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International Finance Corporation

# Study of Food Safety Inspections

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## 1.0 Summary

Foodborne diseases<sup>1</sup> are globally spread public health problems that reduce economic productivity and pose great burden to health systems. Hundreds of millions of people suffer from communicable and noncommunicable diseases caused by contaminated food and water both in developed and underdeveloped countries. The global incidence of foodborne disease is difficult to estimate, but it has been reported that in 2007 alone 2.2 million people died from diarrhea diseases.<sup>2</sup> A great proportion of these cases can be attributed to contamination of food and drinking water. Additionally, diarrhoea is a major cause of malnutrition in infants and young children. In industrialized countries, the percentage of the population suffering from foodborne diseases each year has been reported to be up to 30%. An estimated 76 million cases of foodborne disease occur each year in the United States. The great majority of these cases are mild and cause symptoms for only a day or two. Some cases are more serious, and CDC estimates that there are 325,000 hospitalizations and 5,000 deaths related to foodborne diseases each year. Costs of food borne diseases for the US community are estimated to be 5 to 6 billion dollars in direct medical expenses and lost productivity.<sup>3</sup>

The most severe cases are associated with old people, babies and young children, persons with chronic diseases which reduce their immune system function, but also, in healthy people exposed to a very high dose of a contaminant. Apart from those microbiological, chemical contaminants may also emerge in food due to high level of exposure to pesticides, fertilizers, industrial or environmental contaminants.

Food is the second most traded group of products globally (fuels and mining products being the first), and export of food rises worldwide from 13% in 2000 to 22% in 2008. In 2008, according to the WTO statistics, food participated in the world export with 1114.0 billion of dollars. It is important to notice that quantities of agricultural products are constantly rising and that need for export is growing.<sup>4</sup>

Consumers worldwide are aware of possible contaminants associated with food and water, and it is a government priority to secure consumer's health through measures that prevent food from contami-

nation. Also, food adulteration is additional problem in consumer protection where governments have an important role in prevention and control. Industrialization and increased mass production, urbanization, new food technologies and processing methods, changing lifestyles, increased worldwide tourism and international trade in foodstuffs, increased contamination of the environment and increased consumer awareness pose significant challenges for food safety systems organization.

Food safety is an important part of the national health, agricultural, economic, environmental and even defense policy. At the national level, food safety should be secured through proper legislation and enforcement of rules. Bodies responsible for enforcement are different inspections in charge of control of plants, animals intended to be used as food, animal feed and final products to be used as food for humans.

Since food is traded globally contaminants present at one location could be disseminated easily. Prevention of contaminants during primary production, processing and distribution of food proved to be the more effective than investigation of possible units of contaminated final food products. The role of the official inspection has changed from end – spot – check control to authorities which provide information and consultation to all stakeholders in the contact with food chain. Inspectors work with producers in order to inform them on the legislative requirements explaining to them how to apply such requirements, they provide information to extension services and in the same time they serve as the information providers to consumers who demand wholesome information on food safety issues and especially in case of food safety emergencies. In the same time a great deal of the traditional inspection work remained, and they still control whether food business operators act in accordance with legislation requirements. In order to inform all stakeholders rapidly and accurately on the status of the inspection control and findings, high level of transparency of data on food safety should be enabled.

The modern approach to inspection is based on risk assessment, but modalities of such approach vary from one country to another. The best practices are recommended by the FAO, WHO, WTO and should be included in national codes of practice.

The scope of this report was to evaluate how food safety practices are applied in developed and transitional countries and to highlight best practices in control, taking into consideration the level of development of countries, their historical background in terms of food regulation, specific characteristics and the importance of food production for the national economy. The report is targeted to policy-

<sup>1</sup> Foodborne diseases, usually either infectious or toxic in nature, caused by agents that enter the body through the ingestion of food.  
[http://www.who.int/foodsafety/foodborne\\_disease/en/](http://www.who.int/foodsafety/foodborne_disease/en/)

<sup>2</sup> Second Formal Meeting of the Foodborne Disease Burden Epidemiology Reference Group (FERG). WHO, 2008

<sup>3</sup> [http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections\\_g.htm#mostcommon](http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_g.htm#mostcommon)

<sup>4</sup> WTO: International Trade Statistics 2009.

makers and government officials engaged in the reform of the official food safety controls system in transition and developing countries. IFC project managers and advisory teams will also find it a useful resource in designing food safety and agribusiness interventions as part of the overall IFC strategy on agribusiness.

The nine countries we examined were chosen according to their: geographical position (countries with or without land borders), historical and economical background (highly developed EU countries, new EU members, the EU candidate countries, so called “third countries” in terms of trade with the EU, underdeveloped countries) and members or candidates for the WTO accession.

### **Summary of the best practices identified recommended for securing food safety systems:**

1. The responsibility for food safety lies primarily with food producers, rather than with inspectors, although inspectors play an active role in overseeing compliance. This principle should apply to both domestic and imported products.
2. The “top-to-bottom” hierarchy in inspection is the most effective way of organization of food control (from the responsible authority at the governmental level to the control at local level).
3. A single inspection body would be probably the most effective solution. But a very integrated inspection system with authorities closely collaborating, sharing information on inspection and respecting other authority’s inspection and laboratory data is also, a good model for a functional food safety system.
4. Central register of FBOs enables accurate planning of inspection activities and provides reliable source for statistical follow-ups. Registration procedures should be simple and preferably on-line. Registration of facilities should be mandatory.
5. In countries where inspections do not exist or need major reconstruction the possible approach would be to start with creating or reconstructing the sector of inspection which is the most important for the country’s economy. That could be preferably the major export sector. Experiences gained and structure developed could serve as a model for other sectors. Implementing the profound reform in one sector which is essential to the country’s budget may produce more effective results compared to starting the overall reform of the food safety system and thus persuade the government to continue with broader reform in various aspects of food safety.
6. Risk assessment is very demanding in terms of scientific and analytical capabilities and financial costs. Data accumulated at the international level (Codex Alimentarius, OIE, IPPC, EFSA, governmental and non-governmental bodies) should be consulted, and risk assessment undertaken only in cases when data do not exist. It must be emphasized that country must provide internationally recognizable data.
7. Use of the regional database and knowledge in country’s policy and specific activities should be facilitated. Such database exist in the EU, New-Zealand/Australia.
8. It is ideal to separate completely risk assessment from the risk management and communication, and appropriate bodies should be assigned to perform these activities. There are, also very functional models where risk assessment and partly risk management are performed by one body, but clear separation of departments within that body and highly professional approach to both areas should be secured.
9. Number of inspection visits is not the condition per se which secures that food safety objectives are met. Inspection needs to be risk based, with frequency and fees adjusted to the level of risk posed by specific type of product/technology. Facilities/producers assigned tone risk group may change the group if situation in their facility or safety of their products/processes change. Methods for assessing the risk associated with products/processes/facilities should be publicly available.
10. Import border posts for high risk commodities should be determined, properly equipped and operated by adequately trained inspectors.
11. The budget for the inspection must be secured in the responsible ministry. It needs to be adjusted to the national food safety objectives. While some activities (such as continuous supervision needed in slaughterhouses) tend to be covered partly or fully by businesses’ fees, the bulk of the ongoing supervision work has to be covered by the general budget fund and food safety supervision as a whole cannot be based on cost recovery from enterprises.
12. According to the WTO requirements certificates issued by competent authorities working according to the internationally accepted practices have to be recognized in trade. Recertification according to national rules is often done with food safety concerns given as the reason, but is actually income driven or the way to stop free trade of certain commodities.
13. Sampling of imported or domestically produced goods should be performed according to the annual plan and in cases when non-conformities are observed in documentation, or if previous experiences with the same importer/producer pose concern, or when notification on food safety risks associated with certain

- product were placed through Rapid Alert System or some other regional system.
14. Number of inspectors in the country must be adjusted to the number of FBOs and their geographical distribution in each region.
  15. Qualifications of inspectors have to be appropriate to the type of inspection they perform.
  16. Private inspection bodies and authorized and trained veterinarians/plant health specialists can perform official inspection when authorized by the official body responsible for such inspection. They must audit according to rules prescribed by the relevant authority in order to perform inspection equivalent to those of public inspectors. Authorization of private inspection bodies and individuals to perform official inspection should be time limited and audit of their work should be performed with the same frequency as the audit of work of governmental inspectors.
  17. Training of all inspectors in modern inspection practices should be regulated and in accordance with the annual plan. Such are trainings in: in the HACCP system implementation and auditing, principles of risk based inspection, inspection of GMO, border inspection, plant health, animal health, sampling. When check lists for the inspection are created, training in application of check lists should be provided.
  18. Publicly available inspection reports (or reports accessible by password to FBO whom inspector has been visited) secure objectivity in the inspection approach. Additional instruments such as check lists enhance objectivity and could be used to assess the quality of inspector's performance.
  19. Collaboration among authorities should secure share of inspection documents and thus help lowering costs and number of inspection visits to the single entity.
  20. Reduction of old and new pathogens is a measure of success of the national food safety system. Health and agriculture authorities must collaborate in this area.
  21. Food inspectors have to anticipate that their role is not only in control but also in advising food producers/trade/catering in practices through which food safety situation could be improved.
  22. Food inspectors must be impartial, free of any conflict of interest, well educated and objective. They are often, the last obstacle between the unsafe product and consumer. They have to be properly paid in order not to be corruptive and their role in protection of public health must be recognized.

## 2.0 Glossary<sup>5</sup>:

**Food safety** is secured through legislative and control system. The control is enforced by inspection and laboratory control of food.

**HACCP (Hazard Analysis and Critical Control Points)** is a preventive food safety management system which identifies, evaluates, and controls hazards which are significant for food safety.

**Control measure:** Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

**Corrective action:** Any action to be taken when the results of monitoring at the CCP indicate a loss of control.

**Critical Control Point (CCP):** A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

**Critical limit:** A criterion which separates acceptability from unacceptability.

**Deviation:** Failure to meet a critical limit.

**HACCP plan:** A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.

**Hazard:** A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

**Hazard analysis:** The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

**Monitor:** The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

**Validation:** Obtaining evidence that the elements of the HACCP plan are effective.

**Verification:** The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

**Risk based** food inspection program is one that uses an inspection approach that evaluates and focuses on the reduction of risk factors known to cause or contribute to foodborne illness and to promote active managerial control of these risk factors and uses the associated risk level of a food operation to determine inspection frequency.

**Foodborne diseases (FBD)** can be defined as those conditions that are commonly transmitted through ingested food. FBD comprise a broad group of illnesses caused by enteric pathogens, parasites, chemical contaminants and biotoxins.

**Good hygienic practices (GHP)** are all practices regarding the conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

**Good manufacturing practices (GMP)** are practices for the control and management of manufacturing of foods, pharmaceutical products, and medical devices.

**Food business operator (FBO)** – any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements

**Primary production** – those steps in the food chain up to and including, for example, harvesting, slaughter, milking, fishing.

**European Community Food and Veterinary Office (EC FVO) report** deals with the structure and functioning of the food safety system in the EU countries of third countries (those intending to export food, animals and feed to the EU).

**Health and Consumer Protection Directorate General (DG SANCO)** has a mandate to ensure that food and consumer goods sold in the European Union (EU) are safe, that the EU's internal market works for the benefit of consumers and that Europe helps protect and improve its citizens' health.

**Salmonella, Campylobacter, Shigella, Cryptosporidium, E. coli** – food and water borne pathogenic bacteria.

**CARDS program** – The EU Community Assistance for Reconstruction, Development and Stabilization.

<sup>5</sup> Definitions according to Codex Alimentarius Commission document: CAC/RCP 1-1969, Rev. 4, 2003

### 3.0 Methodology:

In order to assess different experiences and models of regulation of food safety, nine countries from different regions in the world were selected. Countries differ, in terms of the history of food safety systems, present food safety systems, economical strength, cultural and political heritage and present state of participation in the world food trade. Data for this study were collected from different sources:

- data from country reports made by the FVO, Dg Sanco, FAO, WHO
- official data on food inspections available to public at official web sites
- direct interviews with officials
- official data on laboratory inspection provided to public at official web sites
- data provided by officials or relevant sources from selected countries i.e. consultant companies or individuals working in the field of food safety and having reliable information. The set of questions was sent to them by the author of the study.

The author choose to analyze data from 2007, since in most of the countries included in this report these data were systematically processed. Where possible data for 2008 were presented. The FVO and DG Sanco inspection reports proved to be the very systematic and reliable sources, and officials always addressed the author to these reports in countries where such inspections were performed. In cases where data from 2007 lacked because no database was created before 2008, (as was the case in Uganda), data from 2006 were used. Also, there because of the lack of any data base prior to 2006, no comparison with the previous period could be made.

It has to be emphasized that each country has a different type of data collection and reporting and though the same set of questions was sent to each country, replies differed substantially. Some data couldn't be compared to other countries, since the methodology for acquiring such data were not based on the internationally recognized models (in Serbia and Croatia data on sanitary inspection control).

## 4.0. Findings:

Food safety is nowadays a key element in terms of the country's economy, health situation and defense. Agriculture and food production participate in different percentage in the Gross Domestic Product, with 1.3-4.5% in developed countries and 4-12% in the medium sized economies. In the underdeveloped countries, share is even greater, being 37% in Uganda. It is important to notice that in the USA, which is high at the list of the most developed countries, agro-business sector plays a very important role with 10% of the GDP being acquired from the sector (Table 1).

Agriculture, food production and food trade are very vulnerable due to high potential for unintentional contamination, risk of fraud or even bioterrorism. As population tends to agglomerate in urban areas, the exposure to risk becomes even higher than before. Industrialization and global trade pose specific burdens for contamination of food and dissemination of contaminants at long distances. Fast transport nowadays, adds to potential risk of transfer of contaminants.

Food security, being one of the major issues in underdeveloped countries could be jeopardized by pests, plant and animal health diseases. Supply of food in those countries relies mostly on domestic production and in some of them even basic commodities are lacking and have to be supplied in form of the food aid. Underdeveloped countries are dependent of export of certain types of food commodities (fish, coffee, cocoa) and their production and storage are usually associated with poor food safety practices. They often fail to pass high scrutiny tests in import countries, are recalled or even for a long time banned for import, and this can further aggravate the poor economic situation in the export country.

**Table 1: Comparison of economic data between 8 countries**

Country	GDP (PPP) in 2007 (billion \$)	GDP per capita (PPP) in 2007 in \$	Population	Share of agriculture in GDP (%)
Croatia	70	15.700	4.443.000	5.9
Denmark	203.7	37.391	5.515.287	1.3
New Zealand	172	30.000	4.213.418	4.4
Poland	637	16.500	38.500.000	4.0
Serbia	80.7	10.900	7.379.000	12.3
Slovenia	54	23.000	2.000.114	2.0
Sweden	346.2	38.300	9.200.000	1.5
Uganda	33.57	1.100	32,369,558	37
USA	14.110	46.800	307.212.000	10

Food safety systems should be posed on three pillars – regulations, enforcement control and laboratory testing:

- Regulations provide necessary basis for food control and they empower control bodies to check the approach to food safety which producers and handlers have applied;
- Food control being in the past exclusively the role of the government authorities, is transferred, more and more, to private inspection bodies and to producers themselves. Roles of inspectors, division of authorities, inspection practices and effectiveness of inspector's control still vary greatly from country to country. Sometimes inspection practices pose a great burden in terms of costs of taxes, laboratory tests, working days lost due to inspection, unnecessary certification costs, overlapping of inspections, sometimes unclear demands given by different inspections, etc;
- Laboratory testing requires scientifically sound basis, must reveal real hazards, be reliable and performed according to the internationally accepted best principles.

## 4.1. Results of the study:

The study showed some common principles around which inspections were organized and are functioning, but also, differences in approach and results from country to country.

### 4.1.1. Legislative basis

In order to secure the solid basis for the food safety system legislation should be:

- based on the internationally recognized standards and recommendations and regularly updated
- clear
- not contradicting
- basic laws should be followed with sub-law documents and guidelines for the implementation, thus fully regulating one area
- in countries which are or will be candidates for the EU accession and in third countries wishing to export to the EU, relevant EU regulations should be consulted when updating food regulations.

In Sweden and Denmark laws and sub-law documents regulating food safety area are fully harmonized with the EU regulations, directives and codes of practice. In Slovenia, Poland, Croatia, Serbia major laws are harmonized with the EU, but there are sub-law documents which still need harmonization. In the USA legislation is very fragmented, with number of decrees and amendments. In order to overcome this situation a new law document is submitted to the Senate, with the aim to strengthen the over-fragmented US legislation framework and to introduce risk based inspection in facilities, oblige manufacturers to take more responsibility for the prevention of food-borne illnesses and hand the Food and Drug Administration (FDA) further punitive powers. In Uganda, only regulations in the area of fish production are harmonized with international principles, and work in harmonization was started in the coffee production area.

### 4.1.2. Division of responsibilities:

Control of food safety should be performed by professional bodies trained in import/export and inland inspection. Division of responsibilities should be as clear as possible, taking into consideration the level of expertise, capacities of each inspection body, number of premises to be inspected and the level of development of the food safety system in a particular country:

- *the well organized centralized model with “self control”* – as a result of the BSE crisis need for the enhancement of the efficacy of the food

safety control system in the EU and other developed countries was anticipated. It resulted in Denmark with a reform of the food inspection which produced a centralized inspection system with the hierarchy in implementation of food regulations conducted from the top to the local level. The Danish Ministry of Food Agriculture and Fisheries at the central level takes the overall control over work of the Regional Offices (veterinary, plant protection and fish inspection) in order to secure food safety from “farm to table”. It controls the performance of local laboratories, too. This system is based on control of risks and the authority provides guidance to producers in application of so called “self control” and government inspection deals directly in very precise areas. The central level keeps an exhaustive record of FBOs. The system is a very good example of functional and straightforward organizational model.

- *the decentralized model* – in Sweden, we anticipate decentralized system with three levels of authorities: central, regional and local. The primary production control is performed at the regional and local level, and authorities at the central level control major producers and import of high risk products. The local bodies being aware of their own lack of capacities for the extensive job they are responsible, are willing to transfer their authorities to the regional level. Control bodies at the regional level are independent in their work and report once per year to the central body, in some cases they do not fully follow recommendations in inspection practices given by the central body. Inspection in Sweden should be risk based, according to acting regulations. The register of FBOs is not centralized and different bodies approve establishments. The Swedish inspection system originates from the country’s constitutional organization where independent local administrative units unified under Swedish crown. In terms of functionality, it would be better if the food inspection follows one directive given by the responsible authority.

In Denmark and Sweden clear division of responsibilities between different ministries responsible for food safety was performed. In both countries the ministry in charge of agriculture has the overall responsibility for the food safety.

- *the application of the “self control” in the decentralized system* – New Zealand has not yet fully consolidated food safety system control. The food regulatory model is based on application of the current ‘Regulatory Model’ (i.e. the three-tier model where the government involvement is relatively small, the control agencies on the local level manage the system, but

the most important role is the self-control role exercised by producers themselves). It is important to underline that major differences are obvious between the approach to food inspection at the regional level (where an advanced form of risk based inspection is applied in larger size operators according to the food safety law) and at the local level (where only basic GMP and GHP practices are checked in small and medium sized FBOs according to outdated rule-books). The duality of existing regulations should be overcome by applying the food safety law on the whole territory of the state. There is an obvious shortage of trained inspectors at local level and they need to be properly trained in order to inspect according to risk based principles.

- *reform of legislation and inspection of one type of commodities serving as a model for other types of commodities within the same country – model for the underdeveloped countries* – the Uganda's economy is dependent on finances coming from the export of fish and coffee. The export of fish was twice banned due to presence of contaminants in products exported to the EU. That was the reason to develop fish inspection and train inspectors in control of raw fish and products. Besides building of an inspection, the regulatory area for fishing and fish processing and control was created and the register of FBOs in this area was made. The performance of this inspection and capacity building in this sector serve as a model for other sectors (honey production, fruit).
- *Other models:* when coordination among responsible bodies is still weak – in Poland ministry in charge of agriculture and Ministry of Health share responsibilities in food safety. Inspection's responsibilities do overlap in the area of food hygiene where both authorities inspect premises and practices. Also, the overlapping is visible in the control of hygiene of transport vehicles and animal welfare, where Ministry of Transportation and ministry in charge of agriculture perform control independently. There is an evident lack of veterinary inspectors at the local (district) level and this is partially overcome by allowing licensed veterinarians to perform duties of inspectors. There is a centralized register of FBOs at the country level. The food safety system in Poland underwent serious reform from the ex-Soviet model of regulations and inspection to the nowadays model based on the EU regulations and precautionary principle. Poland succeeded in implementation of the risk approach in veterinary inspection, but sanitary inspection still works according to ordinances which prescribe frequency of inspection visits

and sampling. An important number of food processing facilities still operate in poor sanitary conditions and there is a serious concern about their future. Some 21.000 FBOs are small scale operators with less than 9 employees. They frequently have no strength to implement the proper HACCP system. By January 2010 producers which were given the grace period have to adjust their facilities and procedures according to the EU hygienic requirements or they should close their operations. This is an example of two tier system (one level of standards for export and another for domestic production) which can be tolerated for a certain period of time in order to give smaller scale producers time to adjust to stricter standards or to close. In Poland the grace period was 3 years.

In Slovenia the reform started in 1990 from the previous ex-Yugoslavia model with a number of authorities involved in food safety and huge overlapping in responsibilities. Still, some duplication of inspection over the same production or operation are present (import of food of plant and of animal origin and animal feed, production of animal feed, control over hygiene in food establishments). The coordination among ministries is achieved through so called "panels" and is institutionalized by a specific piece of legislation through which are governmental bodies obliged to collaborate and share information on food safety among themselves. Each ministry keeps its own register of FBOs and same FBOs may be registered in both registers. The similar situation to the Polish situation is here also observed, all producers must apply food safety practices based on the HACCP system and all products produced in facilities which were registered for domestic production only, must be removed from the market by January 2010 (again 3 years grace period).

Croatia's chart of division of responsibilities looks pretty streamlined, but in practice the overlapping is noticed in control of food of plant origin in import and in control of hygiene and practices in food processing establishments. There is an evident lack of coordination of inspection activities among responsible authorities and no common FBOs register exists. Both ministries for health and agriculture authorize production premises. The system is still in the phase of reconstruction, number of state officers is decreasing (veterinary inspectors) and some responsibilities will be transferred to authorized veterinarians. Being the candidate for the EU accession, Croatia is succeeding in adopting new regulations harmonized with the EU, but the implementation process is demanding more time and resources both from the governmental and private entities.

In Serbia the new organization of food control has been installed according to the new Law on Food Safety being operational since June 2009. The ministry in charge of agriculture is the principal authority in the food safety area and performs control of primary and secondary production through the so called "General Inspectorate". Retail and catering are controlled by the Sanitary Inspection. The division of responsibilities as given in the Food safety Law is clearly defined. The register of FBOs was made by both ministries separately and would have to be centralized and updated. Previously, no collaboration between ministries in charge of food safety existed. Transfer of responsibilities was abrupt (in one day when the new Food Safety Law came into force), database on inspection of facilities which were under Ministry of Health and Social Welfare did not exist and Ministry of Agriculture and Rural Development is for months working on register of FBOs and on collection of data on food contaminants out of records of officially authorized testing laboratories.

- **The USA model** – in the United States, federal regulations covering food safety are fragmented and complicated. There is also, high level of overlapping in inspection jurisdictions. FDA has a responsibility for inspection over 80% of all food products at the market as well as numerous producers. The shortage of FDA inspectors exists and state inspectors perform inspection instead of the FDA. Almost, 20% of state inspectors do not follow instruction for inspection given by the FDA. The USDA has a very good organized meat inspection and plant protection service where guidelines for inspection practices are followed from the central to the local level. Both ministries control border posts. HACCP system is mandatory according to legislation. The USDA has guidelines and trainings for producers and inspectors in HACCP. It is implemented in large and medium size produces, but the number of small scale producers still have to implement it.

#### 4.1.3. Separation of risk assessment from risk management and risk communication:

The internationally recognized independent scientific opinion should be the ground for the national risk analysis system.

- **Food safety agencies:** in order to create independent bodies in the EU and in New Zealand agencies for risk assessment (scientific evaluation of all known and potential health risks associated with foodborne hazards) were created. In the EU countries there is a central European Food Safety Agency (EFSA) where delegates from all member states participate in the risk as-

essment process through various scientific panels. Members and candidate countries use recommendations and risk assessment data provided by EFSA for basis of their national regulations. National food safety agencies in the EU countries follow the model of EFSA, they implement recommendations provided by EFSA into drafts of the national legislation and perform risk analysis only in cases where some national specifics exist.

In Croatia the Croatian Food Agency was created with the same mandate, it works in close collaboration with the EFSA and performs risk assessment by itself only in cases which are very specific for the country. Otherwise it uses the expertise gathered at the EU level. This Agency is a model for other countries in the region, and it was followed by the Food Safety Agency in Bosnia and Herzegovina with which it collaborates extensively. The Swedish National Food Authority (NFA) is a risk assessment body with risk management in veterinary area, only, and the place where data on the overall inspection activities are collected and used when risk assessment process is undertaken. It collaborates closely with the EFSA and provides scientific data for the EFSA panels.

New Zealand is a very good example of separation of risk assessment, management and communication in one national agency outside the EU:

1. risk assessment, and only a part of risk management (some inspection activities, see the chapter 4.3) are performed by the NZFSA
2. risk communication and standard setting is performed by the Food Standard Agency Australia and New Zealand. This is a model of one common agency serving two countries and having the advisory role, helping governments and their responsible bodies in issuing standards and requirements, providing expert opinions in cases of non-conforming commodities, food emergencies, recalls, providing information to consumers, etc.
3. risk management is performed by inspection authorities. This segment needs to be strengthened by better integration of inspection authorities, but division of responsibilities within risk assessment-management-communication area is performed in the ideal way.

In the USA, risk assessment is performed by number of scientific and non-governmental bodies. In Poland, Slovenia, Serbia risk assessment is performed by scientific community upon request of governmental bodies, but in Poland and Slovenia being the EU member countries recommendations from the EFSA are usually followed with exemptions of some specific situation where scientific

explanation for the deviation of the internationally recommended ranges for pollutants exist.

#### 4.1.4. Inspection practices:

The responsibility for food safety in most of selected countries lies primarily with food producers, rather than with inspectors, although inspectors play an active role in overseeing compliance. This principle applies to both domestic and imported products.

**A. Domestic production – Inspection practices should be based on risk determination for each producer:** in Sweden and Denmark a comprehensive, risk-based approach to inspection is obtained with the focus on the entire food supply chain, placing primary responsibility for food safety on food producers with the government providing oversight.

In Denmark a very good system of self inspection of facilities overseen by inspectors, exist. Danish Veterinary Food Authority has a scheme for determining the general level of risk to be attributed to each facility. Facilities are classified in six risk groups based on seven risk factors (microbiological and chemical). Retailers are visited by inspector from 3 times per year to once in five years. Inspectors apply the so called: Fourth item approach. They always check:

1. the display of the inspection report with the sign “*Smiley*” (chapter 5.3.4) which illustrates whether the promise is excellent, good, moderate or bad<sup>6</sup>
2. hygiene (of premises and equipment)
3. whether the premises have their own self-checking
4. the fourth item is always changing (labeling, additives, composition of food).

They control implemented HACCP system through the system based on check lists.

Almost 80% of inspections in Sweden are performed as risk based inspection and only some smaller municipalities do not perform risk based inspection (they inspect smaller scale producers, mainly restaurants, catering services and perform traditional control based on the annual control plan of their municipality based on number of FBOs and number of inspectors). In Sweden, an electronic

system for data collection of inspections results is functioning, data from the check lists which inspectors use are imported in the hand computers during inspector’s visit. The system is covering about 70% of municipalities and allowing the central level (NFA) to have insight into data from the major part of the territory.

**Other models:** In Slovenia, the risk based plan for inspection is made and the process of implementation is under way. In New Zealand and the USA frequency of inspection of imported food is based on risk. In the USA, the need for the risk based inspection approach was recommended by scientific community, and even, by President Obama, himself. Inspection of smaller scale producers at the local level in New Zealand is covering mostly hygiene of premises and risk based inspection approach is applied to medium size and large producers and performed by regional inspection level.

Poland succeeded in implementation of the risk approach in veterinary inspection, but sanitary inspection still works according to ordinances which prescribe frequency of inspection visits and sampling.

In Croatia and Serbia risk based inspection approach is under development and respective capacities have to be built.

In Uganda no capacities for risk based inspection exist.

**B. Imported commodities – successful model of “equivalency” of inspection:** In the EU, USA and New Zealand imports of live animals and products of animal origin, which are considered at high risk, enter through approved border inspection posts. These shipments cannot clear the port or border crossing without veterinary approval. Shipments containing products the EU considers lower risk, such as: fruits, vegetables, cereals, and spices, must meet less strict requirements.

The EU and the US approach to import of high risk products of animal and plant origin is based on the “equivalency” or control of the performance of inspection bodies and producers in countries which are potential exporters, in order to comply with practices applied in the EU countries or the USA, themselves. In the EU, an inspection body – Food and Veterinary Office (FVO) performs audits of regulatory and control bodies, as well, as controls of practices implemented in production units in order to allow export from those countries and facilities to the EU. The FVO published numerous annual reports on control of inspection systems in the EU and so called Third countries (those wishing to export to the EU). The US Department of Agri-

<sup>6</sup> According to the Danish Food Act “the enterprise will be fined, if the enterprise omits displaying the control report, or the streamer, if the enterprise refuse to show appendix to control report to the customer, if the enterprise unrightfully displays an elite smiley at the its website, if the enterprise omits displaying the control report at the its website, or if the enterprise misleads the customers. A possible exception to the above is that the food control authority may except an enterprise from the requirement to display the control report in case the report is faulty.”  
[http://www.webreg.dk/magnoliaPublic/UNB/Ansøger\\_NY/Selvstudie\\_UK/Fodevarelovgivning/SmileyOrdningen.html](http://www.webreg.dk/magnoliaPublic/UNB/Ansøger_NY/Selvstudie_UK/Fodevarelovgivning/SmileyOrdningen.html)

culture established the practice of inspecting processors in their country of origin and has inspection offices in countries where major importers to the US come from. This practice proved to be successful in preventing contagious animal and pest diseases and contaminated products to be introduced into the USA, and as a result of this practice, the FDA plans to follow the same path.

#### 4.1.5. Fees:

##### Good practices in inspection of domestic production:

- *fees calculated according to the real time needed for the inspection:* in Denmark, Sweden, New Zealand and USA the inspection of domestic facilities is paid by facilities themselves, according to the duration of time inspectors have spent in the facility, with the exemption of the USA where domestic inspection is paid from the USDA budget. In Sweden and Denmark fees for inspection control are charged mostly from the budget. If inspection was requested from producers or if some non-conformities are found during inspection, than facilities are charged and there is a defined rate per hour of inspector's work to be paid.

**Other practices:** In Slovenia and Serbia domestic inspections are paid from the ministry's budget and only fines are charged. In Croatia checks are charged according to the quantity and type of products. Checks performed by authorized veterinarians are paid by producer to the veterinary organization whose veterinarian performed the check (85% of the sum, and 15% are redirected to the state Fund for Animal Health Protection).

##### Good practices in import:

- *mutual recognition of certificates and analysis* – In Slovenia, Sweden, Denmark and Poland, according to the EU principles, documents on products coming from the EU countries are regularly checked and lots are not sampled at border posts, with exemption when some non-conformities in documents were observed, or if through the FAO's Rapid Alert system the notification concerning specific producer or product is sent. If some non-conformities in results of analysis are found, than the next shipment should be mandatory checked and sampled and if compliant, the inspection returns to the annual check plan. Commodities coming from so called "third countries" non – EU countries, are tested according to the testing scheme of each ministry, but mandatory the first time the producer sends a shipment and than in 3-6 months periods if no non-conformities were found. In case they were found, the inspection becomes regular

or more frequent. Importer is paying only in cases when non-conformities are found, otherwise fees are charged from the budget. In New Zealand and USA, importers pay for the laboratory testing only if some non-conformities are found on testing.

**Other principles:** In Uganda, producers pay for laboratory testing, while inspection control is financed from the ministry's budget. Laboratories accumulate substantial financial sums from testing of samples.

Comparing percentage of the ministry's budget used for inspection it is seen that 76% in New Zealand and 48% in Serbia are spent on financing of inspection performance. In the USA some 16% of the USDA budget is earned from inspection fees and charges and in Sweden 0.01% of the national budget is used for the NFA activities (part of these activities are performing veterinary inspection in large and some medium size producers). Having in mind the size of the USDA, New Zealand or Swedish budget it is obvious that food inspection has a good financial basis and that food safety is an important issue in these countries.

In Serbia and Croatia in import of food, each lot is sampled and samples sent to laboratory for testing on sensory, microbiological and in majority of cases chemical analysis. These analysis are paid by importers (directly to the laboratory), and this practice proved to be inappropriate, since it leaves the space for corruption of inspectors. In domestic production inspectors either accept laboratory analysis (samples taken by producers and tested by some third part accredited laboratory), or inspectors sample by themselves and send them to the laboratory of their choice for testing.

#### 4.1.6. Number of inspectors:

Lack of inspectors could be overcome by:

- training and authorizing private veterinarians to perform inspection
- accrediting private inspection bodies
- self inspection performed by food producers themselves

In New Zealand, USA and Poland there is an evident lack of inspectors at the local level. In Sweden, inspection is performed by private inspection agencies as well as by governmental inspectors. In Croatia there is a shortage of sanitary inspectors at the local level, while in order to decrease the number of governmental employees, one third of veterinary inspectors who have to retire will be replaced by trained and authorized county veterinarians. The authorization for veterinarians to perform inspection will be issued on 5 years. (Table 2)

**Table 2: Comparison of number of inspectors and average number of inspection visits in nine countries**

Country	No of FBOs /full time employed veterinary inspector	No of FBOs /full time Ministry of Health inspector	No of FBOs/full time phytosanitary inspector	No of inspection visits/premise/year
Croatia	12.7	205		1-1.2
Denmark	37		1:117.5	0.35-0.5
New Zealand	5.7	73.4		1
Poland	5	46.6	66	1.9
Serbia	8.5	92.5		0.4-1.5
Slovenia	1.6	236	33	0.35-1.6
Sweden	2.75 (NFA) <sup>7</sup> 73.4 <sup>8</sup> -163 <sup>9</sup>			0.65
Uganda (Fish inspection)	0.27			
USA	0.84	151		0-0.4

Data on number of FBOs per inspector show that situation in veterinary inspection in 9 countries is rather compensated either with adequate number of state inspectors or combination of private and state inspection services. On the other side, inspections within ministries of health in all countries except in Denmark, suffer from lack of trained inspectors and high number of FBOs per inspector. The reason for this situation is that ministries of health are mostly responsible for small and medium size producers, retail and catering sector and the number of such FBOs is high in each of selected countries. On the other side, veterinary inspection deals with lower number of enterprises and inspectors have a smaller list of facilities they have to take care of. Data from Denmark show the high number of facilities per inspector, but this is only relative 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 high number of smaller producers, a single inspector has to take care of 33 (Slovenia), 66 (Poland) or even up to 117 (Denmark) producers. Having in mind that this is a lower risk area it is manageable to organize the inspection with smaller number of inspectors. It is obvious that in Denmark where self inspection is a practice, one inspector can be responsible for the large number of producers, while

in the same time in countries where such practices are not so widely spread, the number of FBOs per inspector must be lower.

#### 4.1.7. Training:

Inspectors need both basic and continuous training. The basic training is needed at the beginning of their work in order to prepare them for their individual work. They need to acquire principles of inspection performance as required by the authority they work for.

- **Curricula and specific training:** training of public veterinarians to perform official control is provided in Sweden and Croatia and this is a good example how a lack of inspectors can be overcome by using professionals adequately trained to perform inspections. In the same time inspectors have to be trained in specific aspects of the inspection of drinking water and food. It is usually not enough only to instruct them how to inspect food in general, but they have to specialize in the inspection of certain types of food (inspectors for food of animal origin, inspectors for food of plant origin, phytosanitary inspectors).

In underdeveloped countries there are obvious human capacity needs in food inspection as could be seen in Uganda. When starting food inspection services, or reconstruction of existing ones, a close attention should be paid to curricula and specific training of future inspectors.

- **Continuous training:** since the food industry is one of the fastest developing, new technologies and risks specific for certain types of products or technologies are emerging. In order to keep pace with these problems inspectors need continuous training. The HACCP system was introduced in order to identify risks and to keep them under control and food industry profited a lot from it. In order to understand and use the existing HACCP system or some other system of food safety implemented in the company, the inspector must have a good command of principles and practices associated with this system.

Training in the HACCP system principles, implementation and auditing is now the practice in the most developed countries with functional food safety systems.

In Denmark veterinarians receive classroom training in veterinary public health and food inspection as part of their veterinary degree course of study. Veterinarian when applying for the inspection job receive on-the-job training at the establishment level. Veterinary technicians often have experience as a slaughterhouse

<sup>7</sup> in counties number of veterinarians who also perform inspection varies from 0.5-4 per county

<sup>8</sup> without primary producers

<sup>9</sup> with primary producers

workers. They are educated at the Danish Meat Trade College. The 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 RVFAC. Special emphasis is placed on HACCP, SSOP and supervisory training.

The FSIS has a practice to train food inspectors from countries from which food is exported to the USA in modern aspects of food inspection: HACCP system implementation and control, sampling practices, risk based inspection. The idea is to train those who could be future trainers in their own countries. This practice provides safer food for export in those countries, but also, has a beneficial effect to domestic food safety in countries where FSIS trained inspectors. The same practice is applied by the EU authorities which use resources (for example: Swedish NFA or Danish DVFA) in the EU countries to train inspectors from “new members” and “third countries”.

In the EU countries according to the EC regulations member states are obliged to make annual training plans for inspectors and to organize them (Denmark, Sweden, Poland, Slovenia). Since regulations have to be transposed into the member countries’ legal documents, continuous improvements in inspectors practices and knowledge are secured. In Serbia and Croatia, inspectors from FVO and DG Sanco come to inspect the inspection systems, control of epizootics, control of plant diseases, GMO, control in emergency cases legislation, laboratories and food producers/companies (which could be potential exporters to the EU).

Ministries have to provide finances for training of inspectors and in the EU and USA, some 5% of the ministry’s budget is allocated for these purposes.

- **Use of check lists:** The modern approach to inspection audit is to use specific check lists and guidelines. This helped made more quantifiable inspection reports, provided common approach to the inspection practices and secured higher level of objectiveness in the inspectors’ work. In all countries we studied, check lists for food inspection are either in use or under preparation and guidelines for inspection are created at the national level. In the EU member countries, included in our study, those guidelines are created according to the EC Regulations 854/2004 and 882/2004.

#### 4.1.8. Quality control of inspection performance:

Quality control of inspectors’ performance is one of the means for the enhancement of the efficacy of the control system. It is best performed as:

- **Internal quality supervision:** In Denmark there is a set of internal audit systems for control of quality of inspection work in all directorates. Regional offices control effectiveness and accuracy of inspector’s work by checking samples of their reports thus controlling their clarity, uniform approach, accuracy in terms of legal requirements. A yearly performance conference for each DVFA employee is required by Danish law. There are written guidelines describing how the performance conferences should be conducted. The performance conferences are documented and retained by the supervisor of the employee in a confidential personnel file. Quality supervision, consisting of an administrative component and a program component, is conducted for veterinarians and non-veterinary technicians at least once every two years. The quality supervision report is maintained at the RVFAC. This is required by an official contract between the RVFAC and the DVFA. Each veterinary inspector is supposed to participate in one educational conference per year, and Records on inspections are kept on the regional level, but the software is uniform, so the Head office of DVFA can have insight in their data. “Expert groups” meetings of CEOs from regional offices and central level officials serve as forums where experiences in the approach to the implementation of legislation are exchanged. This is a part of the technical assistance from the central to the regional level.

In Sweden there is a “internal audit system” where National Food Administration and SBA audit performance of each County administrative board, and every CAB makes audits on every municipality in their region. They perform audits using data which each municipality must send electronically to CAB and CAB must forward it to the NFA. Three groups of parameters sent are used for assessing performance: microbiological, chemical contaminants and labeling. SBA performs audits on border post inspection according to the same parameters.

In Slovenia Veterinary Administration and Inspectorate for Agriculture, Forestry and Food have implemented internal audit systems. VARS is dealing exclusively with control of inspection work (are inspectors following rules and guidelines for inspection work and are they inspecting promises according to acting laws and regulations).

Director of the VARS regional office or Head of a section according to authorization of Director of VARS regional office is checking performance of each veterinary inspector at least once in 3 years (this is called verification of inspector's performance). They verify whether each inspector performed control over program for self inspection in premises he is responsible to control.

- **External quality assessment:** in the USA – an external review is organized according to data which FSIS acquires on the annual level. Two boards: the National Advisory Committee on Meat and Poultry and the National Advisory Committee on Microbiological Criteria For Foods assess data and provide impartial, scientific advice to Federal food safety agencies for use in the revision of their work and further development of food safety and inspection practices.
- **Combination of internal and external model:** In New Zealand the quality of the inspection services performance is assessed through internal and external third party audit. Assessors' competence is controlled by peer review, dual audits, audit report evaluation, internal auditing and auditor training.

#### Other models:

- The procedures for inspection performance audit can be provided through the ISO 9001 system implementation in inspections. This is the case in Poland and Slovenia in their sanitary inspections, and in Serbia this type of the auditing system is under construction in the General Inspectorate. Internal controls of the work of veterinary inspection in Poland are performed at least once per year. There are overall quality checks and some specific performance checks (are inspectors working in accordance with acting instructions).
- Special governmental body organized for control of inspection's performance: in Croatia, the State Inspectorate controls the performance of all inspections and this is a specific model where a special governmental body collaborates and audits work of all inspections in the country.

#### 4.1.9. Sampling:

The best results are achieved when companies implement the preventive approach based on the HACCP system and inspectors:

- **sample in case of non-compliance or according to the annual sampling plan:** in Denmark, Sweden, New Zealand, USA and in Slovenia sampling is done only if inspector presumes that some non-compliances are existing or upon complaint from consumers.

The annual sampling plans have to result from collaboration between responsible authorities, and to address the real risks for the population and environment. In all EU countries these plans are submitted to the FVO for approval. In Serbia and Croatia such plans are approved by the FVO for products of animal origin, while in the same time, ministries of health make their own annual sampling plans which are not so much risk driven and are broadly covering all groups of commodities. Such plans sometimes lack the product specific pathogens or some other characteristic types of contamination.

When preparing the annual sampling plan it is important to adjust the number of samples and frequency of sampling according to the size of production or according to severity of contaminant. The annual sampling plan has to be a tool for monitoring of certain contaminants, and each year plans have to be adjusted to the actual situation (incidence i.e. presence of contaminants in certain food, prevalence of animal or plant diseases in the country, prevalence of human food and water borne diseases). The good examples are from Denmark and Sweden where each year a sampling plan is adjusted to results of the previous year. The annual sampling plan is financed by the state budget in all countries we studied since it helps the state to keep under control human, animal and pest diseases.

The end spot sampling is still performed in Croatia, Serbia, Poland as the regular practice.

#### 4.1.10. Transparency

Producers and consumers are entitled to information regarding the status of the inspection report or recalls. Good practices are:

- **Internet access:** Denmark, New Zealand and the USA have very transparent systems of inspection work with reports of inspection being accessible on the internet in all stages of activities related to the certain case. Also, data on recalls are very easily accessible either from official sites or from sites of consumers' associations. In Sweden data are accessible electronically, while in Slovenia, only partially accessible.

In the USA detailed information about recalls, inspection activities and annual reports are available to the public.

Transparent inspection work is a safeguard from subjective approach and corruption. Also, as in Denmark and in New Zealand, if producers can assess electronic copies of reports and indicate in which stage is the correction of non-conformities, this could lower the frequency of follow-up visits to facilities and subsequently lower the costs of inspection (Table 3).

#### Other methods:

In Croatia and Serbia they cannot be assessed publicly and only FBOs in question get the printed copy of the inspection report. In Poland data on inspection (annual reports, periodical reports) are shared between inspection but are not available to the public.

**Table 3: Percentage of follow up visits of total No of annual visits**

Country	Follow up visits (%)
Croatia	20-30
Denmark	18
New Zealand	3
Poland	25
Serbia	10-20
Slovenia	20
Sweden	Not available
Uganda	Not available
USA	Not available

#### 4.1.11. Number of inspection authorities visiting FBOs:

Good practices are:

- *Clear division of responsibilities and recognition of results between inspections* – in Sweden only food inspectors visit FBOs regularly
- *Functional common food inspection body* – should be the most efficient and the most financially justified both from the governmental and producers' perspective.

Slovenia and Serbia other inspections visit food producers, too. Such are: ecological inspection, inspection on workers safety, fire inspection, metrology inspection. The more different inspections visit each premise, the more working days are spent, this adds to production costs and limits capacities for development of new products or implementation of new procedures, standards, etc. On the other hand, case of New Zealand shows that even though only food inspectors regularly visit premises, both analysis and fees charged by one

inspection body are not recognized by another two, so financial costs and lost of working hours is significant. The same mutual non-recognition of food inspections reports could be noticed in the USA, Croatia, Slovenia and was the case in Serbia until clear division of responsibilities came into force.

#### 4.1.12. Foodborne diseases:

Several elements of food safety systems are critical in control of foodborne illnesses.

They are:

- **traceback procedures**, or the ability to trace products "one step forward and one step back" which in the EU member states is mandatory. Food and feed business operators must be able to document the names and addresses of the supplier and customer, the nature of the product and date of delivery. They must have systems and procedures in place that allow for this information to be available to inspectors upon their demand. Exporters in non-EU countries do not need to meet this requirement, but EU importers should be able to identify their direct supplier in trading partner countries. Also, in trading countries mandatory animal identification programs for certain livestock species must be installed. In the EU countries from our study, as well as in New Zealand, USA, Croatia, Serbia animal identification is mandatory and trace back is secured for products of animal origin. For products of plant origin trace back is efficient in USA, New Zealand and the EU countries, while in Serbia and Croatia it is under development;
- **cooperation between government veterinarians and public health officials** is important in prevention, eradication and control of numerous animal diseases or pathogens which could be transferred to humans (avian influenza, BSE, strains of *Salmonella*, *E.coli* and other pathogens). The ability to test new pathogens and to connect specific strains found in human material with the food that caused the epidemic is essential in prevention and eradication of sources of infection. Well equipped laboratories with trained personal, accredited methods, proficiency testing among laboratories and information exchange between authorities are essential in control of food pathogens. Also, results from annual monitoring plans and information from the international community (international agencies and authorities in neighboring countries) could greatly enhance capabilities of a country to control food pathogens.

Food borne diseases are numerous worldwide and inspection performance could be measured by trends in food borne diseases during certain period of time. Only scientifically based and fully functional food and water control systems provide significant improvement in foodborne diseases epidemiological data. Otherwise, these data either show the constant number of foodborne infections or even worsening during time. There is no common principle in gathering or presenting the epidemiological data, so comparison between countries is difficult to make. Nevertheless, in Denmark real breakthrough was obvious in terms of *Salmonella* control with first, government organizing the national action plan and second, transferring the responsibility for maintenance of this plan to producers. The Swedish food and feed production and control system proved to be very effective in control of *Salmonella* in domestic production and in identification of pathogens in imported goods. In New Zealand annual plans for several food pathogens are functioning. The practice to trace also, *Campylobacter*, *Listeria monocytogenes*, *E.coli O157:H7* in food and feed proved to be very important in pathogen reduction in New Zealand, the USA, Denmark, Sweden.

- **recall procedures** which provide the ability to stop products that could be hazardous to human or animal health. Information about recalls being easily assessable help strengthening the public awareness on food safety.

**Table 4: Data on recalls**

Country	Recalls
Croatia	Not available
Denmark	0.7 (import)
New Zealand	1.2 (import) 0.3 (domestic)
Poland	2.4 (domestic)
Serbia	3.8 (import) 12 (domestic)
Slovenia	1.2 (import)
Sweden	0.3 (domestic)
Uganda	Not available
USA	0.9 (domestic)

Data on recalls for domestic products are not publicly available in Slovenia and Denmark, while they are not easily accessible for imported goods in Poland, USA and New Zealand. In Croatia no data on recalls were publicly accessible. (Table 4)

**Fig 10. Risk based approach**



In the EU countries and in the USA there are databases of non-governmental organizations keeping records of food recalls (both domestic and imported goods). They are good examples of public taking part in the food safety system. Accessibility of reports on recalls and foodborne risks is the way to perform the risk communication which is the third pillar of the risk based approach to food safety (Fig.1)

## 5.0. COUNTRY REPORTS

The most functional model is the Danish risk based food safety system with the centralized inspection model.

The Swedish and New Zealand models are showing particularities of decentralized systems with good coverage of the food safety systems at the central level and gaps at the local level. These two countries, on the other hand, have very good food safety agencies where expertise in development of regulations and their implementation is gathered. Both countries are good examples of the regional collaboration in matters of food safety.

Slovenia, Croatia and Serbia emerged from the same model of the food safety system and transformed their systems according to the EU model (with Slovenia being the most harmonized with the EU). They are good examples of transitional countries still remodeling inspection and Croatia and Serbia going towards one inspection agency. Poland is a model of the transitional system, too. These four countries are good examples for the reform of the food safety system in the CIS countries, since the historical background is similar.

The USA model is a good example of the organization of import inspection.

The Uganda model can be recommended for countries which develop their food safety system *de novo*.

## 5.1. CROATIA

Croatia is a Western Balkan country, a candidate country for accession to the EU, with population of 4.443.000 inhabitants (2007), GDP (PPP) of \$ 70 billion (according to Croatia Statistical Office data) and GDP per capita of \$15.700 (according to EU-ROSTAT). The value of agriculture and food production in 2007 was 5.9% of the GDP. Agriculture and food production sector is increasing but much slower than other sectors since 2005. The export (being 8.420 million Euro) markets for agricultural and food products from Croatia are Bosnia and Herzegovina, Serbia, Montenegro, Macedonia and from the EU Member States – Italy, Slovenia, Germany, Austria. The main export commodities are sugar, processed products, fish and molluscus, cereals and tobacco. The majority of import (value of 18.601 million Euros) came in 2007 from Italy, Germany, Brazil, and Hungary. The agro-food sector provided 9,6% of the net export and 8.1% of the net import in 2007.<sup>10</sup>

### 5.1.2. Legal framework

A. In Croatia the **Food Act (46/07)** – basic food safety law, harmonized with the EU Regulation 178/2002 was adopted. This Act sets general overview and requirements on food and animal feed safety defining: obligations of the food business operators, the official control system, food laboratory operation requirements, obligation for food manufacturers to implement HACCP (all FBOs by January 1, 2009), establishment of the Croatian Food Agency, crisis and emergency situation management, and clearly defines responsibilities of relevant authorities regarding food control (food of animal origin is the main responsibility of the ministry in charge of agriculture and food of plant origin of the ministry in charge of human health).

B. According to the **Law on State Inspectorate (1999)** there is one central administrative body called the State Inspectorate, responsible directly to the Government of Croatia, which integrated the performance of 12 various inspection which before this integration were dispersed in four ministries. The State Inspectorate covers: commerce and crafts supervision, catering and tourism, quality of products, supervision in agriculture (wine-growing, fishing industry and cattle breeding) and forestry, labor relations and occupational safety, electric power supply and mining and pressure vessels supervision. The Headquarters are located in Zagreb – the capital, and five Regional Units, their headquarters being in Rijeka, Split, Osijek, Varazdin and Zagreb. Regional Units have 44 Branch Offices.

The State Inspectorate, is competent for the overall inspection over the economic entities. The State Inspectorate coordinates the work of other inspections with work of inspections directly involved in food safety.

All inspectors (and thus inspectors dealing with food safety, also) in Croatia work according to the Law on State Inspectorate which prescribes the area of inspector's work and authority. Inspectors can initiate the inspection, conduct it, issue opinion, prescribe different measures (fines, closing of facilities or parts of facilities, recall products from the market, and initiate the legal offence procedure – submit to court a request for trial). In case when business entity complains to the inspector's decision, the complaint is to be submitted to the State Inspectorate, where the Chief Inspector nominated a specific committee to deal with complaints. Inspectors perform announced and non-announced visits (upon their own decision). There is a prescribed amount of fines depending on type of non-conformities met. Within this law, a general methodology of sampling performed by inspectors is defined (sampling of feed food of animal origin is precisely defined in Veterinary Law 41/07 and rulebooks and for phytosanitary purposes in the Plant Health Act 75/05). If a complaint is found to be justified, the inspector has to revise his decision in 8 days, if not justified the decision is final and the inspector has to oversee the implementation of decision.

C. **Rulebook on the Official Inspection of food, feed and animal health (46/07)** prescribes in detail: inspection procedures, possibilities of transfer of certain inspection work to other bodies or individuals (see later in the 4.1.1.) and ways of controlling these bodies or individuals, inspection reports, sampling, laboratory testing, crisis management, control of good coming from import, recall procedures, collaboration with customs, guidelines for the development of the multiannual control plan, activities of the EU bodies in the food control (requirements for training of inspectors, payment scale for the permanent inspection control over slaughtering, fishing, milk production, import of goods).

D. **Law on Sanitary Inspection (2008)** gives the authority to sanitary inspectors to initiate and perform: inspection, sampling, recall, confiscate, closure, prescribes fines. This Law is in accordance with the Law on State Inspectorate and the **Law on Official Procedures (2009)** which prescribe the same authorities to inspectors.

### 5.1.2. Responsible authorities for food safety (Fig.2):

The Ministry of Agriculture has responsibility for food of animal origin and the Ministry of Health

<sup>10</sup><http://server01.globaldizajn.hr/mps.hr/UserDocsImages/publikacije/Bro%C5%A1ura%20Hrvatska%20poljoprivreda.pdf>

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

**A. Ministry of Agriculture, Fisheries and Rural Development (MAFRD)** – 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)<sup>11</sup> of the FAO and contact point is in MAFRD.

There are three Directorates involved in Food Safety:

- **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, and disposal of animal by-products. Inspection covers border and inland inspection with: state veterinary inspectors, border veterinary inspectors, 20 county offices and Zagreb (the capital) city office. Total number of veterinary state inspectors is 164<sup>12</sup>. It is planned that the number of state inspectors should decrease to 96 and that 180 authorized private veterinarians should receive training in order to be able to perform inspection (authorization to be valid through the 5-year period).

**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, and

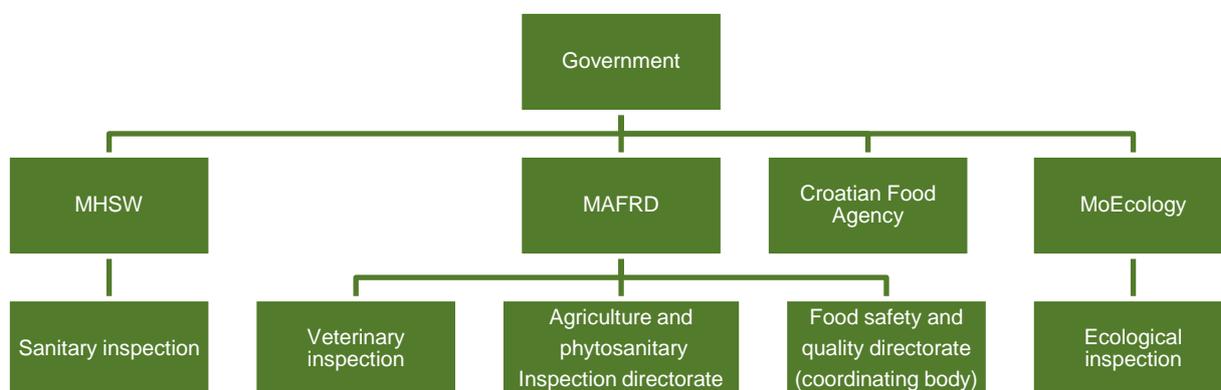
- **The Food Industry Directorate** – in charge of regulation of food quality, labeling, wine regulations, traditional food products, natural mineral and table water.

**B. Ministry of Health and Social Welfare (MHSW)**

- **Directorate for Sanitary Inspection** is responsible for regulation and control of food safety of products of non animal origin, novel and dietetic products in food production – control exhibited in production, retail and in import. Total number of sanitary inspectors in the country is 205<sup>13</sup>. They are organized in the head office at the central level and in 21 counties as 81 field “Operative Units” at the county level.

**C. Ministry of Ecology** – responsible for regulation and inspection of waste (solid and water).

**Fig. 2. Organization of the food safety inspection in Croatia**



<sup>11</sup> Rapid Alert System for Food and Feed (RASFF) is a system put in place in 1979 as a network that allows the EC and EU member states to share information and take immediate actions in case some food presents danger to health. Legal basis for the system is made in Regulation EC 178/2002.

<sup>12</sup> www.mps.hr

<sup>13</sup> www.mzss.hr

**D. 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 and has 8 scientific boards covering different issues from animal and plant safety, animal welfare, to food safety and residues in food and feed. They provide scientific opinion and risk assessment to regulators and public.

Collaboration of inspection services is obtained directly through their monthly meetings and through the Croatian Food Safety Agency.

The Agency is a model of similar agencies in the region, for example the Bosnia and Herzegovina Food Safety Agency.

**Table 5. Division of inspections**

Area	Inspection authority
Animal health	State veterinary officers and authorized veterinarians in counties
Food of animal origin	State veterinary officers Sanitary inspectors MHSW
Import of animals and food of animal origin	Border state veterinary inspectors
Feedingstuff and animal nutrition – import	Border state veterinary inspectors Phytosanitary inspectors, Customs office
Feedingstuff and animal nutrition – production	State veterinary officers Phytosanitary inspectors,
Animal byproducts	State and county veterinary inspectors
Veterinary medicines authorization and distribution	Veterinary inspection
Veterinary medicines residues	State veterinary inspection, Sanitary inspection MHSW
Food and Food hygiene	State and county veterinary inspection, Agriculture inspection, Sanitary inspection MHSW
GMO	Agriculture inspection Sanitary inspection MHSW Ecological inspection
Import of food of plant origin	Agriculture inspection, Sanitary inspection MHSW, Customs authorities, Phytosanitary inspection
Plant protection products authorization and sale	Phytosanitary inspection, Sanitary inspection MHSW
Plant protection products residues	Sanitary inspection MHSW, Veterinary inspection, Phytosanitary inspection
Animal welfare	State veterinary inspectors and authorized county veterinarians
Plant health	Phytosanitary inspection
Restaurants, shops	Sanitary inspection MHSW, Agriculture inspection

### 5.1.3. Register of FBOs:

There is no central register of FBOs. Each ministry has its own register. Total number of registered FBOs is 45.700. According to the official Veterinary Office Register (2009)<sup>14</sup> there are 1321 active producers. There are some 449.896 agricultural holdings according to the Official Statistical Office data from 2006 (the register should be updated in 2009)<sup>15</sup>.

In this moment there is no coordinated control plan or coordinated monitoring plan and inspection is not yet done on the risk basis. According to obligations which Croatia has in the process of association to the EU, monitoring plans have to be coordinated in order to identify the real treats for food safety. Until the new Law on Sanitary Inspection (2009) was issued, both sanitary and veterinary inspections were controlling the area of production of food of animal origin.

### 5.1.4. Frequency of control and fees

Both ministries have their annual inspection plans. The annual monitoring plan for residues in food of animal origin was accepted by the FVO. Inspectors visit each FBO at least once a year and if non-compliances with regulations are identified additional inspection visits may follow (1-2). Duration of inspection visit is from 0.3-3 days depending on the type of inspection (60-70% of working time per year inspectors spend in field work according to the official Report on control activities in 2007). 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 MHSW is financed from the governmental and the county budget according to the Framework Plan of Food Inspection.

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

<sup>14</sup> <http://www.mps.hr/default.aspx?id=6677>

<sup>15</sup> [www.dzs.hr](http://www.dzs.hr)

**Table 6. Data on inspection in 2008<sup>16</sup>**

Total number of inspectors (veterinary +sanitary)	369
No FBOs in sanitary inspection register	45.700
No FBOs in veterinary inspection register	1380 <sup>9</sup>
No of veterinary inspectors	164 <sup>9</sup>
No FBOs per veterinary inspector	12.7
Average No of veterinary inspector visits per FBO	1.2
No of inspection visits as percent of Audit Plan (%)	97%
No of sanitary inspectors	205
No FBOs per sanitary inspector	210
Average No of sanitary inspection visits per FBO	1.5
Percentage of visits with registered nonconformities	Not available
Annual number of Follow –up visits (% of all audits)	20-30%
Annual No of appeals	Not available
Annual No of recalls	5.81%

### 5.1.5. Sampling:

Sampling is performed by veterinary and sanitary inspectors. Total number of samples taken for microbiological analysis was 40.900 in 2007, of which 5.81% were non-compliant with the national regulations, also 31.308 samples were analyzed on chemical parameters and 3.51% of samples were non-compliant.<sup>17</sup> It is important to stress that the number of inspection samples is not the sum of both microbiological and chemical samples, since the same specimen can be analyzed on both. Comparing with results from 1996-2006 no significant changes could be observed (5.81-7.44% of microbiological and 3.51-6.12% of chemical non-compliances were found).<sup>18</sup>

Laboratory analysis of samples taken by inspectors in import control are paid directly to laboratories by importers. Testing of samples in production and retail is paid by the respective ministry, with exemption when samples prove to be non-conforming with regulations when producers or retailers pay the laboratory fees. Samples tested for purposes of the annual monitoring plan sampling are financed from the budget of the ministry (either of agriculture or health depending which one took samples).

Overlapping of sampling by two ministries existed until latest version of the Law on Sanitary Inspection (2008) was issued, since Food Act was not in

accordance with the previous Law on Sanitary Inspection (1999) which allowed sanitary inspection to control all types of FBOs.

### 5.1.6. Visits of controlling bodies other than those participating in the food safety system control to FBOs:

- Fire inspection
- Safety on work
- Metronomy (inspection of measurements)

### 5.1.7. Quality control of food inspections:

One of the roles of the State Inspectorate is to control the performance of inspections. It is merely the performance according to legal requirements and to financial output. Quality assurance systems in inspections dealing with food safety have to be implemented and regularly assessed and that will be a basis for further improvement in inspection work. Also, that will help obtain higher level of objectivity in inspection work.

### 5.1.8. 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 was not significantly updated since 1990. Results of this monitoring can be acquired only if official request is proceeded to the Sanitary inspection.

Integration of data in the central IT system for inspections was recommended in the report of the EU control mission when Croatia applied for the candidate status to the EU.<sup>7</sup> In 2008 the central IT system was introduced in the sanitary inspection. Central IT system is under development in the MHSW.

### 5.1.9. Training:

Annual training of inspection is responsibility of each inspection according to the Croatia Food Act. Sources of funding are merely from the EU pre-accession funds and from these sources the capacity building and training of the Sanitary Inspection was done in the period 2002-2006, capacity building in prevention of zoonosis and control over pesticide Residues.

Separate trainings in the HACCP were organized for inspectors and for producers. Since the HACCP is mandatory in production of food of animal origin since 1999, numerous premises improved their performance and this resulted in licensing them for export to the EU. Yet, a significant number of premises doesn't comply with the EU requirements.<sup>19</sup> Training on implementation of check lists for grad-

<sup>16</sup> Obtained through personal interview with officials and from official web sites

<sup>17</sup> Annual Report of the Institute of Public Health

<sup>18</sup>

<http://www.seefsn.org.yu/documents/croatia/Croatian%20Country%20profile.pdf>

<sup>19</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)

ing establishments was conducted in 2005 and check lists are in use.<sup>20</sup> In 2008/2009 veterinary inspectors were trained in assessment of HACCP.

It has to be emphasized that State Inspectorate had trainings organized for inspectors dealing with food quality, but since food quality and safety are different issues that cannot be taken into consideration when dealing with food safety.

#### 5.1.10. Food borne diseases:

Number of food borne infections ranges from 8000-10.500 per year, with salmonellosis representing the 50% of the total number of infections. Data from 2007 show 3500 cases of salmonellosis. Number of outbreaks ranges 50-100 per year and besides *Salmonella species* causes are frequently *Streptococcus species* and parasite *Trichinella*.

According to the official data number of food associated outbreaks varies between 50-100 annually, with the total of 8000 – 10.500 cases, of which salmonellas are registered in 3500 cases in 2007 (or almost 50%). The main sources of *Salmonella* were eggs and meat.<sup>21</sup>

There is no significant difference between data for 2007, 2008 or 2009 as reported by the Institute of Public Health<sup>22</sup>.

#### 5.1.11. Summary:

Since 1990 Croatia has made a lot of changes in the food safety inspection. Starting from the end-point checking prescribed by the ex-Yugoslav legislation to the process control in food of animal origin export facilities and facilities which 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. They collaborated in preparing DG SANCO missions<sup>23</sup>, CARDS projects<sup>24</sup>, adjusting legislation process etc. They, also collaborated in development of the National Food Safety Strategy<sup>25</sup> where a comprehensive analysis of the situation in Croatia was made and directions for further work indicated.

There are still important issues to be addressed such as: complete harmonization of legislation with the EU (secondary legislation mainly), to improve coordination among authorities, to ensure impartiality of inspection work, to proceed with training of inspectors and implementation of skills especially towards risk based inspection control, to reform sampling schemes for food of non-animal origin, to strengthen foodborne diseases surveillance and to support the introduction of own-check systems based on HACCP principles and good hygienic practices.

<sup>20</sup> Veterinary Directorate data 2009

<sup>21</sup> Strengthening food safety and nutrition policies and services in South-eastern Europe, WHO 2009

<sup>22</sup> <http://www.hzjz.hr/epidemiology/news/index0702.htm>

<sup>23</sup> DG SANCO – EU Directorate General for Health and Consumers checks the situation in the EU and third countries in terms of practices and harmonization to the EU rules

<sup>24</sup> CARDS program – The EU Community Assistance for Reconstruction, Development and Stabilization

<sup>25</sup> [http://ec.europa.eu/enlargement/pdf/croatia/screening\\_report\\_12\\_hr\\_internet\\_en.pdf](http://ec.europa.eu/enlargement/pdf/croatia/screening_report_12_hr_internet_en.pdf)

## 5.2. Denmark

The Kingdom of Denmark consists of five regions and 98 municipalities. It is estimated that there are 5.515.287 inhabitants (2009) and GDP in 2008 was \$203.7 billion (PPP). Agriculture participated in the GDP with 1,3%, industry 25,7% and services 73%. According to IMF the GDP per capita was 38 400 \$ in 2008 and 37.391 \$ in 2007.

Approximately 65% of Denmark's total land mass is used for agricultural purposes and production is extensive, so that Denmark produces enough food to feed four times its population. In 2008 export of food and agricultural products valued 17.6% of the total export value. More than two thirds of agricultural production is exported to over 200 countries and 61% goes to the EU with Germany, UK, Italy and France being the biggest buyers. Also, USA, Japan and the Eastern Europe are very important export markets for Danish food and agricultural products. Main agricultural products are meat, milk, grains, seeds, fish and shellfish of which 4.5-5 million metrics tons of milk, 25 million pigs, 120 million broilers and vast quantity of eggs, beef and dairy products are exported annually.<sup>26</sup>

### 5.2.1. Legal framework

A. The **Law on foodstuffs**<sup>27</sup>, fully in line with EC Regulation 178/2002.

B. **Law on self-control in food-producing undertakings**<sup>28</sup> with amendments that treat matters as the traceability of products, the maintenance, cleaning and disinfection of premises, and personal hygiene in primary production and food processing undertakings. There are Annexes, dealing such as: fish and fishery products, meat products, and crustaceans and mollusks.

C. Orders dealing with: materials that come in contact with food, contaminants, on special provisions for the organization of the official control of animal products (defining official inland and export/import control, penalties).

The reform of the food safety system started in 1997 and resulted in centralization of the Danish food safety system. A new agency – The Danish Veterinary and Food Administration (DVFA) consolidated practically all food safety functions and including inspections in the of control of food of animal origin. Before inspection functions were distributed among the Ministry of Health, 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 which were previously distributed among several state agencies. Since before the reform municipal inspectors used to be a part of small system, to foster the acceptance of new approach and reinforce the new agency's mission was one of the main challenges of the reform. In order to solve the problem DVFA moved employees to centralized locations and held monthly meetings on new system.

So, now Danish food system has following structure:

### 5.2.2. Responsible bodies for regulations and control of food safety

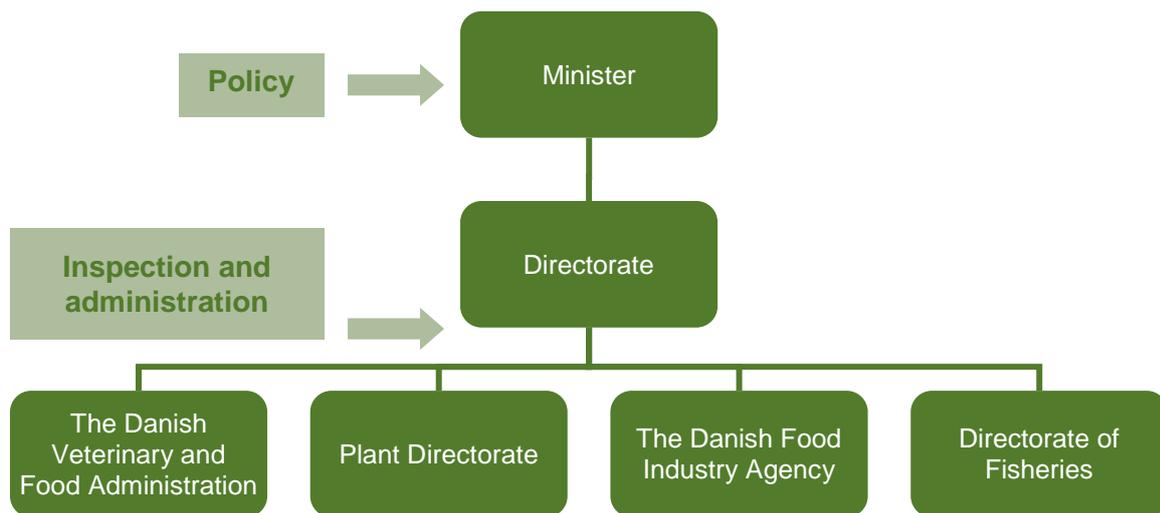
**A. Ministry for Food, Agriculture and Fisheries (MFAF)** – is the main body responsible for regulation and control of food safety. In Denmark the hierarchy in implementation of food regulations is conducted from the top to the local level. The Ministry itself and the permanent Secretary are responsible for determination of policy in agriculture, fisheries and food production, as well as for development of the food safety policy. The so called “Department” is divided into four separate bodies – “Directorates”. They are: the Veterinary and Food Administration, the Plant Directorate, the Danish Food Industry Agency and the Directorate for Fisheries. The fourth level of the organization are the individual labs and institutes under these directorates – they are responsible for research, development, and analysis for the Danish government.

<sup>26</sup> <http://www.dst.dk/>

<sup>27</sup> Denmark (Greenland). Decree No. 523,2004

<sup>28</sup> Denmark (Greenland). Order No. 888,2005

Fig 3. The organizational structure of the Danish Ministry of Food, Agriculture and Fisheries



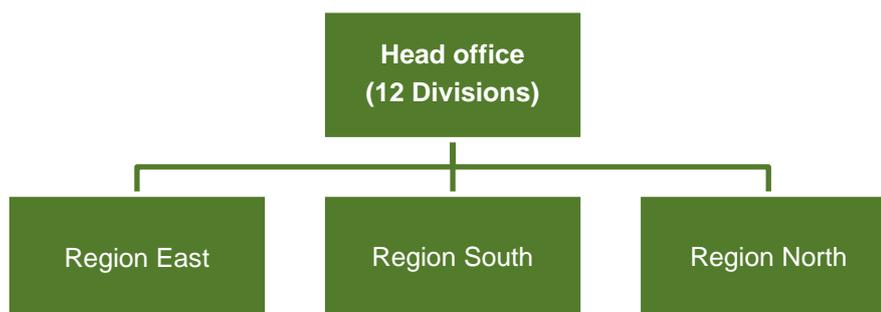
**The Directorate's** responsibility is to cover the whole food chain “from farm to table” and to ensure that basic food law (Danish Food Act) is implemented. It executes its authority through four agencies which have both administrative and control function:

**a. The Veterinary and Food Administration (DVFA)** mission is to promote safety, health and quality. It is responsible for: animal health, animal welfare, zoonosis protection, safety of food of animal origin, healthy eating habits of population, quality of food, control of residues, control of organic food, ethical considerations.<sup>29</sup>

The DVFA is, responsible for issuing regulations, food inspection, feed inspection, provision of information and advice in primary and secondary production of food. The Danish Food Act provides the foundation for one overall national food and veterinary inspection authority. Within the 12 divisions of the Head office 8 are dealing with food safety, animal health and welfare and feed safety.

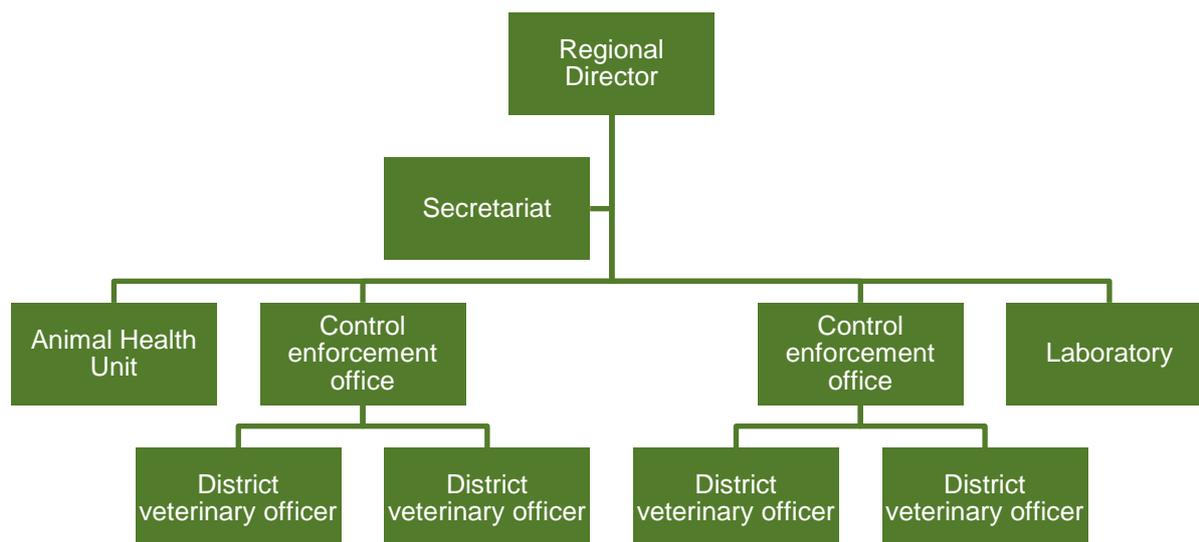
The control role of DVFA is decentralized and executed by 3 Regional Offices (fig. 3) and their 11 regional units – each one is Regional Veterinary and Food Control Authority which is important in streamlining the national policy from top to bottom (Fig 4). The Regional Authorities are knowledge centers 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.

Fig 4. Structure of the DVFA



<sup>29</sup> www.fwm.dk

Fig 5. Structure of the Regional DVFA office



The DVFA employs about 540 full-time employees, while the 10 Regional Authorities employ about 1.370 full-time employees.<sup>14</sup>

Two specialist research institutions are also connected to the DVFA: The National Veterinary Laboratory (SVS) and the National Institute for Virus Research (SVIV). Their role is in the veterinary emergency service. SVS mission is to prevent and combat both livestock disease and food-borne human diseases originating in primary livestock production (zoonoses). SVIV 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 the reference laboratory which instructs local private control laboratories in methods and problem-solving techniques for carrying out control analyses. In collaboration with the accrediting authority, the DVFA evaluates whether the quality of the control laboratory's work is acceptable.

The Food Inspection's Flying Squad is located in all three regional offices and works with the control and enforcement offices to check the accounts and documents of enterprises with particular thoroughness.

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 so-called self-inspection programs with systematic

action plans to ensure that regulations are observed in the handling of food products and livestock. A company's self-inspection program have to ensure – at 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>30</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.

Roles of the inspection:

- information to producers on how to implement regulations
- registration of food business operators and assessment of the company by inspection of pre-conditions for the production unit (authoriza-

<sup>30</sup> [http://www.uk.foedevarestyrelsen.dk/Inspection/Self\\_inspection\\_programmes/forside.htm](http://www.uk.foedevarestyrelsen.dk/Inspection/Self_inspection_programmes/forside.htm)

tion, approval or registration must be performed prior to production or selling of food products)

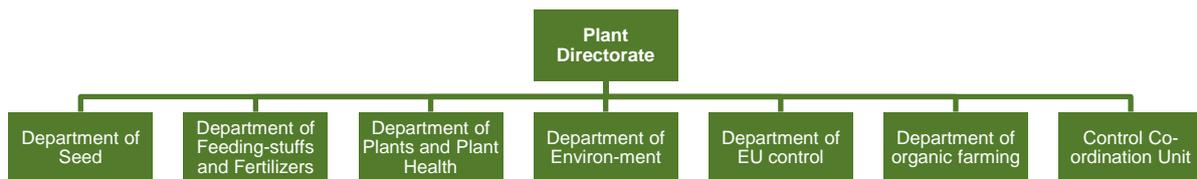
- sampling (determined by the inspection authority or at the central level – for example the residue monitoring scheme or monitoring of certain pathogen at the national level)
- risk based inspection – on the need basis
- to trace the source of the problem along the production line
- sanctions sufficient to enable that regulations are respected
- uniformity of effects – at the national and sector level

The DVFA is moreover required to co-ordinate the control process – such as by harmonizing professional assessments and techniques, and by ensuring that guidelines for the prioritization, reporting, and frequency of inspections are complied with. Evaluation of regional follow-up in special areas – new inspection methods (i.e. organic, inspection for export to USA). Thus the DVFA conducts annual visits to regions in order to be acquainted with their work and sometimes takes part in the inspection visit in order to harmonize the inspection work on the national basis.

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.

**Fig. 7 Danish Plant Directorate**



**b. The Danish Plant Directorate** is responsible for inspections of companies and farms and controls: seeds, animal feed production and safety, health and quality control of plants, production of fruit and vegetables, organic farming and EU agricultural schemes. Plant Directorate is engaged in policy, legislation, control and provision of services to authorities and private sector. Inspections are conducted by six district offices. There are 428 employees in this Directorate of which 115 are in regional offices.

**c. The Danish Directorate for Fisheries** is responsible for hygiene inspections at sea and fresh water (vessels except freezing and cooking vessels) and where the fish is landed, at auctions, and the premises of the first buyer. The Directorate has two regional inspectorates and seven regional offices. The total staff is 245 of which 95 are in the inspectorates. There are, also four inspection vessels with 80 employees.

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

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

**Table 7. Division of inspections**

Area	Inspection authority
Animal health	Regional Veterinary Food Authority
Food of animal origin	Regional Veterinary Food Authority
Import of animals and food of animal origin	Regional Veterinary Food Authority & Customs Services
Feedingstuff and animal nutrition	Plant Directorate
Animal byproducts	Regional Veterinary Food Authority
Veterinary medi-	DVFA and Regional Veterinary

Area	Inspection authority
cines authorization and distribution	Food Authority
Veterinary medicines residues	Regional Veterinary Food Authority
Food and Food hygiene	Regional Veterinary Food Authority
GMO	Regional Veterinary Food Authority Plant Directorate Danish Environmental Protection Agency
Import of food of plant origin	Regional Veterinary Food Authority
Plant protection products authorization and sale	Regional Veterinary Food Authority Plant Directorate Danish Environmental Protection Agency
Plant protection products residues	Regional Veterinary Food Authority
Animal welfare	Regional Veterinary Food Authority
Plant health	Plant Directorate
Restaurants, shops	Regional Veterinary Food Authority

### 5.2.3. Register of FBOs:

There is a detailed register of facilities producing food of animal origin for export and local consumption. Total of all such premises is 4400. Total number of food and feed producing establishments is 49.600 and there are 69.730 registered shops and restaurants (as of January 2008).

### 5.2.4. Frequency of control and fees:

The Danish Veterinary and Food Administration checks that everyone selling food complies with the law, so that consumers health and rights are protected and that consumers were not misled by producers' descriptions of their goods. The FBOs responsibility is that food is safe. The monitoring of food in Denmark is the task of the 3 regional food authorities that regularly check on all food producers. Checks typically take place in the form of an unannounced visit. In certain cases, the regional monitoring authorities may warn of the inspection in advance. Irrespective of whether the inspection is announced or unannounced, the company must be prepared to devote the time necessary to review its activities in cooperation with the inspectors. During their visit, the inspectors will often take samples of raw materials, semi-finished goods, packaging or additives.<sup>31</sup>

There are no prescribed values of fees and fines. Fines are prescribed according to values that previous similar case was fined for. There are four sanction instruments: warnings (no legal status but important for risk ranking), enforcement notice

(ban, required correction, training, consultancy), administrative fine (prescribed when it is the first time and when it is not serious problem) and reporting to police for prosecution (complicated or repeated frauds).

Quarterly regions have to report to the Head office and thus system of control and effectiveness is maintained. Facilities are inspected according to the level of risk and frequency of inspection is lowered as the level of risk decreases or if at four visits within the same year there were no remarks on hygiene or safety. Such establishments are called – “Elite”, and will receive fewer inspections. One third of all food and feed producing establishments has the “Elite” status.

DVFA has a scheme for determining the general level of risk to be attributed to each facility. Facilities are classified in six risk groups based on seven risk factors (microbiological and chemical). Retailers are visited by inspector from 3 times per year to once in five years. Inspectors apply the so called: Fourth item approach. They always check:

1. the display of the inspection report with the sign “*Smiley*” which illustrates weather the promise is excellent, good, moderate or bad<sup>32</sup>
2. hygiene (of premises and equipment)
3. weather the premises have their own self-checking
4. the fourth item is always changing (labeling, additives, composition of food).

Wholesalers are inspected from seven times per year to once in every two years.

So called “*Smiley approach*” was introduced in Denmark in 2001. It has become one of the most well known public schemes. Now smiley-reports are to be posted in all supermarkets, at groceries, bakeries, butchers, greengrocers, in kiosks, restaurants, pizzerias, canteens, hospital kitchens and elderly homes. Even the outdoor hot-dog stands have them. At each inspection a number of control areas are checked. The Smiley given by the inspector equals the result for the worst area. All results and the inspectors' remarks are published on the inspection report. There are four different Smileys. They symbolise that the inspector either:

<sup>31</sup> [http://www.uk.foedevarestyrelsen.dk/Inspection/The\\_monitoring\\_of\\_food/for\\_side.htm](http://www.uk.foedevarestyrelsen.dk/Inspection/The_monitoring_of_food/for_side.htm)

<sup>32</sup> According to the Danish Food Act “the enterprise will be fined, if the enterprise omits displaying the control report, or the streamer, if the enterprise refuse to show appendix to control report to the customer, if the enterprise unrightfully displays an elite smiley at the its website, if the enterprise omits displaying the control report at the its website, or if the enterprise misleads the customers. A possible exception to the above is that the food control authority may except an enterprise from the requirement to display the control report in case the report is faulty.” [http://www.webreg.dk/magnoliaPublic/UNB/Ansøger\\_NY/Selvstudie\\_UK/Fodevarelovgivning/SmileyOrdingen.html](http://www.webreg.dk/magnoliaPublic/UNB/Ansøger_NY/Selvstudie_UK/Fodevarelovgivning/SmileyOrdingen.html)

-  had no remarks, or
-  has emphasised that certain rules must be obeyed, or
-  issued an injunction order or a prohibition, or
-  issued an Administrative Fine, reported the Company to the Police or withdrew an approval.
-  The elite-smiley is awarded to enterprises who have received the happy smile on the last four inspection-reports – and no 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. All results and the inspectors' remarks are published on the inspection report. 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>33</sup>

In 2008 DVFA performed 250 checks in transport of animals (targeted at loading places, each year another group is selected for control).

Animal feed is control by DPD twice a year in production establishments and once a year on farms which have HACCP implemented. The focus is on control of:

- HACCP/GAP implemented
- Traceability
- Control of the end products
- Storage, separation, transport
- Cleaning.

In import feed is controlled only if arriving from the source that proved historically to be unsafe, otherwise only check of documents is performed.

The DPD controls seeds, planting material in inland production and in export/import. Usually, they visit each FBO they control, once per year.

**Table 8. Data on inspection (2007):**

Total number of inspectors	2220* <sup>34</sup>
No DVFA inspectors	1617
No of inspectors at DPD	428
No of inspectors at Directorate for Fisheries	175
No FBOs for veterinary inspection	4400
No of registered FBOs at DVFA	49.700
No FBOs for inspection of Directorate for Fisheries	502

<sup>33</sup> "Smileys keep food safety high in Denmark."  
<http://www.uk.foedevarestyrelsen.dk/Inspection/Smiley/forside.htm>

<sup>34</sup> Full time employees

Total No of FBOs registered by DVFA	50.302
Annual No inspection visits by DVFA	61.434
No of visits / DVFA inspector	38
Average No of DVFA inspection visits per year/ premise	0.5
Annual number of inspection visits to FBOs by DPD	16.050
No of inspections per DPD inspector/year	37.5
No of DPD inspections per FBO/year	1.0
No of fishery inspectors per FBO	0.35
Number of inspection audits conducted as a percent of Audit Plan (%)	Over 95%
Annual number of inspection reports (all inspections)	42.000
Percentage of audits with registered nonconformities	7,5%
Annual number of follow up visits (%)	18%
Annual number of appeals	Not available
Annual number of recalls – domestic products	Not available
Annual number of confinements at border inspected by DVFA and DPD	13.000
Annual number of recalls – import	100
Annual No of samples (food and meat at slaughtering) according to the National sampling plan	2119 + 250.000 samples on BSE <sup>35</sup> and TSE <sup>35</sup>

### 5.2.5. Quality control of inspection performance:

Activities of inspections vary from monitoring, sampling, inspection, 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 control effectiveness and accuracy of inspector's work by checking samples of their reports thus controlling their clarity, uniform approach, accuracy in terms of legal requirements. The RVFAC is responsible for the initial hiring, training and payments of inspectors. Veterinarians receive classroom training in veterinary public health and food inspection as part of their veterinary degree course of study. Veterinarian when applying for the inspection job receive on-the-job training at the establishment level. Veterinary technicians often have experience as a slaughterhouse workers. They are educated at the Danish Meat Trade College. The 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 RVFAC. Special emphasis is placed on HACCP, SSOP and supervisory training.

<sup>35</sup> BSE-Bovine Spongiform Encephalopathy; TSE – Transmissible Spongiform Encephalopathy

A yearly performance conference for each DVFA employee is required by Danish law. There are written guidelines describing how the performance conferences should be conducted. The performance conferences are documented and retained by the supervisor of the employee in a confidential personnel file.<sup>36</sup>

Quality supervision, consisting of an administrative component and a program component, is conducted for veterinarians and non-veterinary technicians at least once every two years. The quality supervision report is maintained at the RVFAC. This is required by an official contract between the RVFAC and the DVFA. Each veterinary inspector is supposed to participate in one educational conference per year, and Records on inspections are kept on the regional level, but the software is uniform, so the Head office of DVFA can have insight in their data. "Expert groups" meetings of CEOs from regional offices and central level officials serve as forums where experiences in the approach to the implementation of legislation are exchanged. This is a part of the technical assistance from the central to the regional level. Also EC FVO conducts regular audits of facilities and inspections providing them with insight in harmonization of the country approach to the EU practices.

Despite very extensive action taken by all authorities involved in the food safety, there are still areas where additional action is needed. According to the report made by DG Sanco in 2008, when they visited selected slaughterhouses and milk processing establishments comments like:

"reporting system should be assessed in order to ensure that the official reports reflect the real situation in the establishments; authorities should re-assess the approvals for all approved food establishments to ensure that they comply with relevant Community legislation; and to training of inspectors should be improved".<sup>37</sup>

### 5.2.6. Sampling:

During inspection visits, inspectors take samples of raw material, additives, semi-finished material, send them to laboratories affiliated to the DVFA 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. In 2007 DVFA took 56.252 samples as a part of the national monitoring plan for various contaminants and components, and 22.000 samples were taken at the regional level. Some 370 samples were taken on GMO analysis. Also, 600-700 samples per year of feed are taken by DPD. Eight laboratories are involved in the realization of the National plan for control of residues: three in Denmark and five in the EU.

The sampling plan for each year is prepared to be respective to the projected annual production of food stuff which will be sampled. Also, it must take into consideration new pathogens, or threats from known pathogens. Thus in 2008, Denmark was suggested by the DG Sanco to enhance number of samples of salmon and to take into consideration the new pesticides on the market.<sup>38</sup>

### 5.2.7. Training

Training of veterinary inspectors and those controlling food of animal origin and feed is an obligation according to the Regulation EC 854/2004. The annual training plan is existing. In the 2009-2010 period all food inspectors for DVFA will be trained on general control issues and on specific based on competence needs. DPD has also a training scheme for all inspectors in this authority. DVFA also, coordinates and carries out in-service training programs in dialogue with the regions, and organizes experience Exchange Meetings among inspection personnel in the regions.

### 5.2.8. Transparency

There are information available at the Internet on the status of the inspection report and general public is informed at retail points about the results of the "Smiley" campaign. There is a monthly report on food recalls at the European food and feed recall site and information based on Rapid Alert System could be found at the site of the Danish Ministry for Food, Agriculture and Fisheries. The annual sampling plan is submitted to the EC FVO and DG Sanco and adjusted to the situation in the country. The example of this is the extending of the monitoring plan for border inspection posts for 2010 according to recommendations of the DG Sanco control in 2009.<sup>23</sup> Reports on sampling are available at the DVFA Intranet.

### 5.2.9. Food borne diseases

#### *Salmonella control program*

The national Salmonella control program for eggs was launched in 1996-2002. The main source of Salmonella were eggs and poultry production. In 1995, 60% positive flocks were identified, while

<sup>36</sup> <http://www.fsis.usda.gov/OPPDE/FAR/Denmark/Denmark2008.pdf>

<sup>37</sup> Final report of a mission carried out in Denmark from 21 October-31 October 2008 in order to evaluate the follow-up action taken by the competent authorities with regard to official controls related to the safety of food of animal origin, in particular meat and milk. DG Sanco 2008.

[www.ec.europa.eu/food/fvo/act](http://www.ec.europa.eu/food/fvo/act)

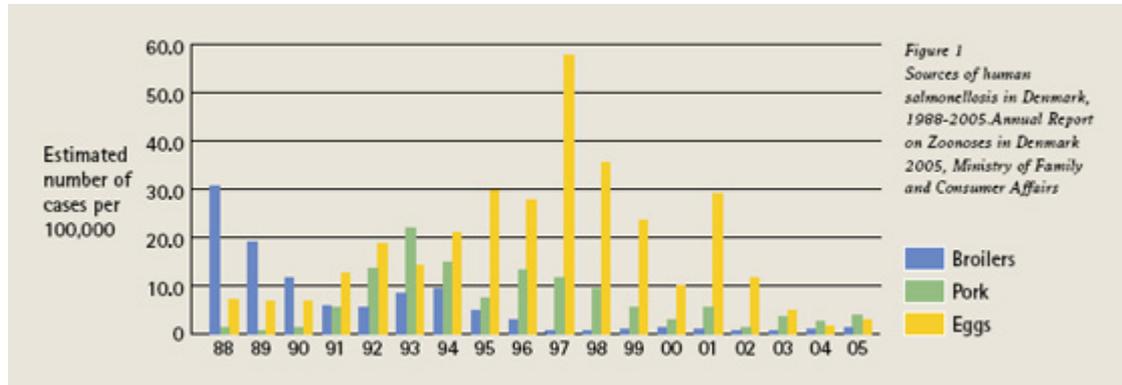
<sup>38</sup> [http://ec.europa.eu/food/fvo/ap/ap\\_denmark\\_8083\\_2009.pdf](http://ec.europa.eu/food/fvo/ap/ap_denmark_8083_2009.pdf)

after only one year of application of this program the percentage fell to only 10% and than remained in the range 2-10% by 2002 (Picture 1). In 2002 the responsibility for Salmonella control was transferred to producers (and Danish poultry council is

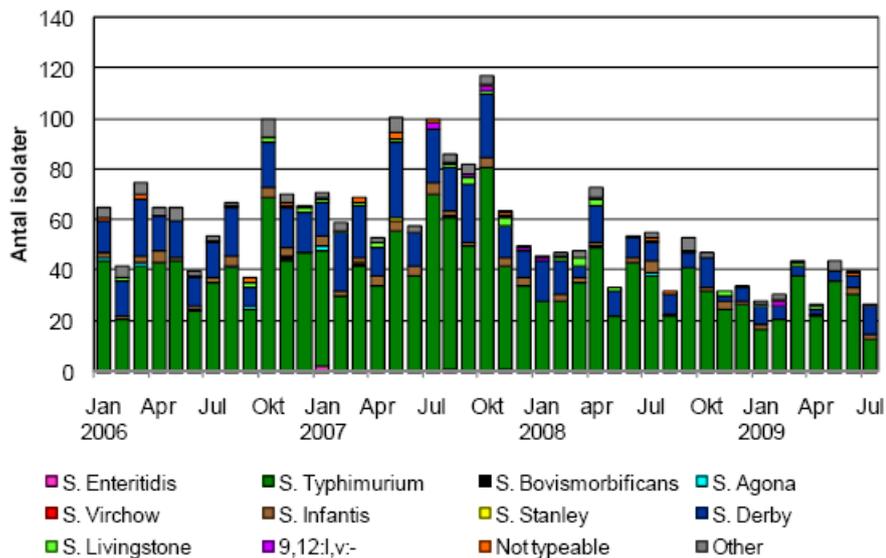
to follow results and report to DVFA) and remained at the level of 2-5% in pig production, while in poultry production it staid at 5% in 2005, and fell to 1% in 2006-2009 in all industrial holdings.

**Picture 1. Sources of the human salmonellosis in Denmark 1988-2005.**

Source: Official web-site of the Danish Pork producers association.



**Picture 2. Salmonella in pork cuts in Denmark 2006-2009.** Source DVFA.



In 2007, 1649 laboratory confirmed episodes of salmonellosis were reported corresponding to 30.2 cases per 100,000 inhabitants. This is similar to the 2006 findings. An outbreak of 1054 cases was registered in 2008 probably associated with production of pig meat hams.<sup>39</sup>

The five year (until 2010) plan is to decrease the number of *Salmonella* and *Campylobacter* outbreaks and to improve microbiological situation in food production.

Probably owing to the small size and population of Denmark, and to the vigilance of the Danish system, there have only been few documented cases of minor incidents. There does not appear to be any large scandals, and the minor cases have involved diseases that have afflicted the rest of Europe as well.

<sup>39</sup> Eurosurveillance Edition 2008: Volume 13/ Issue 44

### 5.2.10. Summary:

A new consolidated approach to Food Safety system in Denmark showed number of benefits. Such as:

Reduce of overlap in inspections. 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 being based on an individual food product's safety risk and on an individual company's food safety record. That reduced number of inspections in general and has made more resources available for inspections of higher risk companies and foods. As a result a new "Smiley approach" was introduced and has proved effective in raising food safety.

Besides the consolidation made, enforcement of food safety regulations is more consistent and improved the food safety system's effectiveness. It also streamlined communications, made clearer responsibilities, and improved service delivery as a result of having a single contact.

It is important to emphasize the practice of "self inspection" implemented by Danish producers where plans for "self inspection" are approved by the relevant food safety inspection. Along with approval of plans of establishments which is also performed by inspection, this is a model of advisory inspections' approach to producers.

Being one of the biggest exporters of food in the EU, Denmark is implementing all principles and practices required by the EU legislation, and remarks from the EU control missions are respected as guidelines how to harmonize the approach to food safety with acting EU legislation and real situation in Denmark and the EU. Governmental and private sector collaborate closely as shown in case of eradication of zoonosis where government initiated the process which was further followed with actions made by the private sector, since they realized the importance of food safety for their businesses.

### 5.3. New Zealand

New Zealand has the population of 4,213,418 inhabitants. The country is divided in 16 regions and one territory and also has three dependent islands. GDP (PPP) in 2007 was \$172 billion according to the IMF with GDP per capita \$30,000. Agriculture participates with 4.4% in the GDP and industry 26%.

Nearly 80% of the food produced in New Zealand is exported, providing almost the half of all export earnings. Main agricultural products are: dairy products, lamb and mutton; wheat, barley, potatoes, pulses, fruits, vegetables, wool, beef, and fish. Main export partners are: Australia 22%, US 11.5%, Japan 9.2%, China 5.3%, UK 4.6% (2007). Main import partners are: Australia 20.7%, China 13.4%, US 9.7%, Japan 9.5%, Singapore 4.9%, Germany 4.7% (2007). Imported food participates with 20% in the whole consumption of food.

#### 5.3.1. Legal framework

In New Zealand there are numerous legislation documents that are linked with each other in the area of food safety.

**A. The Food Act 1981** (amended several times, the last done in 2007), which defines:

- relevant terms, such as, food and sale,
- outlines prohibitions on sale (including unfit food),
- prohibits misleading labeling and advertising,
- provides powers of enforcement and offences,
- contains provisions to make regulations and food standards.<sup>40</sup>

This regulation was amended in 2002 and the risk based component of food inspection was incorporated in the document, thus letting authorities to adjust frequency of inspection according to the risk level attributed to the specific FBO.

**B. The Food Hygiene Regulations 1974**, still enforced in counties and setting rules for registration of temporary or permanent FBOs and allowing inspections in these FBOs. The Food Act 1981 permits counties to enforce the Food Hygiene Regulations 1974. Also, in counties (Napier City Council, Hastings District Council, Auckland City Council and others) there are "Bylaws" which treat qualifications of food handlers and their training in food safety.

**C. The Animal Products Act (1999)** defining "individual risk management programmes" for all primary processors of animal material and prod-

ucts, and certain secondary processors of animal products for human or animal consumption, to operate under registered and independently verified risk management programmes suitable to their own particular animal material, products, and operations, unless they are regulated by other regulations, or unless they pose negligible risk. Also, this Act regulates animal product standards, export of animal material and products and home kill and recreational catch.<sup>41</sup>

**D. The Australia New Zealand Food Standards Code 2002** and additional **Food Standards** in New Zealand only, treating different areas (residues, imported goods, cheeses produced from raw milk, food of uncooked meat, fortification of bread with folic acid).<sup>42</sup>

**E. The Dietary Supplements Regulations 1985** define "dietary supplements," state the maximum daily doses for some nutrients, list food additive permissions and labeling requirements. As with other foods, it is the manufacturer's/importer's responsibility to ensure their products are safe and comply with the legal requirements (no approval is required, the Food Act 1981 refers).

#### 5.3.2. Food safety system

Food safety system in New Zealand was reformed in 2002 when a new consolidated approach to food safety was presented by establishing the New Zealand Food Safety Authority (NZFSA). Before the reform 2 ministries (the Ministry of Agriculture and Forestry and the Ministry of Health) were responsible for food safety. Such approach resulted in appearance of inconsistencies between the two ministries' food programs and in order to make the system effective and efficient New Zealand's government consolidated food safety responsibilities of the two ministries into one autonomous governmental agency the NZFSA.

Today food safety system is managed by:

- Ministry of Agriculture, Forestry and Fisheries
- Ministry of Health
- New Zealand Food Safety Agency (NZFSA)
- Food Standard Agency Australia and New Zealand.

**A. Ministry of Agriculture and Forestry (MAF)** – provides information, analysis and advice to the Government on issues affecting the economic and environmental performance of the sectors. MAF's department – the Biosecurity Authority Clearance Services coordinates numerous governmental agencies (Ministries of Tourism, Economic Development, Foreign Affairs and Trade, Health, private

<sup>40</sup>[http://www.legislation.govt.nz/act/public/1981/0045/latest/DLM48687.html?search=qs\\_act\\_the+food+act+1981\\_resel&p=1&sr=1](http://www.legislation.govt.nz/act/public/1981/0045/latest/DLM48687.html?search=qs_act_the+food+act+1981_resel&p=1&sr=1)

<sup>41</sup>[http://www.legislation.govt.nz/act/public/1999/0093/latest/DLM33511.html?search=qs\\_act\\_the+food+act+1981\\_resel&p=1#DLM33511](http://www.legislation.govt.nz/act/public/1999/0093/latest/DLM33511.html?search=qs_act_the+food+act+1981_resel&p=1#DLM33511)

<sup>42</sup><http://www.nzfsa.govt.nz/policy-law/legislation/food-standards/index.htm>

sector, regional councils, environmental groups, etc). Its primary goal is to identify and manage any potential biosecurity risks at the border and to provide domestic and offshore technical inspection and clearance services including control of animal welfare, pests and diseases of plants and animals. The Authority has 1000 employees: veterinarians, scientists, quarantine inspectors, and general staff – across New Zealand and overseas.<sup>43</sup>

The national budget for 2007 was \$10.688.276.000 of which for MAFF 0,5% was named. The budget of the MAFF is built on 1/3 from the governmental budget and 2/3 from non-tax revenues.

Around \$500 million is spent annually on biosecurity in New Zealand, with activities undertaken by central government, regional councils, industry and private landowners. It is estimated government agencies are responsible for \$304 million of this sum.

New Zealand spent in 2007 almost \$318.million for funding of the Biosecurity Agency (governmental funds along funds from local councils and landowners taxes) of which \$32 million was spent on pest management, and \$19 million on Tuberculosis prevention and eradication program.

**B. Ministry of Health** – through a system of control of food safety at the regional (council) level securing:

- A system for routine and regular surveillance and monitoring of risks, based on risk assessment methodology. Ministry of Health published guidelines how to implement the HACCP system in FBOs. The Environmental Health Officials perform inspection of FBOs at the local level and report to the council's health authorities.
- Surveillance and control of foodborne illnesses.

**C. New Zealand Food Safety Agency (NZFSA)** was founded in 2002 and until 2007 operated as a semi autonomous body attached to the New Zealand Ministry of Agriculture and Forestry. Since 2007 it is an independent governmental agency with the overall management responsibility for the food safety system. NZFSA is the controlling authority for: imports and exports of food and food-related products as well as controlling authority for:

- food for sale (imported, locally produced and distributed and food produced for export)
- primary processing of animal products and official assurances related to their export
- exports of plant products, and
- use of agricultural compounds and veterinary medicines.

Control of food safety in New Zealand is organized across three levels:

1. Central government through NZFSA;
2. Regionally through 12 Public Health Units (in District Health Boards);
3. Locally through 73 Territorial Authorities.

NZFSA is responsible for New Zealand's food policy and regulation in the domestic production and trade, import and export sectors. The role of the agency is in proposing regulations, management of risks, dissemination to public the information about risks, education of industry and public in application of precautionary approach to safety of food, minimizing the costs of regulatory actions/ interventions for domestic producers and importers/exporters, utilization of capacities in order to improve business opportunities for domestic and export focused food industries, work at the multilateral and bilateral level to ensure neither international standards nor importing country standards pose unjustified technical barriers to trade and export certificates.

In managing of the food safety, the agency contracts with Public Health Units of the Ministry of Health to implement and monitor state food safety programs, recalls, investigations, inspection of certain types of food businesses, and inspections of imported food.

Territorial Authorities currently implement food safety plans they developed by themselves with limited assistance from the central government. When some initiatives have been taken by individual Territorial Authorities, the benefits have been limited to the particular Territorial Authority. This situation is recognized as not ideal, and presently, 70% of Territorial Authorities work more closely with central government in voluntary implementation of the new food risk-based regulatory documents and collaborate through cluster groups of geographically close Territorial Authorities with NZFSA as a lead and central coordinating agency.

The Structure of the NZFSA is: Policy Group, Science Group, Standards Group, Market Access Group, Agricultural Compounds and Veterinary Medicines and Approvals Group, Compliance and Investigation Group, NZFSA Verification Agency (NZFSA VA), Finance Group, and the Communications Group.<sup>44</sup>

NZFSA VA audits the risk management programs of food producers and processors, and provides export certification for products of animal origin (meat, game, honey) and seafood covering around 1200 premises.

<sup>43</sup> <http://www.maf.govt.nz/mafnet/index.htm>

<sup>44</sup> <http://www.nzfsa.govt.nz/>

The agency has 210 veterinarians located in 80 offices throughout the country including all export meat processing premises. Circuit staff cover smaller processing operations that have no permanent presence. The agency is completely self financing with an annual turnover of about \$22 million, all recovered from industry.<sup>45</sup>

**D. Food Standard Agency Australia and New Zealand.** New Zealand and Australia have a very good collaboration in a number of issues according to bilateral treaties and agreements. In the food safety area that is the Agreement between the Government of Australia and the Government of New Zealand concerning a joint food standards system (the Food Treaty). An Australia and New Zealand Food Regulation Ministerial Council, supported by official committees such as the Food Regulation Standing Committee (FRSC), and the Implementation-Sub-Committee, provides oversight of the system and policy guideline to the standards setter, Food Standards Australia New Zealand (FSANZ). The Food Regulation Standing Committee advises Ministers on policy matters and the Implementation-Sub-Committee develops and oversees a consistent approach across jurisdictions to the implementation and enforcement of food regulation. FSANZ is funded by the New Zealand and the Australian governments.

New Zealand participates at all levels of the joint food standards system. Areas of collaboration include policy development, standards and systems, incident response, science, communications, local government operations, and compliance and enforcement. It provides not only for the sharing of information but also the generation of information to the mutual benefit of both agencies.

FSANZ is an independent statutory agency established by the *Food Standards Australia New Zealand Act 1991* and the Parliamentary Secretary to the Minister for Health has executive responsibility for FSANZ.

The goal of the FSANZ is: A safe food supply and well-informed consumers. FSANZ develops food standards, joint codes of practice for industry, covering the content and labeling of food sold in Australia and New Zealand. The FSANZ develops Australia-only food standards that address food safety issues – including requirements for primary production – and maximum residue limits for agricultural and veterinary drug residues.

In Australia, FSANZ takes national coordination of food surveillance and food recall systems, providing food handling advice to consumers, conducting research and supporting the Australian Quarantine and Inspection Service in the control of imported foods.

FSANZ has offices in Canberra and Wellington, New Zealand and staff of 130 employees from the Australian Public Service, and 16 employees in New Zealand.<sup>46</sup>

FSANZ and other government agencies in Australia and New Zealand monitor the food supply to ensure that it is safe, and that foods comply with standards for microbiological contaminants, pesticide residue limits and chemical contamination. FSANZ has a Bi-National Surveillance and Enforcement Strategy which allows food/health agencies in Australia and New Zealand to discuss and share information about monitoring and surveillance of the food chain in Australia and New Zealand. FSANZ acts as the central point for collection of Food surveillance data from public health units in Australia and to the lesser extent in New Zealand. This data include results of general compliance testing, and specially targeted surveys conducted in the various jurisdictions.

### 5.3.3. Division of responsibilities and register of FBOs

The regulatory systems and measures applied to domestic food underwent a significant review in 2002, so that government involvement and compliance costs imposed on the food sector are minimized. Any government involvement and regulatory controls are risk based and science-based as far as possible, producers have responsibility for producing safe and suitable food, regulatory requirements are applied consistently and equitably across sectors and groups and trade and commerce of food and associated products are facilitated.

Due to a wide range of inspectors coming from the NZFSA, Public Health Officers, Environmental Health Officers and third party auditors participating in the control of the food safety system, it is difficult to estimate correctly the number of auditors per FBO (since some of them may work only a part of their working time in official inspection) Table 9.

<sup>45</sup> <http://www.nzfsa.govt.nz/verification-agency/>

<sup>46</sup> <http://www.foodstandards.gov.au/monitoringandsurveillance/foodsurveillance.cfm>

**Table 9. Data on New Zealand control of food safety of domestic products – NZFSA and agencies under its jurisdiction in 2007-2008**<sup>47</sup>

Sector	Control body	Number of registered FBOs
Primary processors (e.g. meat – slaughter and dressing, dairy – processors incl. dairy farms and egg producers)	NZFSA Verification Agency for Meat, Seafood and Poultry sectors	1076
Secondary processors of animal product may opt for coverage of third party inspection or in NZFSA regime.	Third party verifier (NZFSA approved) for Dairy i.e. “Assure Quality” scheme for dairy industry	1076
Wine producers	Third party auditors (NZFSA approved 40 auditors)	251
Retail and restaurants	Control of Registration per Food Hygiene Regulations 350 Environmental Health Officers (from 73 Councils)	25000
Manufacturers and big retailers	Operation of a Food Safety program – Third party auditors (40 approved)  NZFSA presently operating a trial for food service sector – 209 Environmental Health Officers trained by NZFSA	2171  350 FBOs applied for this control

### 5.3.3.1. Example of food hygiene control at the local level (examples from different counties):

Control of Registration and food hygiene is performed by the Council Environmental Health Officials according to the Food Hygiene Regulations (1974). It is performed in accordance to hygienic standards implemented in the premise.

In the Auckland County a Performance Assessment System (PAS) score for setting license fees exists since 2002. The assessment is based on:

- the Food Hygiene Regulations 1974,
- the Bylaw 15 (2008) on Food Premises (defining actions to be taken if premises are unhygienic and defining trainings and qualifications in food safety for FBOs personal) and
- best food hygiene practice.<sup>48</sup>

During assessment the following is examined:

- the physical condition of the premises
- the conduct of the operator and staff
- cleaning and sanitizing of the premises
- training of staff
- food safety procedures.

The grading scheme is very popular with the public, showing the hygienic conditions in the premises and helping them to choose place to eat or buy according to the food safety level it has.

An inspection will be carried out by an Environmental Health Officer prior to registration and a grading of the premises will be provided as follows:

**Table 10. The model for grading premises applied in Auckland County**

Grade	Description
A	Premises being of superior standard
B	Premises meeting the minimum statutory requirements.
D	Premises being just below standard.
E	Premises being well below standard.
N	Grading not applicable.

A 'C' grade is not available so that is clearly separate those that comply with requirements and are highly graded, from the lowly graded premises.

The standard grade must be disposed on a publicly visible place in order to inform customers on the hygiene status in premises. At the Porirua County the officers evaluate the premises taking the following into account:<sup>49</sup>

- The suitability of the premises layout, wall, floor and work surfaces, the adequacy of hygiene facilities including hot and cold water supply and the toilet and waste facilities including grease trap.
- Food practices – The degree of food manufacture, preparation or handling carried out on the premises.
- Hygiene cleaning programme.
- Staff training.

Officers carry out inspections in addition to those set by owner's premises grading if hygiene compliance is an issue. The owner may be required to pay a fee for these inspections and premises risk assessment may be downgraded.

The Porirua Council's Environmental Health Officers assess establishments in order to identify:

- The possible risk or risks to the public inherent in the type of operation being carried out on the premises.
- The size of the business.
- The food handling practices employed on the premises.
- The time officers spend inspecting the premises and frequency of those inspections.

<sup>47</sup> NZFSA Annual Report 2007-2008

<sup>48</sup> <http://www.aucklandcity.govt.nz/Council/services/foodpremise/grading.asp>

<sup>49</sup> [www.pcc.govt.nz/A-Z-Services/Food-Premises---Registration/Food-Premises---Inspections](http://www.pcc.govt.nz/A-Z-Services/Food-Premises---Registration/Food-Premises---Inspections)

Registration fees are based on the premises risk assessment. Registration fee will reflect premises risk assessment. The system is devised to encourage responsible and safe food practices. The grading system is designed to allow to improve risk grading and reduce the annual fee payable.

Inspection is based on risk and there is a scale which determines the frequency of inspection and registration fee levels according to grade assessed:

**Table 11. Porirua county the frequency of inspection and registration fee levels**

Inspections		A	B	C
No. inspections/year	Premises Grading	Fee Level	Fee Level	Fee Level
1	Excellent	A1	B1	C1
2	Very Good	A2	B2	C2
3	Ungraded	A3	B3	C3
4+	Ungraded (High Risk)	A4	B4	C4

### 5.3.5. Frequency of control and fees:

**Table 12. Data on inspection performed by NZFSA 2007-2008<sup>42</sup>**

No veterinary inspectors in NZFSA	210
No FBOs under veterinary inspection jurisdiction	1200
No of inspectors/FBO	0,2
No of approvals on persons, facilities, food safety plans submitted by FBOs	3575
Annual No of audits to premises due to complaints, breaking the legislation, etc.	228
Annual No of visits in order to approve food safety plans/inspector	22
Total annual No of visits to FBOs	1180
Average number of visits/FBO	1
% of non-compliances	2.9%
% of the annual audit plan realization	100%

Data from the Annual Monitoring Plan show that producers in New Zealand have a very high level of self control over the production of food and application of agrochemicals, veterinary medicines and hormones and that a very low number of foodstuff have higher levels of contaminants than those allowed by legislation. The data for the 2006-2007 show only one sample of food of animal origin to be non conforming on residues of chemical contaminants. In 2007-2008 the monitoring was performed on food of plant origin, and only 14 samples were non conforming. These data do not differ significantly from the period of 2001-2002.<sup>42</sup>

#### 5.3.5.1. NZFSA Fees and charges are based on: Food (Fees and Charges) Regulations 1997

Fees and charges for most activities are charged at

\$48 for the clearance request plus \$96 per hour payable in 15 minute units after the first 15 minutes, with a minimum charge of \$24. Some other activities undertaken by employees of the New Zealand Food Safety Authority are charged at \$137.25 per hour payable in 15 minute units with a minimum charge of \$34.30.

**European Community and New Zealand sanitary agreement for animal products. Council Decision 97/132/EC.** EU charges only apply to clearance applications relating to products as specified in Council Decision 97/132/EC Annex VIII – Animal Products for Human Consumption exported directly from the European Union.

EU charging rates are \$33.75 for the clearance plus \$73.12 per hour.

### 5.3.6. Recalls and food with high risk:

Domestic production: according to the NZFSA data there were 14 official recalls of domestic products and 11 voluntary (industry driven) in 2007-2008. Also, 14 incident situations were recorded which required action and specific measures from NZFSA, Public Health Service of Ministry of Foreign Trade.

The number of recalls due to microbiological contamination or inadequate labels decreased comparing to 2006 when 20 recalls were registered.

Import: NZFSA processed 9,381 import permits in 2007. Almost 32% were not on the risk priority list, and 13% of all permits were for high risk food coming from the USA, China, Thailand and Malaysia. There were 114 confinements that didn't receive import permit and were returned to the country of export.<sup>42</sup>

### 5.3.7. Funding of the food safety inspection is performed by NZFSA itself:

In 2008/09, food safety line of the budget is appropriated to \$63.5 million. Government funding represents 36% and the remaining 64% will be mostly cost recovered from industry. Of the cost recovered functions almost 80% comes from auditing and verification functions provided to animal products sectors. Costs are charged on an actual cost for services provided (time taken plus any disbursements, travel etc). The rest of the budget comes from compliance functions, the organic official assurance program, services provided to the industrial sector, and agricultural compounds, and veterinary medicine services and these costs are recovered by levy based on a businesses production or throughput.<sup>50</sup>

<sup>50</sup> According to World Bank "The levy system formally requires that a fee be paid by any enterprise whose effluent discharge exceeds the legal standard. NEPA regulations specify variations in effluent standards by sector and fees

**Table 13. Budget of the NZFSA for 2007-2008<sup>42</sup>**

Name	Sum in \$	% of total
Budget of NZFSA	59.055.697	100
Budget for primary production inspection and monitoring of pathogens – Regulatory program	18.022.480	30.52
Veterinary inspection + inspection of Public Health Institute abilities to perform according to NZFSA standards – Regulatory standards	23.823.397	40.34
Inspection audits of premises – System audit and enforcement	3.002.506	5.1
Sum used for emergency situations	220.225	0.4
<b>Sum used for the activities related to inspection</b>		<b>76.36</b>
Consultation and food safety information to FBOs	2.724.588	
FS policy advise to the Government	2.452.253	

### 5.3.8. Quality control of inspection work:

Quality of the inspection services performance is assessed through internal and external third party audit. Assessors' competence is controlled by peer review, dual audits, audit report evaluation, internal auditing and auditor training. Control of assessors competence was performed by third party auditing in 25% of all audits performed in FBOs and showed that auditing process was completely performed according to guidelines prescribed by NZFSA.

95% of investigation files were prepared for prosecution with sufficient evidence to initiate criminal proceedings. In 2007, eleven such cases were prepared and all proceeded to prosecution and all cases were won.<sup>32</sup>

### 5.3.9. Training

Training of local authorities to exhibit the inspection audit according to requirements of the NZFSA is underway. In this moment they perform control of hygiene in premises according to Food Hygiene Regulation from 1974, but they will have to build human capacities to audit processes and implementation of the risk management (HACCP) food safety system in production.

### 5.3.10. Transparency

There is an online instant answering service for FBOs on the status of the auditor's report on inspection and all FBOs can insert online into that report all activities they have undertaken regarding

proposals given in the report. FBOs can register their facility online, too.

Number of media releases, publications, e-mail information on food safety and inspection are provided throughout a year.

### 5.3.11. Visits of controlling bodies other than those participating in the food safety control to FBOs:

Three levels of authorities exist-central, regional and local with subsequent list of approvals, registrations, verification, and official assurances. Authorities are excludable and rival (their use by one agency or governmental body does not detract from their use by another), and benefits can be directly attributed to those persons requiring the particular function.

### 5.3.12. Foodborne diseases:

The rate of campylobacteriosis significantly dropped since in May 2006 a new strategy for reduction of campylobacteriosis was launched. The number of cases was 80-85/100.000 inhabitants in 2006 and fell to 25-30/100.000 inhabitants in 2008 (about 1050 cases per year). Still the problem is not yet solved and in May 2008 some 380 cases were reported, while in June 275 new cases appeared. Salmonellosis has a steady downfall since 2005 with 1300 cases in 2008. The plan for reduction of *Salmonella species* and *Listeria species* in food for 2008/9 is in place.<sup>51</sup>

### 5.3.13. Summary

New Zealand's food regulatory regime has not been thoroughly reviewed (documents were only amended, but their original structure and the structure of the whole legislative system was not changed) for over 30 years. Since 2002 NZFSA has been conducting a major review of New Zealand's domestic food laws in order to:

- address inequities in the way the food industry is regulated across the country
- clarify the roles of the regulators (NZFSA, Public Health Units and Local Councils)
- stem the continued rise in the number of reported foodborne illnesses.

The consolidation of food safety system and transfer of inspection responsibilities at the central level to the NZFSA helped the New Zealand government to streamline communication between the food industry and regulators. The establishment of one agency for which food safety has become a top priority enabled the system to be more efficient. The system became more responsive to food safety crises by establishing a network that quickly deliv-

by pollutant. With the approval of NEPA, local areas may raise both standards and fees above the nationally-mandated levels (in the latter case, these are called over-standard fees). Levies are charged only on the 'worst case' pollutant from each source."  
<http://www.worldbank.org/html/prddr/prdhome/peg/wps06/indexp3.htm>

<sup>51</sup> <http://www.nzfsa.govt.nz/about-us/accountability-documents/statement-of-intent/2008-2011.pdf>

ers information to notify the public of food safety issues. As a result, improved communication has enhanced consumer confidence and improved food safety in the country. The NZFSA is training local inspection authorities in principles of implementation of the risk management approach in food safety (the HACCP system) and thus providing them with knowledge and guidelines in order to establish the uniform approach to food safety control across the whole country.

The establishment of the Food Standard Agency Australia and New Zealand is a good example of the regional collaboration. It enables adoption of same standards in many areas of food safety and quality, thus facilitating trade and using common resources in the development and control of standard enforcement and gathering of information on food safety issues.

## 5.4. POLAND

Republic of Poland is organized in 16 regions, 279 districts and 2478 municipalities. Population in 2009 is estimated at 38,5 million with GDP (PPP) in 2007 of \$637 billion and GDP (PPP) per capita \$16,500. Agriculture participates in GDP with 4% (but 17.4% of working force is employed in agriculture), industry 19,2% and services 53.4%. Main domestic agricultural products are: potatoes, fruits, vegetables, wheat; poultry, eggs, pork, dairy. Food and live animals produced for food participated in gross export with 7.6 % (2003). Increase in export of food and agricultural products is constant and results from 2008 show increase of 14% comparing to export value in 2007. The main market for Polish food and agricultural products (80% of export) is the EU market. The export to Commonwealth of Independent States (CIS) states was 9.4% of the total food and agricultural export. Local production satisfies 85% of local needs and imported food another 15%. Imported food mostly comes from the EU, Argentina, Ukraine (chocolate, meat, cereals, palm oil, sugar). Balance of import to export is positive with most of the EU states.

### 5.4.1. Legal framework

National Strategic Plan for 2007-2013 is aimed to enhance competitiveness of the Polish food and implementation of the preventive measures in food chain. Also, it will support full harmonization of Polish legislation with the EU. According to acting legislation, the HACCP system is mandatory in all objects by January 1, 2010.<sup>52</sup>

### 5.4.2. Authorities responsible for the food safety system:

**A. Ministry of Agriculture and Rural Development (MARD)** cooperates with Ministry of Health on central, regional and district level. Department of Food Safety and Veterinary Matters issues regulations and control function is implemented through 3 central competent authorities -inspectorates:

- a. **General Veterinary Inspectorate (GVI)** – in charge of animal health and welfare, foodstuff hygiene of animal origin, animal feed, pharmaceuticals, rendering. The inspectorate has 10 Boarder inspectorates, 16 region (Voivodship) inspectorates and 304 district (Poviat) inspectorates. General Veterinary Inspectorates prepares annual plans, guidelines and instructions for regional and district inspectorates and collects and analyzes reports on their work. The network of official laboratories is supporting this system. There are 2107 veterinary inspectors: 44 in the GVI, 215 in regions, 1476 in districts and 68 in border inspectorates, and 304 feed inspectors (one in each district). Besides

full time employees there are 5200 practicing veterinarians who perform ante and post mortem inspection in slaughterhouses, supervise certain establishments, issue veterinary health certificates, take samples, take care of animal health. Out of this number in 2008, some 700 were paid from the central budget (budget for the General Veterinary Inspectorate) to perform their services – this was a way of overcoming shortage in veterinary inspectors in districts.

- b. **Main Inspectorate of State Plant Health and Seeds Protection Inspection (SPHSIS)** – at central level 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 boarder inspection posts. Some 1600 inspectors are employed in control at all levels. In each region there is an official laboratory which carries testing of samples taken from inspectors and samples from the monitoring plan. At boarder stations there are 12 diagnostic units.
- c. **Main Inspectorate of Agricultural and Food Quality Inspection** – quality and labeling of GMO (control of traceability) with 17 inspectors (1 at the central level and 16 in regions).
- d. **Agency for Restructuring and Modernization of Agriculture** – keeps central official register of FBOs and agricultural holdings.

**B. Ministry of Health (MH)** – preparation of legislation and control in areas of: food hygiene, pesticide residues, contaminants, import control of food of non-animal origin.

- e. **Chief Sanitary Inspectorate of the State Sanitary Inspection (SSI)** – control of: import of food of non-animal origin, materials which come in contact with food, food additives, GMO in food, food supplement, novel food. Sanitary inspection also, has responsibility for overseeing food processing. It prepares annual plan, guidelines, training for lower levels of inspection and collects their reports. There are 16 regional Sanitary Epidemiological Stations with 1000 inspectors, 318 district with 2500 inspectors and 10 boarder stations. In each region (16) there is an official laboratory which carries testing of samples taken from inspectors and samples from the monitoring plan, there are 3 Institutes nominated by MH to analyze official samples.
- f. **Main Pharmaceutical Inspectorate** – with 15 inspectors who control authorization and import of veterinary drugs.

**C. Ministry of Finance** – provides financing for inspections.

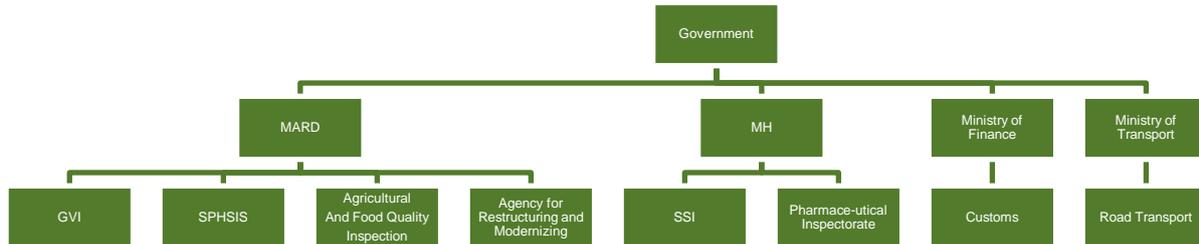
<sup>52</sup> <http://www.un.org/esa/agenda21/natinfo/countr/poland/agriculture.pdf>

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

**D. Ministry of Transport**

**h. Road Transport Inspection** – control of animal welfare during transport (checks vehicles for transport).

**Fig. 8 Organization of the Food safety system at the central level**



**Table 14. Division of inspections**

Area	Inspection authority
Animal health	Regional and district VI
Meat production	Regional and District VI
Food of animal origin	Regional and district VI Regional and district SES
Import of animals and food of animal origin	Regional, district and boarder VI Customs
Feedingstuff and animal nutrition	Regional, district and boarder VI Customs
Animal byproducts	Central, regional and district VI Regional and district SES
Veterinary medicines authorization and distribution	Pharmaceutical inspectorate
Veterinary medicines residues	Regional and district VI
Food and Food hygiene	Regional and district SES
GMO	Aggricultural and Quality Inspection State Sanitary Inspection
Import of food of plant origin	Regional and boarder SES Customs
Plant protection products authorization and sale	Regional Plant Protection Inspection
Plant protection products residues	Regional, district and boarder SES
Animal welfare	Regional, district and boarder VI Road transport inspection
Plant health	Regional PPI
Coldstores, catering	Regional and district VI Regional and district SES
Production of infant formula Baby food production	Central VI
Distribution and sales of infant formula and baby food	Central Sanitary inspection
Retail (both meat and plant products)	District SES

**5.4.3. Register of FBOs:**

According to regulatory requirements all FBOs must be registered. Both GVI and SSI keep their

own registers. Total number of FBOs in 2008 according to REGON Register was 33.000 of which almost 20.000 were small operators (employing less than 9 workers).<sup>53</sup> This register is not accurate since almost 30% of these enterprises either stopped to work or never started. According to the same bulletin there were 6428 FBOs controlled by veterinary inspection.

SSI doesn't have a centralized register (it is under construction – district SES are registering FBOs are keeping register now). According to data in the official statistical bulletin in 2007, there were 11.200 industrial food producers and almost 150.000 manufacturers (small producers – so called "nourishment plants").<sup>48</sup>

An important number of food processing facilities still operate in poor sanitary conditions and there is a serious concern about their future. By January 2010 producers which were given the grace period have to adjust their facilities and procedures according to the EU hygienic requirements or they should close their operations.

**5.4.4. Frequency of control and fees:**

**Veterinary inspection:** According to risk analysis and relevant EC Regulations (852/2004, 853/2004 and 178/2002) official control plan is made. Inspection has check lists for inspection visits. Traceability in meat production and 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 a year, and 5% of farmers who keep food producing animals are controlled once a year. Food processors still struggle with poor basic conditions in facilities and some 1/4 of dairies and 1/3 of poultry processing

<sup>53</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)

facilities are in poor hygienic condition. This also, influences the frequency of inspection visits.

**Sanitary inspection:** Frequency of inspection performed by sanitary inspectors is not determined according to risk based criteria (the risk based system is under development), but specific instructions and ordinances determine the frequency. The sanitary inspection approves FBOs self inspection reports and guidelines for implementation of GHP and HACCP.

**Table 15. Data on inspection in 2007-2008<sup>54</sup>:**

Total number of inspectors (veterinary+sanitary)	5505
Total No of FBOs	Aprox. 19.000
No veterinary inspectors – VI (domestic control) <sup>55</sup>	2005 + 700 private veterinarians authorized to perform inspection
No FBOs for veterinary inspection	6428 industrial facilities + 3500 manufacturers
No of FBO per state veterinary inspector	5
Annual number of VI inspection visits to FBOs	5200
No of follow up visits VI	2.7
Samples taken by VI-annual sampling plan	27.425
Total annual number of samples taken by VI	Aprox. 200.000
% of samples with nonconformities	3-4%
No of veterinarians participating in the annual sampling plan	4268
No samples taken by VI (state and private veterinarians) per annual sampling plan	6.5
No of FBO for sanitary inspection	About 12.500 industrial and almost 150.000 manufacturers
No sanitary inspectors (domestic control)	3500
No of FBO/sanitary inspector	3.57 industrial + 43 manufacturers
Annual No of Sanitary inspector visits to FBOs	11.200 industrial + 110.000 manufacturers
Annual No samples taken by sanitary inspectors	16.254
% of samples with nonconformities	5.8%
No of Plant Protection Inspectors -PPI	1600
No PPI controls	105.000
Average annual No controls/PPI	66
Annual No samples per monitoring plan	2419
Number of inspection audits conducted as a percent of Audit Plan (%) veterinary inspection	Almost 100%

<sup>54</sup> EC FVO: Final country profile on food and feed safety, animal health, animal welfare and plant health: Poland, 2008.

<sup>55</sup> <http://www.wetgiw.gov.pl>

Percentage of audits with registered nonconformities – Veterinary inspection	Example: 25.4% dairies
Average number of Follow up visits – Veterinary inspection	2.5
Number of inspection audits conducted as a percent of Audit Plan (%) sanitary inspection	Not available
Percentage of audits with registered nonconformities – sanitary inspection	0.5% fruit and vegetable processing 3.8 %bakeries
Annual number of recalls – domestic products	2.4%
Fines collected from unfit products (incorrect labeling and law quality)	\$125.000

#### 5.4.5. Sampling plan:

There is a multi annual sampling plan authorized by the EU FVO. According to that plan regional, district veterinary inspectors and practicing veterinarians take samples. In 2007, 27.425 samples were analyzed of which 124 were non-compliant.

PPI took 209 samples on GMO, 410 samples of pesticides in order to control quality of pesticides (combat of fraud) and 1800 samples of plants for pesticide monitoring.<sup>39</sup>

#### 5.4.6. Training

Training is an obligation according to EU Reg 852/2004 and Reg 853/2004. There is an annual training plan for each inspection. Training in traceability is organized continuously. Training for chosen Regional VI and District VI is performed on a cascade way, so that they transmit knowledge to the lower level. Training is financed from the budget of the ministry. Training for SPHIS was organized, by foreign donors, in improvement of the food safety control (600 inspectors) and training in GMO for 300 inspectors. SSI had training on residue monitoring funded by PHARE funds. Report of the DG Sanco control mission states that the harmonization of SSI inspection work at all levels is underway, and that the overall performance is better than in the previous years.<sup>56</sup>

#### 5.4.7. Transparency:

Data on inspection controls, status of inspection visit statements, number of recalls are shared between inspections but they are not publicly accessible. There is an IT system installed for storing of information of inspection visits (reports) in the General Veterinary Inspectorate. Results of the annual monitoring plan are regularly published by the EC FVO.

<sup>56</sup> DG Sanco 7596/2007

#### 5.4.8. Quality control of inspection performance:

In SSI the ISO 9001 system is implemented. The annual work quality control assessment is performed. There are guidelines for inspection performance published by the SSI and the performance is assessed according to adherence to these lines. There is an online inventory of satisfaction of public with the SSI services.

Internal controls of the work of veterinary inspection at each level is performed at least once per year. There are overall quality checks and some specific performance checks. Monthly meetings in field offices are held in order to communicate requests from the central level to regional and local levels.

#### 5.4.9. Number of foodborne outbreaks per year:

Total number of outbreaks in 2007 was 576, or 1,5 outbreak/100.000 inhabitants which is triple EU average number. The main vehicle of foodborne outbreaks in 2007 were food prepared meals from various (>3) raw materials of animal sources (15.3% outbreaks, 17.8% cases) and milk and eggs (17.5% outbreaks, 13.3% cases).<sup>57</sup> *Salmonella* was causative pathogen in 86.7% of cases.<sup>58</sup> It doesn't differ significantly from the 1994-1998 period when 82-97% of cases of foodborne diseases were registered as salmonellosis.<sup>59</sup> There were 3 registered *Campilobacter* outbreaks in 2007 (in the same time in Austria 108 and in Germany 259). There is a probability that reporting methods differ between countries.

#### 5.4.10. Summary

Polish legislation is mostly harmonized with the EU model. Frequency and scope of inspection is still not based on the risk analysis approach, but this 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 FVO and the FSIS indicate that the situation with food safety, GHP and GMP in facilities differs among those facilities which are allowed to export to the EU and other producing for the national market, only. The timeline for implementing the HACCP in all facilities is set to 3 years after accession to the EU. The epidemiological data indicate the triple incidence of food pathogens comparing to the EU, thus signaling that the practices in food safety have to be strengthened following the best international models.

<sup>57</sup> Baumann A, Sadkowska-Todys M: Foodborne infections and intoxications in Poland in 2007; *Przeegl Epidemiol.* 2009;63(2):213-20.

<sup>58</sup> <http://www.eurosurveillance.org>

<sup>59</sup> <http://www.fao.org/docrep/MEETING/004/X6912E.HTM>

## 5.5. SERBIA

Serbia is a Western Balkan country, administratively organized in the central part and one province, further subdivided in 24 counties plus the capital Belgrade. The population of 7.379.000 inhabitants (2009) lives in 161 municipalities, GDP (PPP) \$80.7 billion and GDP per capita (PPP) of \$10.900 (in 2008 according to official statistical data). The value of agriculture and food production in 2008 was almost 12.3% of the GDP. Main agricultural products are wheat, maize, sugar beets, sunflower, raspberries, beef, pork, milk. Agricultural products and food are exported to Bosnia and Herzegovina, Montenegro, Macedonia Albania, Slovenia, Germany, Russia. The agro-food sector provided 16.1% of the net export and 6.8% of the net import in 2008. It is estimated that 1.5 million inhabitants are employed or have the sole source of funding from the agriculture or agro-industry.

### 5.5.1. Legal framework

- In June 2009, a **Food Safety Law** harmonized with the EC Regulation 178/2002 was adopted. This law sets a basis for the implementation of the precautionary principle, HACCP in FBOs, central register of FBOs, division of inspection responsibilities and defines responsibility of producer in terms of food safety. It provides a ground for the risk based approach to food safety, organization of the network of laboratories for testing of food, traceability, management of crisis and the establishment of the National Council for Food Safety, a body which will deal with risk assessment.<sup>60</sup>
- Veterinary Law prescribes provisions on animal health protection and treatment of diseases.<sup>61</sup>
- Law on Plant Protection, states that a list of pesticides and fertilizers that are approved for marketing has to be updated annually.<sup>62</sup>
- The Law on Health Protection from Communicable Diseases includes provisions for surveillance of foodborne diseases.<sup>63</sup>
- The Law on Medicines and Medical Devices includes provisions for pre-market approval for veterinary drugs.<sup>64</sup>
- Number of ordinances that cover issues on the microbiological criteria for food safety, methods for microbiological food safety control, limits of pesticide residues, residues of mycotoxins, residues of veterinary drugs and other contaminant residues in food, provisions on irradiated foods, drinking-water quality, dietary products safety, consumer goods safety, including safety of materials in contact with food staff, competencies

of laboratories and guidelines for food sampling. All ordinances issued after 2000 are harmonized with the EU regulations and Codex standards.

### 5.5.2. Responsible authorities for food safety –

According to the Law on Food Safety, regulation and control of food safety is provided by (Fig.5):

**A. Ministry of Agriculture, Forestry and Water Management (MAFW)** – it is the competent authority and national contact point in the field of food safety system.

- *The Veterinary Office* – responsible for issuing regulations in the area of veterinary health, animal welfare, safety and hygiene of animal products and import and export of food (certification of export facilities), production and safety of feed, registration of FBOs,
- *The Plant Protection Directorate* – regulation of plant protection, plant health, regulation on pesticides and fertilizers
- *The General Inspectorate* – control of safety and quality of food and agricultural products (border control and domestic production).
  - **Veterinary inspection** – control of hygiene and safety in facilities producing food of animal origin, animals for food, feed, facilities where veterinary drugs and sanitizing materials are produced, residues, animal reproduction centers, animal welfare, animal health. Inspectors are divided in 7 border and 25 inland control units. The number of inspectors was 355 in 2008 of which 33 were permanently on boarder inspecting shipments in import. Animal health is further secured and controlled by registered veterinarians (1824) coming from 655 state and private registered institutions, private practices, veterinary stations.
  - **Phytosanitary inspection** (106 inspectors) – boarder (7 units) and inland (6 units). Control of soil, spreading of pests, plant quarantine, registration of facilities producing seed and plant propagation material, import and use of GMO, control of residues, control of production of pesticides and fertilizers.
  - **Agricultural inspection** (117 inspectors) – quality of agricultural and food products, wine and spirits, tobacco, organic production, hygiene and safety of production of food of plant origin, feed, novel food.
  - **Water inspection** – four units for control of water pollution (release of waste waters).

**B. Ministry of Health (MoH)** – issues regulations on food additives, dietetic products and provides

<sup>60</sup> Sl. glasnik RS" No 41/2009

<sup>61</sup> Sl. glasnik RS", No. 91/2005

<sup>62</sup> Sl. glasnik RS No 101/2005

<sup>63</sup> Sl. glasnik RS No 125/2004

<sup>64</sup> Sl. glasnik RS No 85/05

opinion on regulations in food safety and control of contaminants.

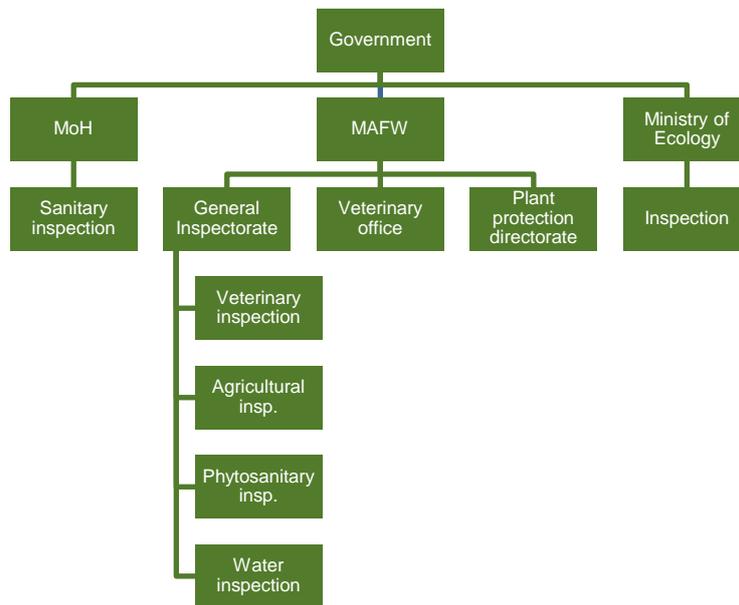
- **Sanitary Inspection** – responsible for control of food safety in retail, catering, additives, products in contact with food, drinking water, mineral waters and table water. Total number of sanitary inspectors is 270. They are organized in the head office at the central level and in 25 regional offices.

- **Agency for Drugs and Medical Devices** – controls production of drugs, certification of drugs.

**C. Ministry of Ecology** – responsible for regulation and inspection of waste (solid and water).

**D. Customs Directorate** – customs control of export and import.

**Fig. 9. Organization of the food safety inspection in Serbia**



**Table 15. Division of inspections**

Area	Inspection authority
Animal health	State and private veterinary officers
Food of animal origin	Veterinary inspectors
Import of animals and food of animal origin	Border veterinary inspectors
Feedingstuff and animal nutrition – import	Border veterinary inspectors Boarder phytosanitary inspectors, Customs office
Feedingstuff and animal nutrition – production	Veterinary inspectors Phytosanitary inspectors
Animal byproducts	Veterinary inspectors
Veterinary medicines authorization and distribution	Veterinary inspection Agency for control of drugs
Veterinary medicines residues	Veterinary inspection Veterinary institutes
Food and Food hygiene	Veterinary inspection, Agriculture inspection, Sanitary inspection
GMO	Phytosanitary inspection
Import of food of plant origin	Customs authorities, Phytosanitary inspection
Plant protection products authorization and sale	Phytosanitary inspection

Area	Inspection authority
Plant protection products residues	Sanitary inspection, Veterinary inspection, Phytosanitary inspection
Animal welfare	Veterinary inspectors
Plant health	Phytosanitary inspection
Restaurants, shops	Sanitary inspection

**5.5.3. Register of FBOs:**

There is no common register of FBOs. Each ministry has its own register. Sanitary inspection registered 25.000 FBOs. Veterinary inspection registered almost 3000 FBOs. Of that number 1200 are slaughterhouses and other are meat processing facilities, dairies, fish farming and processing facilities. According to the new Food Safety Law the register of FBOs will be centralized.

There are some 778.000 individual farmers of which only 125.000 are registered.

**5.5.4. Frequency of control and fees**

In this moment there is no coordinated control plan or coordinated monitoring plan and inspection is not done on the risk basis. Also, a central register

of data doesn't exist. Lack of coordination between ministries is visible.

Both ministries have their annual inspection plans. The annual monitoring plan for residues in food of animal origin was accepted by the FVO. Veterinary inspectors visit each FBO at least once a year and if non-compliances with regulations are identified additional inspection visits may follow (1-2).

Sanitary inspection, historically, was in charge of all premises producing food of plant origin and in charge of inspecting hygiene in premises producing food of animal origin. Also, they inspected food of both plant and animal origin at borders. Since the number of FBOs registered at Ministry of Health was high (25000) inspectors visited plants from once in a year to once in five years. The plan of visits was not made on a risk basis.

Imported goods are sampled only if some notification through the RASFF or the EFSA system is placed. Otherwise, only documentary checks are performed. If some non-conformities in results of analysis are found, than the next shipment of coming from the same producer or importer should be mandatory checked and sampled and if compliant, the inspection returns to the annual check plan. Commodities coming from so called "third countries" non – EU countries, are tested according to the monitoring plan of each ministry, but mandatory the first time the producer sends a shipment and than in 3-6 months periods if no non-conformities were found. In case they were found, the inspection becomes regular or more frequent.

Total budget of the MAFW for 2009 is \$500 million of which 25% will be earned from animal health protection services and from taxes (export certificates, animal health certificates, registering of FBOs). Out of the total budget, almost 48% are planned for financing of the General Inspectorate. It must be emphasized that from June 2009 due to transfer of large number of inspection activities from Ministry of Health to the MAFW, budget for the General Inspectorate must be higher than in previous period. All inspectors are civil servants employed in the MAFW and inspection services are paid directly from the budget of the ministry.<sup>48</sup>

Food safety inspection at the Ministry of Health is financed from the government budget and from the municipality budget according to the Annual plan for inspection.

In case of non-compliances met either in border control, production, catering or retail inspectors in charge determine which level of sanctions should be applied, but having in mind that the prescribed list of sanctions is given in the Food Safety Law,

Veterinary Law, Law on Plant Protection and Phytosanitary Law.

**Table 16. Data on inspection (2008)**

Total number of inspectors (veterinary +sanitary)	848
No FBOs <sup>65</sup>	28.000
No of veterinary inspectors <sup>66</sup>	355
No FBOs per veterinary inspector	8.5
No of inspections in veterinary inspection	31.229
Average No of veterinary inspector visits per FBO	1.1
No of veterinary inspection visits as percent of Audit Plan (%)	90%
No of sanitary inspectors <sup>67</sup>	270
No FBOs per sanitary inspector	92.5
Average No of sanitary inspection visits per FBO/year	0.4
Percentage of visits with registered nonconformities	40%
Annual number of Follow –up visits (% of all audits)	10-20%
Annual No of appeals (veterinary service)	2318
Percent of recalls in domestic production	12%
Percent of recalls in import	3.8%

*\* Register doesn't distinct clearly active FBOs from those which stopped their activities or were never active*

### 5.5.5. Sampling:

Sampling was performed by veterinary and sanitary inspectors. Total number of samples taken by sanitary inspection for microbiological analysis was 83.986 of which 9.27% were non-compliant with the national regulations, also 59.596 samples were analyzed on chemical parameters and 4.64% of samples were non-compliant. It is important to stress that the number of inspection samples is not the sum of both microbiological and chemical samples, since the same specimen can be analyzed on both.<sup>68</sup>

Sampling of food according to the National Residue Plan in products of animal origin and meat is performed by veterinary inspectors and samples are analyzed by laboratories belonging to the network of 12 Veterinary Institutes (public and private).<sup>69</sup>

Laboratory analysis of samples taken by inspectors (boarder or inland) are paid directly to laboratories (state or privately owned) by producers, with the exemption of the annual monitoring plan sampling when analysis are financed from the budget of the

<sup>65</sup> Register doesn't distinct clearly active FBOs from those which stopped their activities or were never active

<sup>66</sup> <http://www.minpolj.gov.rs/download/informator09.pdf>

<sup>67</sup> <http://www.zdravlje.gov.rs>

<sup>68</sup> Institute of Public Health Annual Report 2008

<sup>69</sup> Veterinary Directorate Annual Report 2008

ministry (either of agriculture or health depending which inspection took samples).

#### 5.5.6. Visits of controlling bodies other than those participating in the food safety system control to FBOs:

- Fire inspection
- Safety on work
- Metronomy (inspection of measurements)
- Ecology

#### 5.5.7. Quality control of inspection:

In the MAFW there is a plan to implement ISP 9001 in the General Inspectorate in 2009. The inspection procedure for all inspections is given in the Law on Official Procedures.<sup>70</sup> It deals with authorities of inspectors and procedures he can apply: inspections, reporting, prescribing fines, closing of FBOs, recall.

The Sanitary inspection acts according the same Law on Official Procedures.

In this moment, there is no proper auditing system of the quality of inspection performance and the control is covering only the realization of the planned number of inspections. Also, inspections results show the same number of non-conforming samples for almost 10 years and yet no improvement in inspection performance was made in that period.

Check lists are under construction in the MAFW (there are drafts of check lists for dairy and for meat production). Check lists for production of food of plant origin are also under construction. Central register of objects and of testing laboratories is under construction.

#### 5.5.8. Training:

Annual training plans for veterinary inspection were made and executed by Veterinary Office (38 days in 2008). Among those were trainings in the HACCP system auditing. Trainings of other inspectors from the MAFW are planned for 2009. Sources of funding are merely provided from the budget of ministry and partially from donor funds. Sanitary inspection doesn't have budget for training in food safety for 2009.

#### 5.5.9. Transparency:

Data on inspection frequency are not publicly available. Status of control documents cannot be accessed electronically and producers must get in direct contact with inspectors in order to provide them information on corrective measures they have taken, or to get information on their appeal. The

general public has no access to data. Data on non-conformities found in sampling are not released to the public. Also, data which could be found in the Institute of Public Health Annual Report are not representative for the whole number of samples taken by sanitary inspectors, since they also, send samples to private laboratories and these data are not gathered in any database. Results on samples taken by veterinary inspection are stored in the Veterinary Directorate database.

#### 5.5.10. Food borne diseases:

Number of food borne infections increased from 2002-2006, with salmonellosis decreasing and representing only 9.41% of the total number of food borne infections. In food borne outbreaks *Salmonella species*, *Staphylococcus species* and parasite *Trichinella* are the most common. According to official data number of food associated illnesses varies between 36-50 per every 100.000 inhabitants annually. In 2008<sup>71</sup>

Data from 2007 show that Salmonella was found in 0.04% of samples taken by inspectors. The main sources of Salmonella were eggs and meat.

Data from 2007 survey on food in retail in province Vojvodina showed 18% of samples to be non-compliant from the microbiological standpoint (*Salmonella species*, *Campilobacter*, *Listeria monocitogenes*).<sup>72</sup>

These results indicate that spot checking performed by inspectors cannot be representative for microbiological contamination. The same situation could be found for chemical contaminants. In order to overcome this situation, safety in production, retail and catering should be established on the HACCP principles, and inspectors have to check the efficacy of the food safety system applied. A new Rulebook on Microbiology of Food is drafted and is supposed to enter into force by end 2009. This rulebook will establish a new sampling system which will take into consideration results acquired during certain period (over one month, 2 months, or one year – depending on vulnerability of product in scope). The rulebook is made in line with the EU regulations on microbiology (Reg. 2073/2005 and 1441/2007).

#### 5.5.11. Summary

Since 2000, the reform of food safety is underway in Serbia. The new division of the inspectors' responsibilities finally resolved the overlapping of inspections. New laws and ordinances are harmonized with the EU regulations and Codex Alimentarius standards. The legislative basis for the risk

<sup>70</sup> Zakon o upravnom postupku, Sluzbeni list SRJ 33/97

<sup>71</sup> Institute of Public Health Annual Report 2008

<sup>72</sup> Cent Eur J Public Health 2007; 15 (4): 167-171

analysis (assessment, management) is made, but this approach should be developed in the future period. The HACCP system is required for all producers of food of animal origin and for all other FBOs will be mandatory by June 2011.

Food safety inspection is still relying on the end product testing and is not risk based. Capacity building in inspections is underway (training, building of registers, databases, check lists, guidelines).

## 5.6. SLOVENIA

Since 2004, Republic of Slovenia is a full member of the EU. In 2007, Slovenian GDP (PPP) was estimated at \$54 billion. The nation has GDP per capita higher than other transitioning economies of Central Europe, estimated at \$23,000. Total number of inhabitants in 2007 was 2.000.114. The Budget of the government represents 1.55% of the GDP. The share of agriculture in GDP is around 2%. In 2005, the production of food and drinks contributed 1.7 % to the GDP which is a decline from the previous period.

### 5.6.1. Legal framework

- Agricultural Act<sup>73</sup>
- Act Regulating the Sanitary Suitability of Foodstuffs, Products and Materials Coming in Contact with Foodstuffs<sup>74</sup> amended in 2004 and 2007 and fully harmonized with the EC Regulation 178/2002. A number of sublaw documents (ordinances) regulating: microbiological control, residues, additives, dietetic products, labeling, quality of food products, potable water, etc; are subordinated to this Act. According to amendments of this Act all producers must apply food safety practices based on the HACCP system and all products produced in facilities which were registered for domestic production only, must be removed from the market by January 2010 (again 3 years grace period).
- Veterinarian Act<sup>75</sup> treating animal health and animal welfare, with respective sublaw documents subordinated to this Act.
- Act on inspection control<sup>76</sup> treating education/knowledge of specific inspectors (among them veterinarians, plant protection inspectors, sanitary inspectors)-basic requirements, official identification, authorities (to inspect, close, prescribe fines, recall)
- Act on official procedures<sup>77</sup> defines how the official procedures in inspection are undertaken, procedures and authorities to deal with cases of appeal, defines which cases to be submitted to court for further prosecution
- Act on plant products protection;<sup>78</sup>
- Decree on coordination of the working of ministries and bodies within them with responsibility in the area of food and feedstuffs safety, in their incorporation into the process of risk analysis<sup>79</sup> (Official Journal of the RS, 56/03);

### 5.6.2. Authorities responsible for the food safety system:

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

**A. Ministry of Agriculture, Forestry and Food** (Fig. 10) – where there are three Directorates (for Agriculture, for Food Safety and for Forestry, Hunting and Fisheries) of which the Directorate for Food Safety ensures co-operation within control bodies from this ministry:

- **Veterinary Administration (VARs)** responsible for regulation and control (at border posts and in domestic production) of safety of food of animal origin, animal health, welfare, safety of feed;
- **Inspectorate for Agriculture, Forestry and Food (IRSAFF)** which is responsible for safety of food of plant origin and control of pesticide's residues;
- **Phytosanitary Administration (PARS)** responsible for regulation of pesticide use and regulation and control of plant health, seeds, plant propagating material, fertilizers (at border posts and in domestic production and use);
- **Food Quality Inspection Service (FQIS)** responsible for control of quality of food and labeling.

### B. Ministry of Health

- **The Health Inspectorate (HIRS)** – 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, pre-packed raw meat in retail
- **The Agency for Medicinal Products and Medical Devices** which regulates and inspects production and trade of medical and veterinary health products and manages risk from use of these products.
- **National Chemicals Bureau** – responsible for packaging, labeling and classification of pesticides.

### C. Ministry of Environment and Spatial Planning

- **Inspectorate for Environment and Spatial Planning (IRSEP)** – control of water sources and regulation of environmental issues,
- **Environmental Agency (EARS)** – responsible for waste, disposal plants for pesticides and issues permits for rendering of animal by-products.

<sup>73</sup> Zakon o kmetiljstvu, Uradni list 45/08

<sup>74</sup> Zakon o zdravstveni ustreznosti živil in izdelkov ter snovi, ki prihajajo v stik z živali (ZZUZIS), Uradni list 52/00

<sup>75</sup> Zakon o veterinarstvu, Uradni list RS 33/01

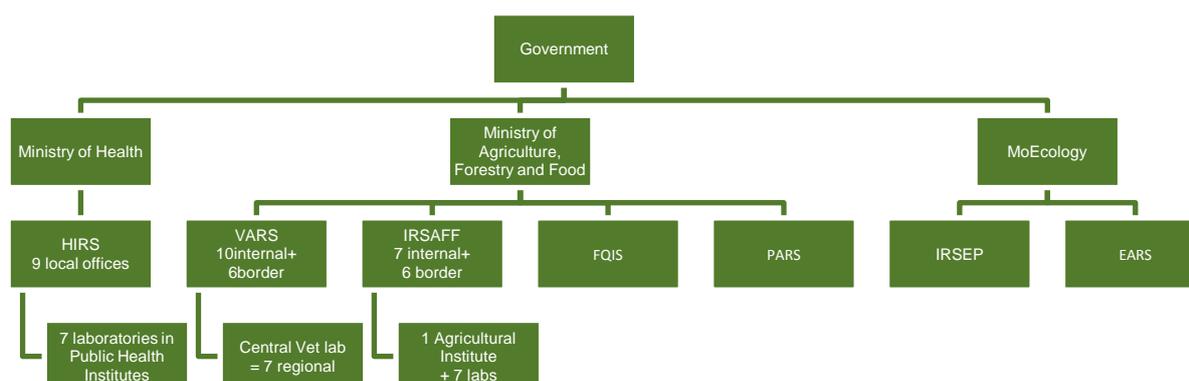
<sup>76</sup> Zakon o inšpekcijskem nadzoru (ZIN), Uradni list 43/07

<sup>77</sup> Zakon o inšpekcijskom postopku, Uradni list 44/06

<sup>78</sup> Zakon o zdravstvenom varstvu rastlin, Uradni list 45/01

<sup>79</sup> Uradni list 56/03

Fig 10. Organizational structure of the food safety inspection system in Slovenia



### Inter – ministerial cooperation:

Legal obligation according to the Decree on coordination of the working of ministries and bodies within them with responsibility in the area of food and feedstuffs safety, in their incorporation into the process of risk analysis. 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.

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

Table 17. Division of inspections

Area	Inspection authority
Animal health	Regional office VARS
Food of animal origin	Regional office VARS IRSAFF, ISQF, HIRS
Import of animals and food of animal origin	Border office VARS
Feedingstuff and animal nutrition – import	Regional office VARS IRSAFF, FQIS, Customs office
Feedingstuff and animal nutrition – production	Regional office VARS IRSAFF, FQIS
Animal byproducts	Regional office VARS HIRS, IRSEP
Veterinary medicines authorization and distribution	Regional office VARS AMPMD
Veterinary medicines residues	Regional office VARS
Food and Food hygiene	Regional office VARS, HIRS, IRSAFF, FQIS
GMO	Regional Veterinary Food Authority

Area	Inspection authority
	Plant Directorate Danish Environmental Protection Agency
Import of food of plant origin	HIRS, IRSAFF, Customs authorities, PARS
Plant protection products authorization and sale	IRSEP, IRSAFF
Plant protection products residues	HIRS, IRSAF,
Animal welfare	Regional office VARS
Plant health	IRSAFF, PARS, Agricultural Institute
Restaurants, shops	Regional Veterinary Food Authority

### 5.6.3. Register of FBOs:

Ministry of Agriculture and Ministry of Health have their separate registers of FBOs. Some establishments are approved for export to the EU and other are registered for domestic production and they export to non-EU countries. There are some 77.000 agricultural holdings, 426 food processing companies and 55.842 feed producing operations registered at the Ministry of Agriculture.<sup>80</sup> At the Ministry of Health Register there are 20.528 FBOs.<sup>81</sup>

### 5.6.4. Frequency of control and fees:

Both controlling authorities have an annual control plan. In the Ministry of Agriculture VARS there is an risk criteria based control plan (2-12 visits per year) with control over traceability included in the plan, and they, also, have the multiannual control plan (2007-2010) approved by EC FVO.

Frequency of control of food safety is determined in the Ministry of Health according to the level of risk attributed to each FBO. Those with low risk level are audited once in 24 months, medium risk

<sup>80</sup> [http://www.vurs.gov.si/en/establishment\\_registers/](http://www.vurs.gov.si/en/establishment_registers/)

<sup>81</sup> [http://www.zi.gov.si/si/zdravstveni\\_inspektorat\\_rs\\_zirs/](http://www.zi.gov.si/si/zdravstveni_inspektorat_rs_zirs/)

level FBOs are audited once in 15 months and high risk FBOs once in 9 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 that 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 case.

In border inspection, documents on products coming from the EU countries are regularly checked and lots are not sampled at border posts, with exemption when some non-conformities in documents were observed, or if through the FAO's Rapid Alert system the notification concerning specific producer or product is sent. If some non-conformities in results of analysis are found, than the next shipment should be mandatory checked and sampled and if compliant, the inspection returns to the annual check plan. Commodities coming from so called "third countries" non – EU countries, are tested according to the testing scheme of each ministry, but mandatory the first time the producer sends a shipment and than in 3-6 months periods if no non-conformities were found. In case they were found, the inspection becomes regular or more frequent.

**Table 18. Data on inspection in 2007<sup>82</sup>**

Total number of inspectors	576
No FBOs registered at VARS	313
No of veterinary inspectors per FBO	1.6
Annual No of visits of veterinary inspectors	5271 + regular presence in slaughterhouses
Average No of visits per veterinary inspector	16.5
No PARS + IRSAF inspectors	72
Average No of visits per inspector (plant protection + phytosanitary inspectors)	55
No of export /import controls performed by PARS+IRSAF inspectors	15.242
No of FBOs registered at PARS	1189
No of premises visited by sanitary inspection	16.146
No sanitary inspectors	87
Total No of premises registered at sanitary inspection	20.528
Number of follow-up visits in 2007	4869
Average No of visits per sanitary inspector	238

<sup>82</sup> DG Sanco Final Country Profile of Slovenia, 7706/2008

Number of sanitary inspection audits conducted as a percent of Audit Plan (%)	78.7%
Percentage of audits with registered nonconformities	10%
BIPs control – total No of samples (VARS+HIRS)	752
BIPs control – recalls	9

**Table 19. Number of inspectors in Slovenia<sup>62, 63</sup>**

Authority	Number of inspectors
MAFF head office	34
VARS	319
IRSAFF	22,5
PARS +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 fte

### 5.6.5. Sampling:

Implementation of monitoring takes place on the basis of a two-year program. The selection of foodstuffs and agricultural products, and of the active substances, is determined in line with recommendations from the EU (Commission recommendation 99/333/EC), WHO, national priorities and on the basis of the professional opinions of authorised performers.

Permanent groups of foodstuffs monitored are: lettuce, potatoes, apples and milk. Variable groups of foodstuffs monitored are: fruits, vegetables, cereals and products.

Approximately 300 samples of agricultural products (150) and foodstuffs (150) are investigated each year.<sup>83</sup>

According to the monitoring plan results values of pesticides higher than allowed per legislative documents are found in 1% of food products and 5% of agricultural products. The aim of the program is to have products without residues of pesticide.<sup>65</sup>

### 5.6.6. Inspections which control processing of food other than food safety inspections:

- Fire inspection
- Safety on work
- Metronomy (inspection of measurements)

<sup>83</sup> Institute of Public Health Slovenia data

Each of these inspections visits food processing facility once a year.

### 5.6.7. Quality control:

The Health Inspection, Veterinary Administration and Inspectorate for Agriculture, Forestry and Food have implemented internal audit systems. Quality Assurance and Internal Audit Service is a department at VARS is dealing exclusively with control of inspection work (are inspectors following rules and guidelines for inspection work and are they inspecting premises according to acting laws and regulations). Director of the VARS regional office or Head of a section according to authorization of Director of VARS regional office is checking performance of each veterinary inspector at least once in 3 years (this is called verification of inspector's performance). They verify whether each inspector performed control over program for self inspection in premises he is responsible to control. Also, the EC FVO controls perform insights into inspection's work (all food inspections) and accordance of their procedures with the EU practices. HIRS has ISO 9001 implemented and procedures for inspection work control are established.

### 5.6.8. Annual training:

Ministry of Agriculture has a budget line for training of VARS inspectors. Training in import controls, implementation of the European Community legislation and practices, training in official feed control, implementation of check lists in slaughterhouses were organized in 2008. Guidelines in good practice for producers of primary products, animal welfare were developed. Ministry of Health will have support from EU funds for training of inspectors in 2009-2010.

### 5.6.9. Transparency:

In Slovenia data on food safety are not accessible from official sites. Check lists and their updates are mounted at the VARS web portal.<sup>84</sup> Data on monitoring could be assessed through the EC FVO reports on situation in Slovenia, or through the EFSA documents.

### 5.6.10. Food borne diseases:

Official data show that an annual number of food-borne illnesses (incidence) according to Ministry of Health data is 600-800/100.000 inhabitants of which 1520 are caused by various strains of *Salmonella* and 940 by *Campylobacter*. In 2007 there were 17 outbreaks, of which 16 from pathogens isolated in food and one from pathogens in drinking water. In 2008 no significant change in data on food borne diseases was reported.<sup>85</sup>

### 5.6.11. Summary

Slovenia reformed the 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 when Slovenia joined the EU, all legislation in this area was harmonized with the EU requirements. In 2006 they incorporated practices and recommendations of the EU "Hygienic package"<sup>86</sup> of legislation and started developing check lists for inspection, along with orientation towards self checking of facilities and inspection control of these programs. From the very beginning of the food safety reform in Slovenia, full harmonization with the EU legislation and practices was performed.

<sup>84</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>85</sup> <http://www.eurosurv.org/>

<sup>86</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.

## 5.7. SWEDEN

Sweden is a constitutional monarchy with population of 9, 2 million inhabitants (est. 2009). The country is divided in 21 counties. The GDP (PPP) in 2007 was \$346.2 billion with GDP (PPP) per capita of \$38,300 (2007 est.). Agriculture accounts for only 1,5% of the GDP (11.760 million USD) and the whole industry segment of 28.9% of the GDP. Main agricultural products in Sweden are barley, wheat, sugar beets, meat and milk. Fishery is also, important as a source of food for domestic population. Export of fish is low due to chemical contamination of Baltic fish. Sweden is importing food products, mainly fruit and vegetables, but also a range of consumer oriented agricultural products (processed fruits and vegetables, nuts, wine, beer, sauces, cake mixes, rice, confectionary) and fish products. Main import markets are those from the EU, USA, Brazil, Malaysia. The import exceeds export almost by 50%.

### 5.7.1. Legislative framework:

**A. Food Act** applies to all stages of food production and distribution and is fully harmonized with the EC Regulation 178/2002. It describes the responsibilities of food control authorities and contains provisions on penalties and appeals.<sup>87</sup>

**B. The Food Decree** which complement the Food Act and defines in detail responsibilities of authorities and specific acts and ordinances which regulate specific issues (drinking water, treatment of food with ionization, labeling, personal hygiene, etc). This document is a sort of synthesis of where in specific legal documents certain issues are addressed, and which body is responsible for issuing such documents.<sup>88</sup>

**C. The National Food Administration Code of Statutes** which consists of documents which directly transpose the EU Directives.

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

### 5.7.2. Ministries responsible for food safety are:

#### At central level:

**A. Ministry of Agriculture** which has the overall responsibility over the agricultural sector, animal health and welfare, plant health, food and feed production, fishery. The ministry gives the policy orientation, proposes a budget according to annual reports received from authorities which are under its jurisdiction. There are 9 departments in the ministry of which four are dealing with food safety:

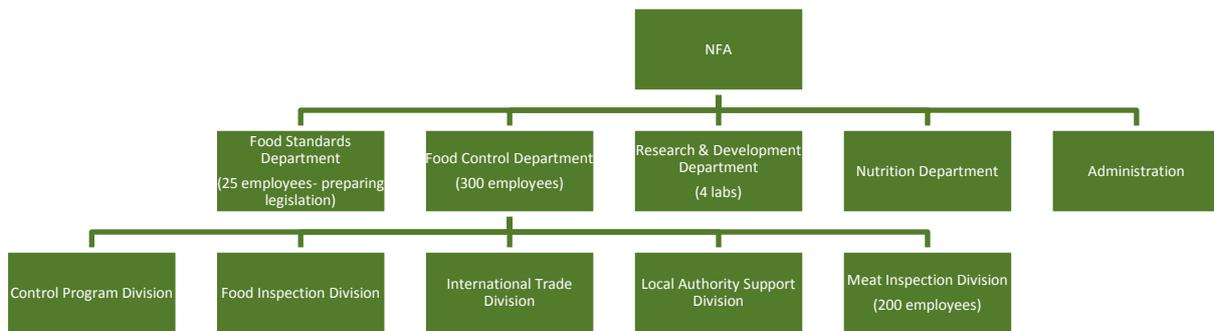
*a. National Food Administration (NFA)* is the authority responsible at the central level to: prepare legislation in the food area, implement direct official control, co-ordinate control of other authorities and report to the government on issues of food. It directly performs controls on 5 border posts (3 ports and 2 airports), all slaughterhouses and cutting plants (Except Stockholm and Gothenburg). It performs controls on all egg establishments, and on larger milk and fish establishments. The NFA has 540 employees (320 in the head office in Uppsala and other throughout the country).<sup>89</sup>

<sup>87</sup> Livsmedelslagen SFS 2006:804

<sup>88</sup> Livsmedelsförordningen SFS 2006:813

<sup>89</sup> <http://www.slv.se/en-gb/>

Fig. 11. Organizational structure of the NFA

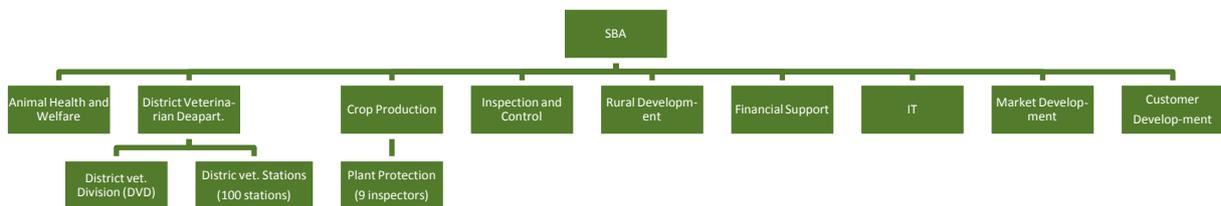


Food Control Department has a staff of 300, of which 200 are in meat inspection. Other inspect food of non-animal origin. The Department implements control over 550 food plants and 5 border posts. It is also responsible for preparing and implementing annual control programs. The National Food Administration charges a fee for import controls on certain foods from third countries (non-EU countries).

Under Research and Development Department are four reference laboratories for food and veterinary residues: 2 for chemistry, one microbiological and one toxicology.

b. *Swedish Board of Agriculture (SBA)* responsible for animal and plant health, control of contagious diseases, feed and animal by-products.

Fig.12 Organizational structure of the SBA



District Veterinarian Department has 430 veterinarians in headquarters and District Veterinary Stations (responsible for direct control of animal health, import of live animals and control of veterinary residues; they also provide services to farmers).

Crop production Department has 100 employees, of which 21 are plant protection inspectors. Department controls GMO, organic production, seed.

Department for Inspection and Control is responsible for phytosanitary control (pests), quality control of fruit and vegetables, feed control, meat classification, animal by-products.

c. *National Veterinary Institute* – the expert veterinary body. Prevention of outbreak of animal diseases and zoonosis, production of vaccines, control of contaminants in food and feed. The largest veterinary laboratory in Sweden.

d. Swedish Board of Fisheries

## B. Ministry of Health and Social Affairs

e. Medical Products Agency

f. Swedish Institute of Infectious Disease Control

**C. Ministry of Finance** – this ministry is responsible for monitoring of the collection of fees from municipalities and regulations which municipalities issue regarding fees. Control over the import/export is performed through:

g. Customs Service

## D. Ministry of Environment

h. Swedish Chemical Agency

i. Swedish Environment Protection Agency

k. Swedish Coast Gard

## I. Regional Level:

County Administration Boards-CAB – (21 counties) – they 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, training for municipality inspectors, they manage appeals to

decisions of municipality control. They report annually to NFA, SFA and Ministry of Finance.

**m. At Local level:**

- Municipality Administration Boards –MABs- (290 boards) – they control food, hygiene and environment. They control establishments dealing with food of animal (small establishments) and plant origin. If one municipality doesn't have capacities for all control it may collaborate with neighboring municipality.
- Municipality Public Health Offices (290 offices) control food of plant origin.

**Table 20. Division of inspections**

Area	Inspection authority
Animal health	SBA CAB
Food of animal origin	NFA CAB
Import of animals and food of animal origin	SAB NFA
Feedingstuff and animal nutrition	SBA
Animal byproducts	Regional & District Veterinary Food Authority
Veterinary medicines authorization and distribution	Medical Products Agency
Veterinary medicines residues	NFA
Food and Food hygiene	NFA CAB
GMO	SBA
Import of food of plant origin	NFA
Plant protection products authorization and sale	Swedish Chemical Agency
Plant protection products residues	NFA
Animal welfare	SAB CAB
Plant health	SBA
Restaurants, shops	Self control

### 5.7.3. Register of FBOs:

There is no national register of FBOs, approvals of establishments are performed by different authorities according to the new hygiene legislation (EC Reg 882/2004). All establishments have to be approved by end 2009. Total number of FBOs (2007/2008) was 65.715, and 80.000 additional primary producers. NFA controls about 500 establishments.<sup>69</sup>

### 5.7.4. Frequency of control and fees (food and feed)

There is an annual control plan according to which premises are visited at 0.2-12 times a year. Both frequency and fees to be paid by the FBO are determined on a risk base – according to the risk level of the type of business and according to previous

hygienic status, so that the authority estimates number of hours that inspector needs to spend for that establishment. Than the number of hours is multiplied by the hourly rate.

For businesses controlled by municipalities, the municipality council defines hourly rate.

For the primary production an annual tax is paid to the CAB.

Sanctions in case of nonconformities are prescribed by NFA, but municipality officials may decide on their own how to approach implementation of 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>90</sup>

**Table 21. Data on inspection 2007-2008<sup>70,91</sup>:**

Total number of inspectors	1195
No plant protection inspectors	21
No inspectors at NFA	300
No FBOs controlled by NFA	550
No veterinary inspectors in NFA	200
CAB veterinary inspectors	43
No inspectors in municipalities (total)	847
No FBOs	65.715 +80.000 primary producers
Annual number of inspection audits to FBOs	42.485
Average number of visits/FBO	0.65
Annual No audits/inspector	35.4
No NFA veterinary inspectors / large& medium size FBOs	1.7
Number of inspection audits conducted as a percent of Audit Plan (%)	Not available
Percentage of audits with registered nonconformities	49%
Annual number of Follow up visits – (%) of all audits	Not available
Annual number of appeals	197
Annual number of recalls – domestic products	44

**Table 22. Number of inspectors (full time employed)<sup>70</sup>**

Authority	Number of inspectors
NFA	250 (200fte) <sup>92</sup>
SBA	36 veterinary inspectors
National Veterinary Institute	198
CABs	43 (36 fte)
MABs	847 (529 fte) food control
Total	1195

<sup>90</sup> DG Sanco Country profile 7705/2008

<sup>91</sup> <http://www.slv.se/en-gb/Group3/Publications/>

<sup>92</sup> fte – calculated on a full time equivalent basis. The number of staff are part time employed as inspectors and the rest of the working time provide services to farmers.

Lack of capacities exists in municipalities. Some 180 full time employees equivalent are needed. Both recruiting and training of inspectors were started since 2006, and expected to be realized to the optimal level by end 2009. Also, some jurisdictions like animal welfare and hygiene are to be transferred to CABs.

The annual budget of the NFA is made of 50% of finances coming from the state budget and 50% from fees for inspection. The total budget is about 52 million dollars.<sup>93</sup>

### 5.7.5. Sampling:

The Annual Control Plan is the obligation of the EU country according to the Regulation EC 882/2004.

The sampling plan for border inspection (microbiological, chemical control) is made according to Regulation EC 134/2004.

Official control on residues requires about 5500 samples for veterinary medicines and hormones in food annually. Also, 1500 agricultural products have to be sampled in 2008. NFA itself, analysis 6000 samples of all food products, of which 693 (2007) came from sampling of imported agricultural and food products from the border inspection. Some 130 samples are analyzed annually on the presence of GMO. Levels of residues in fruit and vegetables from countries outside the EU were higher than allowed in 3-8,1% of samples depending on the country of origin.

Due to high level of pesticides in products of plant origin 44 noncompliances were found on the market in 2007.<sup>70</sup>

### 5.7.6. Budget for inspection:

There is no central budgeting for the food safety system. The overall national budget in 2007 was \$ 5.748.729.000, and the budget for NFA itself was \$ 53.000.000. The annual budget of the NFA is made of 50% of finances coming from the state budget and 50% from fees for inspection.<sup>94</sup>

Municipalities fund inspections through their own funds. It is important to stress that a national plan for training of inspectors at all levels is the obligation according to EC rules, and for that purposes approximately 5% of the budget from each food regulating and control authority is planned.

### Quality control:

NFA prepared guidelines for municipalities how to perform control. These guidelines are available at

the NFA web site. NFA also, produced check lists for different types of food producing operations. These check lists are supported with the computer program where data from inspection visits are stored. Over 70% of municipalities have already implemented computer based programs.<sup>95</sup> This a good way for having insight in inspector's performance and efficacy.

There is a "internal audit system" where National Food Administration and SBA audit performance of each County administrative board, and every CAB makes audits on every municipality in their region. They perform audits using data which each municipality must send electronically to CAB and CAB must forward it to the NFA. Three groups of parameters sent are used for assessing performance: microbiological, chemical contaminants and labeling. SBA performs audits on border post inspection according to the same parameters.

### 5.7.8. Transparency of data on inspection:

Authorities are obliged to publish annual reports and disseminate them to the superior level. Publicly available data are published on official web sites.<sup>96</sup> There is a link to the "Black list" of products and countries of origin of products here consumers can find information on contaminants in food.<sup>97</sup>

### 5.7.9. Visits of controlling bodies other than those participating in the food safety control to FBOs:

There are no other regular auditing in food producing premises beside food inspection. Instead, authorities make different campaigns where they visit different premises and sometimes make audits (workers safety for example). A food producing factory (milk plant, slaughterhouse) is inspected by the NFA if being the large size producer or by municipality inspectors if it is a small size producer.

### 5.7.10. Number of food borne outbreaks per year

There were 4024 food born cases reported to healthcare. There were 11 salmonellosis -human outbreaks with 330 cases reported in 2007.

Data for *Salmonella* found in different food and feed in Sweden in 2007 show that it was found in 4182 samples of which 681 came from domestic production, 3466 from imported goods.

In 2008 there was an outbreak of *Salmonella* infection with one hundred of cases in Denmark, Nor-

<sup>93</sup> S. Slorach: According to NFA data

<sup>94</sup> S. Slorach: According to NFA data

<sup>95</sup> According to data obtained from the supplier of programs Edpconsult

<sup>96</sup> <http://www.slv.se/en-gb/Group2/Food-Control/>

<sup>97</sup> <http://www.slv.se/en-gb/Group2/Food-Control/The-National-Food-Administrations-Black-list/>

way and Sweden, but the source in Sweden was from imported food (pork from Denmark).<sup>98</sup> The Rapid Alert System functions among Nordic countries, but also, at the European level (the RASFF). There was an outbreak with meat from Ireland, too.

#### 5.7.11. Summary

Swedish food safety system is divided on the central, regional and local (municipality) level. Plant protection, control of use of pesticides and control over almost 80.000 producers was transferred in 2009 from the municipality to the regional level, since municipalities lacked resources for control of such a big number of FBOs.

Recommendations from the central level (from the NFA) in some cases are not fully followed at the regional (CAB) level. The NFA provides legislation, guidelines, check lists, laboratory testing, proficiency testing for other food safety laboratories and connection with the EFSA. The centralisation of the inspection services may be a good solution for the Swedish food safety system, this idea was advocated by experts in Sweden, but has not yet been officially recognized. In the meantime, the risk based inspection approach is applied in 70% of municipalities and their inspections are connected on-line with the NFA. Thus, data from inspections are available to the officials at the central level.

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<sup>98</sup> <http://www.eurosurveillance.org>

## 5.8. UGANDA

Uganda is the sub-Saharan, East Africa country with the population of 32,369,558 inhabitants, and with the GDP (PPP) of \$33.57 billion (2007) and the GDP per capita of \$1.100. Major domestic agricultural products are: coffee, fish, tea, cotton, tobacco, cassava (tapioca), potatoes, corn, millet, pulses, cut flowers, beef, goat meat, milk, poultry. The major agricultural export commodities are: coffee, fish and fish products, tea, while cereals are major imported agricultural products. Countries to which products are exported: Rwanda, Libya, Japan, India, Pakistan, Britain, Italy, Spain and Egypt. Agriculture has for several years been the ground of Uganda's economy contributing to 37% of the GDP. Coffee contributed with 19% to the country's exports.

The Economic growth of 8.9% puts Uganda among the fastest growing economies in Africa. Over the last ten years, the economy has greatly transformed moving away from subsistence-based agriculture which used to constitute greater share of economic activity to a mixture of commercial agriculture, services and industry.

### Legal framework

A. In Uganda the main law that regulates food safety is the Food and Drug Act (1964). In 1993 the drug element was taken out of this law and transformed into the Drug Act under the National Drug Authority (NDA). In 2003 the Food Safety Bill was issued but it does not address the new technological developments in the food industry, e.g. safety of genetically modified foods, international food regulations as required by the World Trade Organisation (WTO), or by the European Communities and other international food markets. For example, for food additives and contaminants, packaging and other sanitary and phytosanitary requirements are not covered in it.<sup>99</sup>

B. The Plant Protection and Helath Bill (2003) sets standard in phytosanitary control.

### 5.8.1. Authorities responsible for the food safety system:

#### A. Ministry of Health, Environmental Health Division

- *Department of Environmental Health* – primary body in food safety, co-ordinates food safety matters and supervises (on training and policy matters) the activities of semi autonomous local government units (Districts, Town Councils, Municipalities and a City) who employ Health and Food Inspectors and who are in charge of food inspection. The Division receives less than

5% of the Ministry of Health's annual budget. The Division's mandate is provided under Food and Drug Act issued in 1964 which doesn't cover current issues in the field (i.e. risk management, traceability, etc.). The Division, working in collaboration with other agencies and stakeholders, recently drafted a Food Safety Bill. The Bill makes provision for the Division to serve as a central body on food safety issues, to be supported by technical working groups dealing with specific topics.

Health and Food Inspectors focus on the hygienic and safety standards of the premises, sanitary fittings, utensils, workers health. Inspection of food establishments cover the following: food processing plants, eating places, markets, bakeries, fish or meat shops or stalls, grocery stores, milk shops and slaughterhouses.

- *National Drugs Authority (NDA)* – controls the use and sale of drugs (medical and veterinary) and importation of food supplements.

**B. Ministry of Agriculture, Animal Industry and Fisheries (MAAIF)** has various departments with specifically defined roles and responsibilities in relation to food safety and agricultural health. These include the following:

- *Department of Livestock and Entomology* is responsible for the development of policies and regulations on animal diseases, the development of veterinary inspection procedures, and the inspection and certification of imports and exports of animal products. The Department coordinates national programs to manage rabies, CBPP, Rinderpest, and Food and Mouth Disease, and is involved in the implementation of regional animal disease control programs. It provides technical support to the 700 to 800 veterinary officers working at local levels, in part to inspect and certify animal products. The Department is also the designated competent authority for honey.
- *Department of Animal Production and Marketing* ensures compliance with the Animal Disease Act and Regulations. The department is responsible for formation of standards regarding the quality and safety of livestock and livestock products. In this area it provides training, supervision, and other technical back-up to local governments related to plans and programs for livestock and livestock product handling and marketing. This function is expected to be transferred soon to the Department of Livestock Health and Entomology in an expected restructuring. This will help to avoid duplication/ overlaps.

- **The Veterinary Department** – with the veterinary inspection on the central level yet to be developed.
- **The Crop Protection Department** is responsible for formulating and enforcing regulations related to seeds, agro-chemicals and the management of phytosanitary risks. The Department carries out inspections of imports and exports of planting materials and plant based products, mostly checking for pests and diseases. Where interceptions are made, tests might be conducted at the Kawanda Agricultural Research Institute. The Department issues phytosanitary certificates when these are required for exports. Crop protection officers are located at MAIFF headquarters, at zonal stations, and at an increasing number of border/entry posts. The Department is the so-called competent authority responsible for the inspection and regulation of horticultural commodities for local and international markets. A new draft Bill would designate the Department as the National Plant Protection Office.
- **The Department of Fisheries Resources (DFR)** is responsible for the inspection, certification, and control of fish and fish products consumed locally and abroad. It is responsible for enforcing fisheries regulation, including carrying out inspection of factory premises, processing lines, landing sites, fish transport and export points for adherence to safety and quality requirements, as well as maintaining a national fish inspection and quality control system. The DFR issues a certificate for each consignment of fish prior to export. The Department is responsible for regulating and overseeing the emergent development of aquaculture in Uganda. The DFR, in collaboration with local government (District Councils), directs fisheries resource conservation and management initiatives. Budgetary and other constraints inhibit the effectiveness of the DFR.
- **Directorate of Animal Resources (DAR)** has invested substantial human resources in enhancing its legislative and policy direction capacity, an effort that has produced a number of important outputs such as the animal diseases act, animal welfare act and others.

**C. Ministry of Trade and Industry** – Under this ministry there are: Directorate of External Trade, the Uganda National Bureau of Standards and the Uganda Export Promotion Board. Directorate for External Trade handles WTO matters such as notifications under the SPS and TBT Agreements.

- **Uganda National Bureau of Standards** – Food standards developed by this body are equal to

Codex Alimentarius standards. The body operates four laboratories – for microbiology, chemistry, building materials, and electrical matters – while a fifth, for testing petroleum products, is being developed. Only the microbiological laboratory is internationally accredited.

It has developed new standards for:

- Milk & Milk Products (US 164: 2000)
- Fortified Food Products (US 500: 2003)
- Drinking (potable) water (US 502:2003)

**D. Directorate of Water Development** – responsible for the development and improvement of water sources for communities. Sources have to be accessible, affordable and safe for the user communities. Though the mandate of the water suppliers is to ensure safety of water through “water quality control”.

**E. Ministry of Local Government**

**F. National Environment Management Authority** – In charge of the National Profile on Management of Chemicals and on Development of Environmental Standards.

**G. Uganda National Council of Science & Technology.** Provides expert opinion in Biotechnology and Bio-safety e.g. Genetically Modified Organisms or foods produced through biotechnology.

**H. Ministry of Labor** has an occupational health unit that periodically examines health and safety issues for agricultural workers.

#### 5.9.1.1. Interministerial collaboration:

- **Food Hygiene Advisory Committee** – The Committee is composed of technical experts drawn from key stakeholders in the Food Industry – provides support to the Ministry of Health.
- **National Codex Committee** was founded in 2000. Members: Ministry of Health, the National Agricultural Research Organization, the National Bureau of Standards (the National Codex Contact Point).
- **Uganda Cleaner Production Center (UCPC)** Established in October 2001 with the support of UNIDO100, the UCPC helps firms to become more competitive and to improve environmental management by making more efficient use of raw materials and resources. Firms are taught to use water and energy more efficiently and to implement better waste management to reduce operational costs. The UCPC also helps firms to implement cleaner production technologies by assisting companies to achieve ISO 9000 and 14000 certification. As of 2005, the UCPC has

<sup>100</sup> UNIDO – The United Nations Industrial Development Organization

worked with more than 40 enterprises in areas such as fish processing, sugar, leather, tea and tourism.

- **Commodity Development Boards and Other Public Institutions** – quality management for several traditional export commodities is government by particular agencies or Boards for example: Uganda Coffee Development Authority, the Cotton Development Organization.

### 5.8.2. The food safety system:

Laws and regulations since 2000, were developed according to the recognized international models and following Codex Alimentarius standards, but the food safety system is severely obstructed by obsolete food law from 1964 and the lack of resources required for building a sound food safety control infrastructure, including an adequate force, laboratory facilities, and necessary scientific expertise and research.

Activities for food safety and control are uncoordinated and scattered in ministries and are implemented by different agencies and authorities whose mandates are provided under various laws and regulations.

The food safety and quality problems with food from Uganda intended to export are<sup>101</sup>:

- High moisture content especially for grains;
- Contaminants especially sprayed chemicals, drug residues and foreign matter;
- Most exports are not graded.

The food safety and quality problems with products coming from import are:

- Low quality products;
- Expired products;
- Risk importing diseased products – BSE;
- Risk importing genetically modified products especially beans, meats and maize.

**Table 23. Data on inspection**<sup>102</sup>

Total number of food inspectors	Aprox. 1170
No of veterinary inspectors	Aprox. 800
No of ministry of Health inspectors	320
Fish inspectors	50
No of Health inspectors per FBO	0.01
No of laboratories testing food	7 chemicals, 8 microbiology, 8 biotoxins
No of premises to be visited by Health inspection	32.000
No FBOs registered	12 fish processors 30 honey processors – 3000 honey farmers 15 dairies 10 milk collection centers 12.000 producers of organic cotton and sesame

### 5.8.3. Sampling:

The three main laboratories (ChemiPhar, SGS and UNBS) provide the majority of the laboratory services in Uganda. These laboratories have similar capacity and capabilities. All three have ISO 17025 certification, provide similar services, and support groups of clients. In general these laboratories are operating at about 50% of their capacity. Microbiological laboratories have facilities for both sample collection and logistic system for sample collection and dispatch. Foods tested by microbiological examinations are mainly dairy products and meats. Chemical laboratories are equipped to undertake testing of: pesticide residues, additives, heavy metals and other chemicals, toxins of fish & shellfish, toxic plants & mushrooms, mycotoxins, antibiotics, hormones and radioactive contaminants.

There is a national monitoring program for contaminants such as pesticide residues, heavy metals and mycotoxins in fish and similar programs are now developed for honey, fruit and vegetables.

Currently, some \$1.4 million of testing revenue is generated from the testing of Ugandan food and agricultural products. Fish for exports and maize for regional sale or sale to the World Food Programme account for some 60 percent of this testing revenue. The testing of bottled water also generates significant revenues for certain laboratories. Most other testing is for quality parameters, mainly: coffee, tea, cotton, seeds, and other products.

<sup>101</sup> [http://www.afro.who.int/des/fos/country\\_profiles/uganda.pdf](http://www.afro.who.int/des/fos/country_profiles/uganda.pdf)

<sup>102</sup> DG Sanco 8246/2006

#### 5.8.4. Risk assessment

Capacities for risk assessment and risk management are very limited in Uganda. Systematic data collection and analysis is not performed and normally not sustained over time. Responsibilities are fragmented among various institutions, at the levels of central and local government. Local government in before 2005 didn't obey the recommendations or law requirements set by the central government. Still, crisis management is mainly performed usually with support from the international community.

#### 5.8.5. Register of FBOs

Exists in the MAAIF but only for food processors (neither producers, nor retailers or distributors are listed). There is a separate register in the Ministry of Health, Environmental Health Division, but industrial capacities are scarce, while majority of operators inspected by this ministry are in fact very small scale operators (1-5 employees).

#### 5.8.6. Annual training:

There are no provisions for continuing education according to the WHO country profile<sup>103</sup>.

The government and non-governmental agencies are willing to provide extension and advisory services to the food industry and trade. There is an active USDA program running "Livelihood and Enterprises for Agricultural Development (LEAD)" working on increasing rural productivity, increasing trade capacity and enhancing competitiveness of selected agricultural value chains.

Training in legislation, control and testing for inspectors from 10 districts was held in 2009, yet there is need for "The certificate course in food inspection trained inspectors in international standards, regulations and laws, which will help in penetrating developed countries' food markets" as expressed by the State Minister of Water.<sup>104</sup>

#### 5.8.7. Transparency:

There is not a formulated approach to data gathering and exchange of information among governmental agencies. Various inspections exhibit inspection in premises. There are no publicly available data on inspection reports, sampling. Annual sampling plans for

#### 5.8.8. Food borne diseases:

Notification of cases of food-borne diseases is not required by law. Statistics of foodborne diseases is compiled nationally.

According to Ministry of Health data from 1997-2001 show that 2 million cases per year or 16% of all registered diseases are those that can be attri-

buted to food and water contamination (cholera, typhoid, dysentery, para – typhoid, intestinal worms). Food borne disease are not mandatory reported.<sup>105</sup>

#### 5.8.9. Fish industry – the case of standard setting and development of inspection services<sup>106</sup>:

The Uganda fish processing industry was started in 1988. At present, there are 12 registered companies for fish processing and export and of them 10 companies are operational. All of them are situated on the banks of Lake Victoria and Nile Perch is their main raw material.

The total investment by private investors in fish sector in Uganda is around US\$100 million. The fisheries industry employs over 700,000 people involved in various fishing activities including fishermen, fishmongers, fish transporters and boat builders.

Fish exports have grown from a value of US\$ 5.308 million in 1991 to US\$ 39.78 million in 1996, but fell to US\$ 28.8 million in 1997 due to fish export ban by the European Union over fish quality and safety concerns. This ban was lifted in 1998, but then in 1999 another ban was imposed on fish and fishery products originating from Lake Victoria because of the concern that some fishermen were suspected of catching fish using pesticides. This ban was lifted in October 2000 after the Department of Fisheries Resources (DFR), made a program of monitoring of the levels of pesticides and heavy metals in fish, water and sediments from Lake Victoria, and also intensified monitoring and surveillance of fishing activities on the lake.

Companies have been exporting most of their fresh or frozen fillets to European Union, Japan, Hong Kong, Singapore, Australia, Dubai, Israel and United States of America.

Factories in Uganda are estimated to produce almost 400 tonnes of fish per month. The smallest unit exports 50 tonnes of fillets per month and 400 tonnes are exported by big units on a monthly basis.

In 1997, Spain and Italy detected high levels of bacterial contamination including Salmonella in fish from Lake Victoria. Following an outbreak of cholera in East Africa, the EU banned importation of fresh and chilled fish and imposed mandatory tests on frozen fish, fruits and vegetables from East African countries. The second and longest ban was imposed in March 1999 for pesticide residues. The

<sup>103</sup> <http://www.who.int/countries/uga/en/>

<sup>104</sup> <http://allafrica.com/stories/200908311098.html>

<sup>105</sup> Building a food safety system in Uganda. WHO publications 2004.

<sup>106</sup> [ftp://ftp.fao.org/esn/food/meetings/2005/italy\\_crd6\\_en.pdf](ftp://ftp.fao.org/esn/food/meetings/2005/italy_crd6_en.pdf)

Government requested that the Department of Fisheries Resources and the Uganda National Bureau of Standards develop a comprehensive monitoring programme, which would determine levels of organochlorine pesticides, organophosphate pesticides, PCBs, and trace elements in fish, water and sediments from the lake. This ban was officially lifted in 2000 and fish exports to the EU resumed on bilateral basis.

#### **Situation in the sub-sector:**

- Regulations were lacking or not upgraded in order to meet the fish industry's and international market's requirements and were not fully enforced;
- Fish inspectors did not receive training in Good Hygienic Practices and HACCP;
- No laboratory was accredited and none was applying Good Laboratory Practices;
- Design/operation/maintenance did not meet GHP requirements;
- Fish handling throughout the chain was not in accordance with GHPs (the ice used for preserving fish was the source of contamination).

Three main steps were taken in order to cure this situation:

1. Regulatory area and fish inspection authority were strengthened/developed
2. Technical support to research and training institutions, standardization bodies and laboratory facilities was provided
3. The private sector (fishermen, fish processors and traders, consumers/clients) were, also supported.

The fish inspection services with help of the EU have been streamlined and the capacity of the Competent Authority (DFR) strengthened through<sup>107</sup>:

- training of fish inspectors (fish inspection, HACCP auditing and documentation) and provision of fish inspection equipment;
- preparation of a fish inspection manual, inspection guides and records;
- establishment of a documentation system at the central, district and landing site levels
- introduction of an IT software for fish inspection benchmarking and monitoring.

Achievements in this sub-sector are used as a model for other sub-sectors and the is used as a model in development of the Food Control System.

As a result of strengthening of the fish inspection services, Uganda fish accessed the US market. Factories exporting to the USA implemented the ISO 9001:2000 system and the HACCP. Experiences in these pilot enterprises will also act as a model for other sub-sectors.

#### **5.8.10. Summary**

Uganda needs reform of legislation, strengthening of official control and testing, as well as capacity building for surveillance of food and waterborne diseases. Knowledge of food producers and regulators in international requirements in food safety is limited.<sup>108</sup> Very good example of enhancing capacities in the fishery sector (both of producers and state agencies) is a model for restructuring of the food safety system in Uganda.

At the same time, experiences with reform of the Uganda fishery producing and control sector are a good model for other underdeveloped countries. Implementing profound reform in one sector which is essential to the country's budget may produce more effective results compared to starting the overall reform of the food safety system and thus persuade the government to continue with broader reform in various aspects of food safety.

<sup>107</sup> DG(SANCO)/8240/2006 – MR Final

<sup>108</sup> [http://www.eprc.or.ug/pdf\\_files/occasionalpapers/op29.pdf](http://www.eprc.or.ug/pdf_files/occasionalpapers/op29.pdf)

## 5.9. USA

USA is a constitution based federal republic organized in 50 states and one district with population of 307.212.000 inhabitants with GDP (PPP) \$14.11 trillion and GDP per capita \$46.800.(2007). The share of agriculture in GDP is about 10% according to the USDA with one person in eight working in some area of agriculture or food production. Main agriculture products in USA are: wheat, corn, other grains, fruits, vegetables, beef, pork, poultry, dairy products, fish; while major export commodities are: soybeans, fruit, and corn representing 9.2% of the total USA export value. The 15% of all food consumed in USA is from import. Those are mostly processed products, seafood, fresh fruit and vegetables coming from all around the world, yet the majority from Mexico, South America and Canada.

### 5.10.1. Legal framework:

**A. Federal Food, Drug, and Cosmetic Act<sup>109</sup>** is the major law dealing with food production and control performed by the FDA.

**B. Food Safety Enhancement Act of 2009<sup>110</sup>** is still waiting in the Senate for adoption. It was designed as an amendment to the Federal Food, Drug and Cosmetic Act. The aim of this document is to strengthen the over-fragmented US legislation framework and to introduce risk based inspection in facilities, oblige manufacturers to take more responsibility for the prevention of food-borne illnesses and hand the Food and Drug Administration (FDA) further punitive powers. It would give the FDA the authority to recall contaminated food products, the capacity to quarantine food suspected of being tainted and to impose criminal and civil sanctions on transgressors.

**C. Federal Meat Inspection Act<sup>111</sup>, Poultry Production Inspection Act<sup>112</sup>, Egg Production Inspection Act<sup>113</sup>** describe authorities of inspector in different meat and egg production operations. Executive Orders, Small Business Protection Laws & Other Guidance<sup>114</sup> on how to appeal an FSIS regulatory decision, and how to use the Small Business Administration's Office of the National Ombudsman.

<sup>109</sup> 21 USC 301

<sup>110</sup> H.R. 2749, Prepared for the Congress 111<sup>th</sup> session, from August 3<sup>rd</sup>, 2009

<sup>111</sup> [http://www.fsis.usda.gov/regulations\\_and\\_policies/Federal\\_Meat\\_Inspection\\_Act/index.asp](http://www.fsis.usda.gov/regulations_and_policies/Federal_Meat_Inspection_Act/index.asp)

<sup>112</sup> [http://www.fsis.usda.gov/regulations\\_and\\_policies/Poultry\\_Products\\_Inspection\\_Act/index.asp](http://www.fsis.usda.gov/regulations_and_policies/Poultry_Products_Inspection_Act/index.asp)

<sup>113</sup> [http://www.fsis.usda.gov/regulations\\_and\\_policies/Egg\\_Products\\_Inspection\\_Act/index.asp](http://www.fsis.usda.gov/regulations_and_policies/Egg_Products_Inspection_Act/index.asp)

<sup>114</sup> [http://www.fsis.usda.gov/regulations\\_and\\_policies/Executive\\_Orders\\_Small\\_Business\\_Protection\\_Law](http://www.fsis.usda.gov/regulations_and_policies/Executive_Orders_Small_Business_Protection_Law)

**D. Numerous Directives, Notices and other legal documents** on different issues (Verification of Less than Daily Sanitation Procedures, Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products, on HACCP procedures, Inspection performed by inspection bodies, Laboratory services, Sanitation Standard Operating Procedures, equipment, etc).

### 5.9.2. Responsible authorities for the food safety system:

#### A. Department of Agriculture (USDA)

- a. Food Safety Inspection Service (FSIS)** – has 10 offices of which Office of Field Operations manages inspection and enforcement of activities nationwide through 15 district offices, and 7700 inspectors. FSIS controls domestic production and import of meat, poultry, and egg products regarding safety, wholesomeness and label. This office is responsible for food recalls, too. In slaughter plants, inspection involves examining, before and after slaughter, birds and animals intended for use as food. In egg processing plants, inspection involves examining, before and after breaking, eggs intended for further processing and use as food.

A number of U.S. states have their own meat inspection programs that substitute for USDA inspection for meats that are sold only in-state. Certain state programs have been criticized for bad practices. FSIS is also responsible for assessing whether State inspection programs that regulate meat and poultry products are equal to the Federal program. Products produced under the State programs may be sold only within the State in which they were produced. The 1967 Wholesome Meat Act and the 1968 Wholesome Poultry Act established the "at least equal" standard. FSIS assumes responsibility for inspection if a State chooses to end its inspection program or cannot maintain the equivalent standard.

FSIS plans and administers a national control plan based on risk assessment and implements it in domestic control and in import "reinspection program". Annually, FSIS reviews inspection systems in all foreign countries eligible to export meat and poultry to the United States to ensure that they are equivalent to those under U.S. laws. After the U.S. Customs Service and USDA-APHIS requirements are met, shipments imported into the U.S. must be reinspected by FSIS at an approved import inspection facility. FSIS has about 75 board inspectors who carry out reinspection in approximately 125 official import establishments.

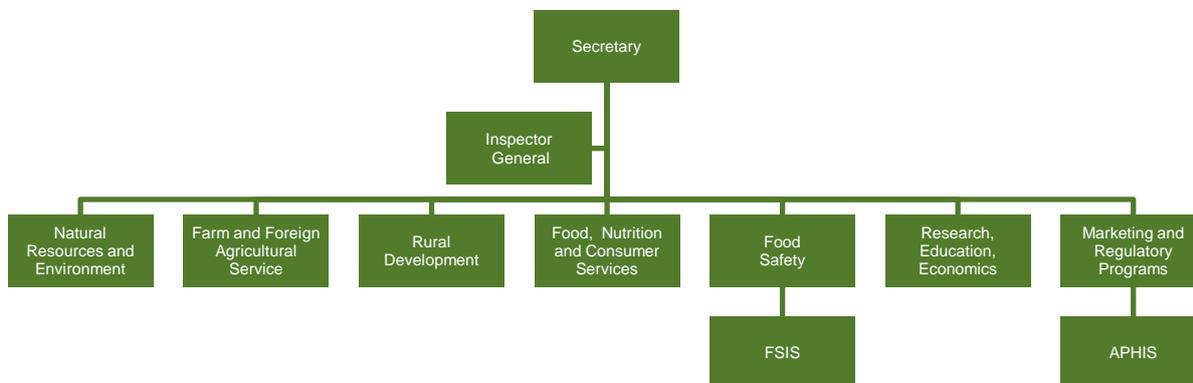
Besides inspection FSIS sets requirements for meat and poultry labels and for certain slaughter and processing activities, such as plant sanitation and thermal processing, that the industry must meet. FSIS tests for microbiological, chemical, and other types of contamination and conducts epidemiological investigations in cooperation with the Centers for Disease Control and Prevention (CDC) based on reports of foodborne health hazards and disease outbreaks. All products under FSIS' jurisdiction receive the USDA mark of inspection after inspectors confirm its safety and wholesomeness. Denying the mark of inspection due to insanitation or a lack of process control, closes down a regulated establishment.

**b. Office of International Affairs** ensures that meat, poultry and egg products imported are produced under standards equivalent to U.S.

food safety standards. International Audit Staff within this office is responsible for verifying that foreign countries previously approved to export meat, poultry, or egg products to the U.S. are maintaining inspection programs that provide food safety protection at a level equivalent to that in the U.S., and actively participates in the planning and conducting of initial team audits in countries seeking first-time approval to ship to the U.S.

**c. Animal and Plant Health Inspection Service (APHIS)** – where The National Animal Health Surveillance System (NAHSS) integrates animal health monitoring and surveillance activities conducted by many Federal and State government agencies; and Plant Protection and Quarantine (PPQ) prevents risks associated with the entry, establishment, or spread of animal and plant pests and noxious weeds.

Fig. 13. USDA organization chart



**Department of Health and Human Services**

**a. Food and Drug Administration (FDA)** – where Center for Food Safety and Applied Nutrition controls almost 80% of the whole USA food supply. It covers all other products which are not controlled by FSIS and a part of the egg products both in domestic production and in import. FDA covers also, live animals intended to be used for food, animal feed, approval and surveillance for new veterinary drugs, medicated feed, all food additives, food packaging, sanitizers. FDA is responsible for ensuring that food products under its jurisdiction are safe, nutritious, wholesome, and adequately labeled. In import it introduced a preventive screening system with FDA inspectors stationed in countries from which important quantities of food are imported to the U.S.

Inspections are risk-based and there is an annual sampling plan according to risk of microbiological or chemical contamination. FDA has

own laboratories for testing samples but can also, outsource testing.

Several states that are major producers of fresh fruits and vegetables (including California, Arizona and Florida) have their own state programs to test products for pesticide residues.

FDA organized Incident Command System training and Rapid Response Teams to enable rapid, localized response to incidents. It keeps the detailed of records. Records are performed from different reasons: biological, chemical, physical contamination, inadequate labeling, presence of allergens.

Data on all shipments are submitted through the electronic systems of the U.S. Customs and Border Protection (CBP) and FDA. The data are screened electronically to determine whether the food appears to present a significant risk to public health. Some foods are then inspected

physically based on perceived risk. Food products of greater concern are physically inspected more frequently.

- b. **State and local health departments** – enforce state laws and control restaurants and retail establishments. They inspect design of premises, best food handling practices and certify food handlers. In some places a letter grade or numerical score must be prominently posted following each inspection or inspection deficiencies and remedial action have to be posted on the Internet.
- c. **Centers for Disease Control and Prevention (CDC)** – it has a public non-regulatory role in conducting disease surveillance and occurrence of food and water borne diseases.

**C. Environmental Protection Agency (EPA)** – responsible for safe drinking water, regulates use of pesticide products and establishes tolerances or maximum legally permissible residue levels for pesticides in all types of food and feed. FDA and FSIS enforce the pesticide residue standards set by EPA for products under their respective jurisdictions.

#### D. Agricultural Research Service

#### E. Department of Homeland Security

- a. **Customs and Border Protection** – in collaboration with all other federal agencies checks imported food.

#### 5.9.3. Training:

To qualify for an entry-level position at the FSIS, the candidate must pass a written test and have either a Bachelors degree or 1 year of job-related experience (in the food industry), demonstrate knowledge of sanitation practices and control measures used in the commercial handling and preparation of food products for human consumption, skill in applying, interpreting, and explaining standards in a food product environment.<sup>115</sup> FSIS inspectors have regular training according to the annual training scheme. USDA collaborates with number of scientific institutions which organize training for inspectors. Trainings in risk based inspection, HACCP, control of meat at import/export are conducted almost every year. FDA trains state inspectors in principles and practices of the FDA inspection work according to the annual plan.

#### 5.9.4. Quality control of the inspection performance:

In order to satisfy recommendation for having the external review, FSIS asked the National Academy

of Sciences to review FSIS data initiatives in order to ensure that Agency decisions are science-based and data driven. The goal for 2008 was to implement the system for auditing of performance of inspection in terms of quality.

**Table 23. Division of inspections**

Area	Inspection authority
Animal health	APHIS and Federal and State agencies
Food of animal origin	FSIS, FDA, State and local health departments
Import of animals and food of animal origin	APHIS FSIS
Feedingstuff and animal nutrition	APHIS, Federal and State agencies, FDA
Animal byproducts	
Veterinary medicines authorization and distribution	FDA
Veterinary medicines residues	FSIS FDA
Food safety plans in premises	FSIS
GMO	APHIS EPA
Import of food of plant origin	APHIS – PPQ
Plant protection products authorization and sale	EPA APHIS
Plant protection products residues	FSIS FDA
Animal welfare	APHIS
Plant health	
Restaurants, shops	FDA, State and local health departments

#### 5.9.5. Register of FBOs:

The Bioterrorism Act<sup>116</sup> since 2003 requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. to register with the FDA. Foreign facilities that manufacture/process, pack, or hold food also are required to register unless food from that facility undergoes further processing (including packaging) by another foreign facility before the food is exported to the United States. There is a possibility to register online.

FDA registered<sup>117</sup>:

- 136,000 domestic food facilities including more than 44,000 food manufacturers and processors and approximately 113,000 food warehouses, including storage tanks and grain elevators (some of facilities have several functions).
- 189,000 foreign facilities which manufacture, process, pack, or store food

<sup>115</sup>

[http://www.fsis.usda.gov/Careers/Food\\_Inspector\\_&\\_Consumer\\_Safety\\_Inspection\\_Positions/index.asp](http://www.fsis.usda.gov/Careers/Food_Inspector_&_Consumer_Safety_Inspection_Positions/index.asp)

<sup>116</sup> <http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm>

<sup>117</sup> <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/FoodProtectionPlan2007/ucm132565.htm>

- FDA or state and local authorities registered more than 2 million farms, roughly 935,000 restaurants and institutional food service establishments, and 114,000 supermarkets, grocery stores, and other food outlets. FDA provides guidance, model codes, and other technical assistance to state and local partners.

FSIS registered 6500 producers/processors.

### 5.9.6. Frequency of control and fees:

**Table 24. Data on inspection in 2007**

Number of inspectors FSIS <sup>118</sup>	7700
No FBOs registered at FSIS	6500
No of veterinary inspectors per FBO	1.2
Total No of activities performed by FSIS inspectors annually (all activities taken including sampling, control of each carcass)	10.500.000 verification procedures
Annual No of food safety assessments (detailed insight in food safety plan and situation in premises)	1500
Average No of inspection visits to FBOs per veterinary inspector	0.4
Realization of the FSIS annual control plan	94.5%
No of FDA inspectors <sup>119</sup>	About 900
No of premises registered by FDA inspection	136.000
No of premises per FDA inspector	151
Annual No of State inspection visits under contract with FDA	10.000
Annual No of State inspection visits under State regulations	40.000

FDA has a responsibility of inspection over 80% of all food products at the market as well as numerous producers. It is visible that there is a shortage of FDA inspectors, so they rely on the network of state inspectors. By 2007 only 80% of state inspections follow FDA recommendations for inspection. Other implement inspection practices developed by their state office.

Inspection is funded from the state budget, but they earn some 16% of their budget on “user fees”. Those are fees charged for the reinspection due to sample failure and additional inspection performed to check if corrective measures are applied and efficient. Also user fees are charged for inspection overtime work, holidays and voluntary inspection.

### 5.9.7. Sampling

National Residue Program – residues of veterinary drugs, pesticides and environmental contaminants are controlled by FSIS in milk, meat eggs. Samples are gathered as per plan and as per inspection sampling. Also, data from samples from board inspection (normal sampling, increased sampling and in-

tensified sampling exist) are included in the national residue program data. To analyze these samples, FSIS has three laboratories, and supports 25 Food Emergency Response Network labs. This network of laboratories consists of Federal, State, and local governmental laboratories, which are performing analysis on 1 biological, chemical, and radiological contamination.

Residue frequent VIOLATOR LIST is present on internet and serves as a good indicator of safety of products coming from different producers.<sup>120</sup>

Control of microbiological pollutants is performed in order to prevent *Salmonella* and new pathogens (*Listeria*, *E.Coli O157:H7*, *Campilobacter*).

FDA controls registered and not-allowed pesticides, additives and environmental contaminants. EPA sets tolerance levels for registered pesticides. FDA registered 7380 producers as high-risk establishments. Those are producing foods with the greatest risk for microbial contamination and those foods requiring specific components for a safe and nutritious product. High-risk establishments are: manufactures, packers/repackers, and warehouses processing products that include: modified atmosphere packaged products; acidified and low acid canned foods; seafood; custard filled bakery products; soft, semi-soft, soft-ripened cheese and cheese products; un-pasteurized juices; sprouts or processed leafy vegetables; fresh vegetables shredded for salads and processed root and tuber vegetables; sandwiches; prepared salads; infant formula; and medical foods.

**Table25. Official sampling 2007<sup>121</sup>**

Type of sampling	No of samples
FSIS Annual monitoring plan for chemical pollutants (veterinary drugs and pesticides)	20.853
No of samples with nonconformities	64
Sampling at regular veterinary control of slaughtering	149.590
No of nonconformities	1360 (mostly antibiotics and sulfonamides)
FSIS Annual monitoring plan on microbiological pollutants	70.300
Recalls by FSIS	58 + 4 public alerts
Annual No FDA sampling at import	5570
No of nonconformities	4550
Annual No FDA sampling domestic	10.700
No of nonconformities	Not available
No of FDA recalls	220
No of samples collected by State inspectors	300.000

<sup>118</sup> [http://www.fsis.usda.gov/Fact\\_Sheets/index.asp](http://www.fsis.usda.gov/Fact_Sheets/index.asp)

<sup>119</sup> <http://www.fda.gov/Food/FoodSafety/default.htm>

<sup>120</sup> [http://www.fsis.usda.gov/PDF/Residue\\_Violators\\_List.pdf](http://www.fsis.usda.gov/PDF/Residue_Violators_List.pdf)

<sup>121</sup>

### 5.9.8. Budget

The USDA budget for 2007 was \$127 billion of which 2% was used in order to increase food safety and security. The FSIS budget was \$865 million (2007) which represents 0.7% of the total annual USDA budget. APHIS budget was 1% of the USDA budget.

Of the whole FSIS budget 83% was spent on federal inspection activities, 7% on State inspection and 1.6% on international inspection.

FSIS gained 154 million for “user fees” and 1.2 million from 177 indictments and 223 convictions regarding food safety.

The major part of the USDA budget is used in reducing food safety and security program vulnerability and increase of effectiveness and efficiency. This means education of producers how to implement precautionary principles in food production (among them HACCP system, traceability, application of animal health and plant health procedures) and how to increase production.

The Food and Drug Administration (FDA) performance budget request for 2007 was \$1,947,282,000 and 9.2% was used for food inspection purposes (\$178,225,000).

In 2010 FDA plans the budget of \$3.2 billion, where \$473 millions will be addressed to food safety (14.8%).<sup>122</sup>

### 5.9.9. Transparency

Detailed information about enforcement and recalls could be found on sites:

<http://www.fda.gov/Safety/Recalls/EnforcementReports>  
[http://www.fsis.usda.gov/FSIS\\_Recalls/Open\\_Federal\\_Cases/index.asp](http://www.fsis.usda.gov/FSIS_Recalls/Open_Federal_Cases/index.asp)

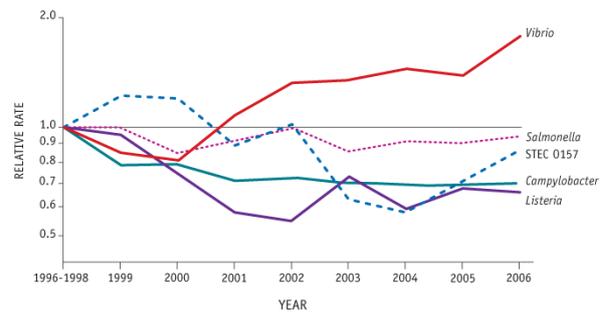
FSIS is planning to develop a new IT system to track domestic inspection activities, including egg products processing.

There is an Investigations Operations Manual for FDA personnel how to perform inspections and special investigations.<sup>123</sup> Also enforcement actions, legal actions are described in manuals.

### 5.9.10. Foodborne outbreaks:

**Fig 14. Relative rates compared with 1996-1998 baseline period of laboratory-diagnosed cases of infection with *Campylobacter*, STEC O157, *Listeria*, *Salmonella* and *Vibrio*, by year.**

Source: FDA – Food Protection Plan 2007.



In 2008, a total of 18,499 laboratory-confirmed cases of infection were identified. The number of infections and incidence per 100,000 population were reported as follows: *Salmonella* (7,444; 16.20), *Campylobacter* (5,825; 12.68), *Shigella* (3,029; 6.59), *Cryptosporidium* (1,036; 2.25), *E. coli* O157:H7 (513; 1.12), *E. coli* non-O157 (205; 0.45).<sup>124</sup>

The percent-positive rate for *Salmonella* in raw broiler chicken fell from 11.4% in 2006 to 7.3% in 2008. Additionally, the percentage of broiler chicken slaughter establishments with *Salmonella* contamination is declining. The percentage of ground beef samples yielding *E. coli* O157 increased from 0.24% in 2007 to 0.47% in 2008 -whether the increase was related to focused sampling of higher risk facilities or improved laboratory detection, or whether the microbial load was actually higher, is unknown. In August 2008, the FDA published a rule allowing irradiation of fresh iceberg lettuce and fresh spinach to help protect consumers from *Salmonella* and *E. coli* O157:H7 (as a lesson learned from outbreaks).<sup>125</sup>

### 5.9.11. Summary

In the United States, federal regulations governing food safety are fragmented and complicated,. There is also, high level of overlapping in inspection jurisdiction (FDA and USDA inspections).

In order to overcome the fragmented food safety legislation a Food Safety Enhancement Act of 2009 is prepared which defines roles of FDA inspectors, gives legal basis for the risk based inspection and basis for their administrative actions. The area of veterinary inspection control remains with numerous legal documents, guidelines, codes of practice in force.

<sup>122</sup>

<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/default.htm>

<sup>123</sup> <http://www.fda.gov/ICECI/default.htm>

<sup>124</sup> <http://www.aamp.com/news/documents/Notice44-09.pdf>

<sup>125</sup> [http://www.fsis.usda.gov/PDF/RBVS\\_Risk\\_Assess\\_Jun07.pdf](http://www.fsis.usda.gov/PDF/RBVS_Risk_Assess_Jun07.pdf)

The federal FDA regulations are not always followed at the state level. Recent outbreaks of food-borne diseases resulting from both animal and non-animal food sources raised great concern about the food safety system efficacy in the USA. Also, President Obama criticized the food safety system as being too spread out, making it difficult to share information and solve problems. “Protecting the safety of our food and drugs is one of the most fundamental responsibilities government has” – he said.<sup>126</sup> The underfunding and understaffing at FDA that has left the agency unable to conduct annual inspections of more than a fraction of the 150,000 food processing plants and warehouses in the country was, also his great concern.

Good practices of training of inspectors, implementation of the HACCP and risk based approach that FSIS applies proved to be very useful. Also, the APHIS is a well consolidated agency.

The recent problems with food of non-animal origin have serious effects on consumers trust in the USA food safety system.

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<sup>126</sup>

<http://www.cbsnews.com/stories/2009/03/14/politics/100days/domesticissues/main4865488.shtml>

## 6.0. LIST OF ABBREVIATIONS

**APHIS** – United States Animal and Plant Health Inspection Service

**CAB** – County Administration Board

**CAC** – Codex Alimentarius Commission

**CDC** – United States Center for Disease Control and Prevention

**CIS** – Commonwealth of Independent States

**DFR** – Uganda The Department of Fisheries Resources

**DVFA** – Danish Veterinary and Food Administration

**DPD** – Danish Plant Directorate

**EARS** – Slovenian Environmental Agency

**FAO** – Food and Agriculture Organization of the United Nations

**FBO** – Food Business Operator

**FDA** – United States Food and Drug Administration

**FVO** – Food and Veterinary Office

**EPA** – United States Environmental Protection Agency

**FQIS** – Slovenian Food Quality Inspection Service

**FSIS** – Food Safety Inspection Service

**Fte** – full time employees

**GAP** – Good Agricultural Practices

**GHP** – Good Hygienic Practices

**GMP** – Good Manufacturing Practices

**GVI** – Polish General Veterinary Inspectorate

**HACCP** – Hazard Analysis and Critical Control Points

**HIRS** – Slovenian Health Inspectorate

**IPPC** – International Plant Protection Convention

**IRSAFF** – Slovenian Inspectorate for Agriculture, Forestry and Food

**IRSEP** – Slovenian Inspectorate for Environment and Spatial

**MAB** – Municipality Administration Board

**MAF** – New Zealand Ministry of Agriculture and Forestry

**MAFW** –Serbian Ministry of Agriculture, Forestry and Water Management

**MAFRD** – Croatia Ministry of Agriculture, Fisheries and Rural Development

**MARD** – Polish Ministry of Agriculture and Rural Development

**MFAF** – Danish Ministry for Food, Agriculture and Fisheries

**MH** – Polish Ministry of Health

**MoH** – Serbian Ministry of Health

**MHSW** – Croatia Ministry of Health and Social Welfare

**NDA** – Uganda National Drugs Authority

**NFA** – Swedish National Food Administration

**NZFSA** – New Zealand Food Safety Agency

**NZFSA VA** – New Zealand Food Safety Verification Agency

**OIE** – International Organization for Control of Epizootics

**PAS** – Auckland County Performance Assessment System

**PARS** – Slovenian Phytosanitary Administration

**RASFF** – Rapid Alert System for Food and Feed

**SBA** – Swedish Board of Agriculture

**SES** – Sanitary Epidemiological Service

**SPHSIS** – Polish State Plant Health and Seeds Protection Inspection

**SSI** – State Sanitary Inspection

**VARS** – Slovenian Veterinary Administration

**VI** – Veterinary Inspectors

**UCPC** – Uganda Cleaner Production Center

**USDA** – United States Department of Agriculture

**WHO** – World Health Organization

**WTO** – World Trade Organization

**SPS** – Sanitary and Phytosanitary Agreement

**TBT** – Technical Barriers to Trade