already used<sup>36</sup>. In 2008–2009 veterinary inspectors went through a HACCP Evaluation Training.

## Transparency

Data on control of residues in food of animal origin are regularly sent to the European Commission. Other types of food are sampled according to the monitoring plan, which has not been significantly updated since 1990. Results of this monitoring can be acquired only with an official request made through the Sanitary Inspection.

The integration of data in the inspections' central IT system was recommended in the report of the EU control mission when Croatia applied for EU candidate status. In 2008, the central IT system was introduced in the sanitary inspection. A similar system is under development in the Ministry of Health.

## Summary

There are still important issues to be addressed within the food safety system of Croatia, such as: complete harmonization of legislation with the EU (secondary legislation mainly), improvement of coordination among authorities; ability to ensure impartiality of inspection work; thorough training of inspectors and implementation of skills, especially towards risk-based inspection control; reform of sampling schemes for food of non-animal origin; strengthening surveillance of food-borne diseases; and supporting the introduction of self-inspection systems based on HACCP principles and good hygienic practices.

<sup>35</sup>[http://ec.europa.eu/enlargement/pdf/press\\_corner/key-documents/reports\\_nov\\_2008/croatia\\_progress\\_report\\_en.pdf](http://ec.europa.eu/enlargement/pdf/press_corner/key-documents/reports_nov_2008/croatia_progress_report_en.pdf)

<sup>36</sup>Data from the Veterinary Inspection, 2009.

# Slovenia

## Institutional structure

Three ministries deal with food safety, plant health and animal health and welfare:

**I. Ministry of Agriculture, Forestry and Food** – which contains three Directorates (Agriculture, Food Safety and Forestry, Hunting and Fisheries) of which the Directorate for Food Safety ensures co-operation within control bodies from this ministry:

*A. Veterinary Administration* is responsible for regulation and control (at border posts and in domestic production) of safety of food of animal origin, animal health, welfare, and the safety of feed;

*B. Inspectorate for Agriculture, Forestry and Food* is responsible for the safety of food of plant origin and control of pesticide residues;

*C. Phytosanitary Administration* is responsible for the regulation of pesticide use and the regulation and control of plant health, seeds, plant propagating material, and fertilizers (at border posts and in domestic production and use);

*D. Food Quality Inspection Service* is responsible for control of the quality of food and labeling.

## II. Ministry of Health

*A. The Health Inspectorate* is the main authority for official control of processing, wholesale, retail and catering of food of plant origin, processed food of animal origin in retail and catering, and pre-packed raw meat in retail.

*B. The Agency for Medicinal Products and Medical Devices* regulates and inspects production and trade of medical and veterinary health products and manages risk from the use of these products.

*C. The National Chemicals Bureau* is responsible for packaging, labeling and classifying pesticides.

## III. Ministry of Environment and Spatial Planning

*A. The Inspectorate for Environment and Spatial Planning* controls water sources and regulates environmental issues,

*B. The Environmental Agency* is responsible for waste and disposal of pesticides and issues permits for the rendering of animal by-products.

### Inter-ministerial cooperation:

According to the decree on the coordination of ministries and the bodies within them, responsibility in the area of food and feed stuffs safety must be incorporated into the process of risk analysis. This is achieved through two “joint panels”- a panel on pesticide residues and a panel on preparation of the multi-annual control plan to be submitted to the European Commission (EC). The plan for 2007-2010 was made and accepted by the EC.

The Veterinary Administration is collaborating with the Customs Office of the Republic of Slovenia in control of transport of food of animal origin and animals across borders. The Administration also organized training for customs officials in the new methods of veterinary border inspection. The two agencies hold monthly meetings to discuss matters of common interest.

**Table 11. Division of inspections**

Area	Inspection authority
<b>Animal health</b>	Regional office, Veterinary Administration
<b>Food of animal origin</b>	Regional office, Veterinary Administration, Inspectorate for Agriculture, Forestry and Food, Food Quality Inspection Service, Health Inspectorate
<b>Import of animals and food of animal origin</b>	Border office Veterinary Administration
<b>Feed stuffs and animal nutrition-import</b>	Regional office Veterinary Administration, Inspectorate for Agriculture, Food Quality Inspection Service, Customs office
<b>Feed stuffs and animal nutrition-production</b>	Regional office Veterinary Administration, Inspectorate for Agriculture, Food Quality Inspection Service
<b>Animal by-products</b>	Regional office Veterinary Administration, Health Inspectorate, Inspectorate for Environment
<b>Veterinary medicines authorization and distribution</b>	Regional office Veterinary Administration, Agency for Medicinal Products and Medical Devices
<b>Veterinary medicines residues</b>	Regional office Veterinary Administration,
<b>Food and Food hygiene</b>	Regional Offices Veterinary Administration, Health Inspectorate, Inspectorate for Agriculture, Food Quality Inspection Service
<b>Genetically modified organisms</b>	Veterinary Administration, Inspectorate for Agriculture, Food Quality Inspection Service
<b>Import of food of plant origin</b>	Health Inspectorate, Inspectorate for Agriculture, Customs authorities, PARS
<b>Plant protection products authorization and sale</b>	Inspectorate for Environment, Inspectorate for Agriculture
<b>Plant protection products residues</b>	Health Inspectorate, Inspectorate for Agriculture
<b>Animal welfare</b>	Regional office Veterinary Administration
<b>Plant health</b>	Inspectorate for Agriculture, Phytosanitary Administration, Agricultural Institute
<b>Restaurants, shops</b>	Regional Veterinary Food Authority

## Register of food business operators

The Ministry of Agriculture and the Ministry of Health have separate registers of food business operators. Some establishments are approved for export to the EU and others are registered for domestic production yet export to non-EU countries.

## Frequency of control and fees

Both controlling authorities have an annual control plan. In the Ministry of Agriculture, there is a risk criteria based control plan (2-12 visits per year) with control over traceability included in the plan. They also maintain a multi-annual control plan (2007-2010) approved by EC Food and Veterinary Office.

The frequency of food safety control is determined by the Ministry of Health according to the level of risk attributed to each food business operator. Those with low risk are audited once every 24 months, while medium risk level food business operators are audited once every 15 months and high-risk food business operators once every nine months.

Inspection is financed from the government budget and from registration fees. When sampling is performed for monitoring purposes it is financed from the ministry's budget, except when non-compliances are found, in which case the owner pays for the laboratory analysis. Sanctions are determined according to the prescribed list, but inspectors themselves may decide which level of sanctions should be applied in certain cases.

In border inspection, documents on products coming from EU countries are regularly checked and batches of goods are not sampled at border posts, unless non-conformities in documents are observed, or if through the FAO's Rapid Alert system the notification concerning specific producer or product is sent. If non-conformities are found, the next shipment from that producer is to be mandatorily checked and sampled. If compliant, the inspection returns to the annual check plan. Commodities coming from so-called "third countries" and non-EU countries are tested according to the testing scheme of each ministry, but mandatorily the first time the producer sends a shipment and then again every three to six months thereafter if no non-conformities are found. If non-conformities are found, inspection becomes more frequent.

Table 12. **Data on inspection in 2007**<sup>37</sup>

Total No. of inspectors	<b>576</b>
No. of food business operators registered at Veterinary Administration	<b>313</b>
No. of veterinary inspectors per food business operator	<b>1.6</b>
Annual No. of visits of veterinary inspectors	<b>5,271 + regular presence in slaughterhouses</b>
Average No. of visits per veterinary inspector	<b>16.5</b>
No. of Phytosanitary + Agriculture inspectors	<b>72</b>
Average No of visits per inspector (plant protection + phytosanitary inspectors)	<b>55</b>
No. of export /import controls performed by Phytosanitary + Agriculture inspectors	<b>15,242</b>
No. of food business operators registered at Phytosanitary	<b>1,189</b>
No. of premises visited by sanitary inspection	<b>16,146</b>
No sanitary inspectors	<b>87</b>
Total No. of premises registered at sanitary inspection	<b>20,528</b>
No. of follow-up visits in 2007	<b>4,869</b>
Average No. of visits per sanitary inspector	<b>238</b>
No. of inspection visits as percent of Audit Plan (percent) - sanitary inspection	<b>78.7 percent</b>
Percentage of audits with registered nonconformities	<b>10 percent</b>
Border Inspection Posts control- total No. of samples (Veterinary + Health)	<b>752</b>
BIPs control- recalls	<b>9</b>

## Quality control of inspection performance

The Health Inspection, Veterinary Administration and Inspectorate for Agriculture have implemented internal audit systems. Quality Assurance and Internal Audit Service, a Veterinary Administration department, deals exclusively with control of inspection work (whether inspectors are following rules and guidelines for inspection work and inspecting premises according to acting laws and regulations). The director of the Administration regional office or the head of a section, if authorized by the regional director, checks the performance of each veterinary inspector at least once every three years. This is called the verification of an inspector's performance. The director or section head verifies whether each inspector performed control over programs of self inspection in all the premises for which he is responsible.

<sup>37</sup>[http://ec.europa.eu/food/fvo/country\\_profiles/CP\\_slovenia.pdf](http://ec.europa.eu/food/fvo/country_profiles/CP_slovenia.pdf)

Table 13. Number of inspectors in Slovenia<sup>38</sup>

Authority	Number of inspectors
Ministry of Agriculture head office	34
Veterinary Administration	319
Inspectorate for Agriculture	22.5
Phytosanitary Administration + regional plant protection and phytosanitary inspection	43.3 + 36 third party inspectors
Feed	3
Food hygiene inspection	12.5
Border inspectors	19
HIRS	88
Total	576 full time employees

## Sampling

Monitoring implementation takes place on the basis of a two-year program. The selection of food-stuffs, agricultural products, and active substances is determined in line with recommendations from the EU (Commission recommendation 99/333/EC) and WHO, and according to national priorities and expert opinions. Approximately 300 samples of agricultural products (150) and foodstuffs (150) are investigated each year.<sup>39</sup>

## Training

The Ministry of Agriculture has a budget line for training Veterinary inspectors. Training in import controls, implementation of the European Community legislation and practices, official feed control, and implementation of check lists in slaughterhouses were established in 2008. Good practice guidelines for animal welfare and producers of primary products were also developed. The Ministry of Health will receive supporting EU funds for inspector training in 2009-2010.

## Transparency

In Slovenia, data on food safety are not accessible on official websites. But checklists and their updates are posted at the Veterinary Administration web portal.<sup>40</sup> Data on monitoring can be accessed through the EC Food and Veterinary Office reports on the situation in Slovenia or through EFSA documents.

## Summary

Slovenia has reformed its food safety system, starting from the traditional model of spot-checking to the risk-based model of inspections. The goals of the reform of the food safety system were defined in the national food safety strategy (2002). By the time Slovenia joined the EU, all legislation in this area had been harmonized with EU requirements. In 2006 Slovenia incorporated the practices and recommendations of the EU's "hygienic package"<sup>41</sup> of legislation and started developing checklists for inspection and moved towards self-checking and inspection control of these programs.

<sup>38</sup>[http://ec.europa.eu/food/fvo/country\\_profiles/CP\\_slovenia.pdf](http://ec.europa.eu/food/fvo/country_profiles/CP_slovenia.pdf)

<sup>39</sup>Institute of Public Health Slovenia data.

<sup>40</sup>[http://www.mkgp.gov.si/si/o\\_ministrstvu/direktorati/direktorat\\_za\\_varno\\_hrano/starasektor\\_za\\_varnost\\_in\\_kakovost\\_hrane\\_in\\_krme/varnost\\_hrane\\_in\\_zascita\\_potrosnikov/](http://www.mkgp.gov.si/si/o_ministrstvu/direktorati/direktorat_za_varno_hrano/starasektor_za_varnost_in_kakovost_hrane_in_krme/varnost_hrane_in_zascita_potrosnikov/)

<sup>41</sup>Set of EU regulations defining hygiene of food, official control, requirements for production under hygiene principles, namely EC Regulations 852/2004; 853/2004; 854/2004 and 882/2004.



# Conclusions and Recommendations

In order to be able to compete for new food markets and increase Ukrainian food exports as well as food safety, the Ukrainian system of state food safety control needs to become more effective and efficient. In other words, it requires substantial reform. A clear understanding of who is responsible and how the country ensures and guarantees food safety is crucial to achieving these goals.

Reform of the Ukrainian system of state food safety control, regardless of the chosen direction, requires understanding and clear vision among state decision-makers, both regarding the development of the reform strategy and in its implementation. It is obvious that the transformation of the current system will be a complicated, demanding and resource-consuming process. That is why commitments from state officials, political support and substantial preparation are vital. Such reform assumes not only institutional transformation, but also significant changes to the concept of state control, shifting from focus at the final stage (when the product is ready and the only possibility to prevent food accident is its utilization) to a new focus on prevention throughout the entire food chain. In addition, legislation must be updated and brought into compliance with international standards.

Thus, improving Ukraine's national system of state food safety control requires:

**1. Reform the current system of state food safety control by creating a single agency, while streamlining laboratory services.** This will allow the state to eliminate such problems as:

- a. Inefficient use of state funds and dissipation of resources and loss of focus on control;
- b. Duplication of functions and lack of coordination among state agencies involved in control;
- c. Existence of too many labs, as many are incapable of testing up to EU food safety standards;
- d. Inability to develop an efficient plan for food safety control that addresses all problematic issues.

**2. Harmonization of national food safety legislation with EU standards and use of horizontal approach.** This will:

- a. Increase the level of food safety in Ukraine, by:
  - Allowing the government to quickly devise and implement new food safety norms and regulations, bypassing the lengthy development process and adoption of numerous by-acts.
  - One of the basic principles of EU food safety is that the primary responsibility for ensuring compliance with food law, and in particular the safety of the food, rests with the food business.
  - Ukrainian producers will be obliged to implement self-control systems based on HACCP principles, which is a must in the EU. And since HACCP is a preventive approach to food safety that optimizes efforts to provide the consumer with safe food, national food business operators will also reduce costs due to food safety controls focused on a ready product.
- b. Increasing export potential and enabling national producers to enter the lucrative EU market;
- c. Reducing costs for national producers who have to comply with Ukrainian safety requirements, which have long been outdated, making the use of modern technologies and safety instruments nearly impossible. Also, in case of export, national producers have long been forced to invent ways of complying with sometimes contradictory national and EU requirements.

**3. Develop a uniform national program of training state food safety inspectors.** All state agencies involved in food safety management need specific educational programs for their experts. Insufficient knowledge is likely to significantly undermine the reform process. Thus, a solid education is key to building adequate food control expertise.

IFC strongly believes that with concerted effort to reach these three policy goals, Ukraine can make significant progress in food safety, boosting sales for food companies and producers and providing a much-needed stimulus to the many regions hit hard by import competition and the global financial crisis.

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