



Reforming Food Safety Regulation in Ukraine: Proposals for Policymakers

48669

A BACKGROUND POLICY PAPER



The contents of this policy paper are protected by copyright.

Neither this policy paper *Reforming Food Safety Regulation in Ukraine: Proposals for Policymakers* nor its parts may be reproduced, copied or distributed in any form without reference to the IFC.

IFC encourages dissemination of this publication and hereby grants permission to the user of this work to copy portions of it for the user's personal, noncommercial use, without any right to resell, redistribute, or create works derived from the contents or information contained herein. Any other copying or use of this work requires the express written permission of IFC.

The information in this policy paper is presented in good faith for general information purposes, and IFC, the World Bank Group, or the Canadian International Development Agency (CIDA), the Dutch Agency for International Business and Cooperation (EVD), the Swedish International Development Cooperation Agency (SIDA) shall not be held liable for any of the information contained herein.

This policy paper does not claim to serve as an exhaustive presentation of the issues discussed herein, and should not be used as a basis for making commercial decisions. Please approach independent legal counsel for expert advice on all legal issues.

All information and materials used in preparing this policy paper are the property of and archived by IFC.

© 2009 International Finance Corporation



Table of Contents

Executive Summary	4
What Needs to be Done? – Key Highlights	6
1. Introduction	8
2. Ukraine’s Agricultural Potential, Weak Investment Climate, and Need to Reform Food Safety Regulation	12
2.1. Relieving Businesses from Unnecessary Regulatory Burdens in a Time of Crisis: the Case of the Dairy Sub-Sector	17
2.2. International Principles of Effective and Efficient Food Safety Regulations.....	20
3. Assessing Ukraine’s Regulatory System on Food Safety	22
3.1. The Legal Framework	22
3.2. Overview of the Food Safety Regulatory System	23
3.3. Institutional Structure of Food Safety Control System in Ukraine.....	24
4. Critical Areas of Food Safety Reform: Outdated De Facto Mandatory Product Standards, Mandatory Certification, and Inspections	26
4.1. The Food Safety Product Standards.....	26
4.2. Mandatory Certification of Food Products.....	29
4.3. The Food Control System: Inspections.....	32
5. Conclusions and Recommendations	36
Recommendations for Policy Makers.....	37
Annexes	42
Annex 1. Principal Legislative Acts Regulating Ukrainian Food Industry	42
Annex 2: Comparative Analysis of Ukrainian Food Safety Legislation and EU Legislation.....	44
Annex 3: General Functions of Controlling Bodies for Safety and Quality of Food and Foodstuffs.....	48
Annex 4. Institutional Structure of State Regulators in Food Industry of Ukraine.....	49
Annex 5. WTO Commitments: Issues of Non-Compliance in Ukraine.....	58



Executive Summary

The agriculture production and food processing industry is a large and indispensable part of Ukraine's economy, both past and present. Ukraine is endowed with natural resources that create a good basis for the potential development of the agricultural sector. Despite this favorable resource environment, performance of the sector remains rather weak.

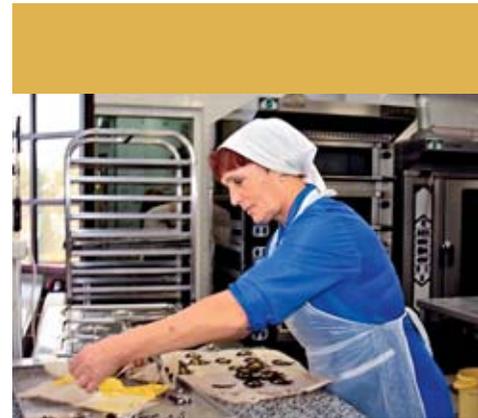
Although there has been slow recovery in recent years, food exports still amount to less than 25 percent of gross output. In 2005, **Ukraine became a net importer of agricultural products from the EU and fully rebounded only recently in terms of net agricultural exports.** The main reasons for this were limited competitiveness of Ukrainian goods **failure to comply with international food quality and safety standards**, and existing legal and practical barriers to trade. At the same time, agriculture in Ukraine remains one of the sectors where the **investment potential is not yet completely realized.** The inflow of FDI remains below its potential a consequence of the weak investment climate and high cost of doing business (Ukraine ranks 145th out of 181 according to the Doing Business 2009 Report of the World Bank).

In view of the current global crisis, it is crucial to relieve Ukrainian business (especially in strategic sectors such as agribusiness) from unnecessary administrative burdens and reform the sectoral regulatory framework in preparation for recovery, and most importantly, to increase the safety of food available to citizens. For example, the full **harmonization** of Ukrainian food products regulation with **WTO commitments** would lead to a **30 percent reduction of standardization costs for agricultural and food products**, while the cost reduction would amount to up to 50 percent in the case of harmonization under a **EU-Ukraine Extended Free Trade Agreement**.

Ukraine continues to use food safety regulations, which are not WTO compliant and are not recognized by most of the world's economies. Reliance on such outdated regulations severely undermines Ukraine's export potential and competitiveness in agriculture and food production. For example, Ukraine is currently only able to export most livestock products (meat, milk) to a limited number of countries (mainly CIS and Africa), while **dairy exports to the EU and other advanced economies total to a mere 11.6 percent** of exports.

Such a food safety system imposes **unnecessary costs on businesses yet does not achieve higher than elsewhere public health and safety results**. The guiding principle globally as expressed in relevant WTO and Codex Alimentarius Commission provisions is that "such systems should be no more restrictive of trade than is necessary to achieve the required level of protection".

This report provides an overview of the main legal, regulatory, and institutional bottlenecks adversely affecting the food safety system in Ukraine, as a way to raise awareness among policymakers and all relevant stakeholders about the need to harmonize the current system with international best practices. The structure of the report is the following: Section 2 analyzes the performance, key sectoral issues, and economic potential of agribusiness in Ukraine; Section 3 provides a legal review of the legislative and regulatory framework in Ukraine, while also assessing the institutional structure of the food safety control system; Section 4 focuses on three critical areas in need of reform, namely: outdated product standards, mandatory certification of food products, and inspections; Section 5 finally provides a detailed set of recommendations and proposed actions for reform.



What Needs to be Done? – Key Highlights



Reforming the food safety system in Ukraine to support full harmonization with EU and other key international best practices is a complex yet strategic endeavor for the growth and prosperity of the country, in consideration of its natural competitive advantage in agribusiness. It would require sustained political support to undertake significant structural reforms in the legislative, regulatory, institutional, and infrastructural spheres. Here are highlighted five possible focus areas to jumpstart the reform process (see Section 5 for details):

Move away from obsolete mandatory standards and harmonize regulations according to WTO commitments. This should be done through:

- **Rigorous observance of Paragraph 299 of the “Report of the Working Party on the Accession of Ukraine to the World Trade Organization”. WT/ACC/Ukr/152, January 25, 2008;**
- **Removal of food from the final provisions of the Ukrainian Law on Standardization since the Ukrainian Law on Safety and Quality of Food Products¹ from May 31, 2007 regulates issues concerning implementation of standards for food;**
- **Definition of the term “standard” used in Ukrainian Law on Safety and Quality of Food Products should be brought in accordance with the meaning used in the WTO Technical Barriers to Trade (TBT) Agreement;**

¹ Law on Safety and Quality of Food Products №771/97-BP from December 23, 1997, as amended by Ukrainian Law on Changing the Law of Ukraine on the Safety and Quality of Food Products No 2809-IV from September 6, 2005.

Abolish mandatory certification of food products. This should be done through:

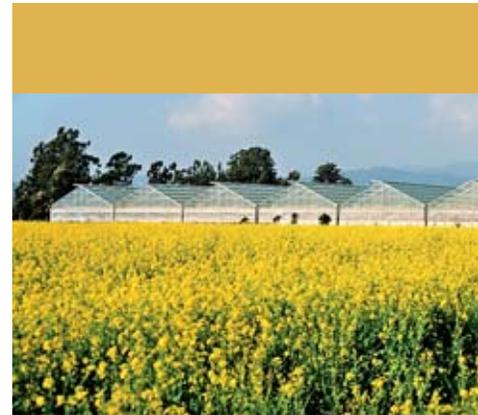
- Repeal of mandatory provisions for food business operators to certify their products through amendments to the following laws:
 - Ukrainian Law on Protection of Consumers Rights No 3161-IV from December 1, 2005;
 - Ukrainian Law on Ensuring the Sanitary and Epidemiological welfare of the population No 4004-XII from February 2, 1994;
 - Decree of Cabinet of Ministers of Ukraine on Standardization and Certification No 46-93 from May 10, 1993.
- Elimination of the part of Order No 28 of February 1, 2005 of the State Committee of Ukraine for Technical Regulations and Consumer Policy (DSSU), which establishes the list of food products subject to mandatory certification.

Establish an integrated food control system or only one food control agency in accordance with international best practices. This should be done by initiating the policy dialogue to identify the most suitable institutional model for Ukraine and amend the four relevant Ukrainian Laws and the Government Decree on food safety management accordingly.

Harmonize Regulations on “Novel” Food with the provisions of the Ukrainian Law on Safety and Quality of Food Products.

Harmonize Regulations on Permitted Food Additives, Flavorings, Levels of Contaminants, Pesticides, and Veterinary Drug and Pesticide Residues in line with international standards and WTO commitments.

Speed up the process of adoption and proper implementation of risk-based criteria in planning and prescribing inspections by controlling agencies, according to international best practices.



1

Introduction²

The agriculture production and food processing industry is a large and indispensable part of Ukraine's economy, both past and present. Ukraine is endowed with natural resources that create a good basis for the potential development of the agricultural sector. Despite this favorable resource environment, performance of the sector remains rather weak. At the aggregate level, agriculture is the fourth largest sector of the economy after manufacturing, transportation and trade in services. In 2007, agricultural production amounted to about 7 percent of GDP, and food processing to roughly 8 percent of GDP. At the same time, agricultural value added dropped by 5 percent in 2007 from the previous year³.

The major impediments for the development of the sector include the lack of efficiency of markets for agricultural, the monopoly of large traders, **the poor quality of food products compared to European and international food safety regulations**, the inefficient subsidy system, and the absence of a land market in combination with a moratorium on agriculture land sales.

² This report has been prepared by the IFC Ukraine Business Enabling Environment Project by a team led by Alberto Criscuolo, Team Leader and Investment Policy and Promotion Specialist, in collaboration with Denis Torkhov, Senior Policy Analyst. The authors would like to thank the peer-reviewers for their support, guidance, and assistance: Tania Lozansky, General Manager, IFC Advisory Service – Europe and Central Asia, Elena Voloshina, Head of Operations IFC Ukraine, Sanjar Ibragimov, Project Manager of the IFC Ukraine BEE Project; Sanda Liepina, Senior Operations Manager IFC BEE; Ivan Ivanov, Senior Operations Manager IFC Linkages; Pablo Saavedra, Senior Economist World Bank Ukraine Country Office; Viktoriya Menkova, Operations Analyst IFC Linkages; Prof. Gordana Ristic, Associate Professor, Institute of Hygiene, University of Belgrade.

³ Source: State Statistics Committee of Ukraine and World Development Indicators of the World Bank 2007.

Despite slow recovery in recent years, food exports still amount to less than 25 percent of gross output. In 2005, **Ukraine became a net importer of agricultural products from the EU and fully rebounded only recently in terms of net agricultural exports**⁴. The main reasons for this were on the one hand increased domestic demand and on the other hand limited competitiveness of Ukrainian goods, failure to comply with international food quality and safety standards, and existing legal and practical barriers to trade.

At the same time, agriculture in Ukraine remains one of the sectors where the **investment potential is not yet completely realized**. The inflow of FDI remains below its potential primarily because investors are delaying investment decisions as a consequence of the weak investment climate and high cost of doing business in Ukraine, which ranks 145th out of 181 economies on the overall “Ease of doing business” indicator of the World Bank’s Doing Business report. This also adversely affects productivity, which remains below its potential due to the slower rate of technology transfer associated with lower levels of FDI, and leaves room for significant improvement (see section 2).

In view of the current global financial crisis, and of its adverse effects on the productive base of the Ukrainian economy, it is crucial to relieve Ukrainian business (especially in strategic sectors such as agribusiness) from unnecessary regulatory and administrative burdens and reform the sectoral regulatory framework in preparation for recovery. For example, the full **harmonization of Ukrainian food products regulation with WTO commitments** would lead to a **30 percent reduction of standardization costs for agricultural and food products**, while the cost reduction would amount to up to 50 percent in the case of product standards harmonization under a **EU-Ukraine Extended Free Trade Agreement**.

Ukraine continues to use food safety regulations which are not WTO compliant and are not recognized by most of the world’s economies. Reliance on outdated food safety regulations that do not comply with international standards severely undermines Ukraine’s export potential and competitiveness in agriculture and food production. For example, Ukraine is currently only able to export most of its livestock products (meat, milk) to a limited number of countries (mainly CIS and Africa), while **dairy exports to the EU and other advanced economies total to a mere 11.6 percent** of these exports. Such a food safety system imposes **unnecessary costs on businesses yet does not achieve public health and safety results**. The guiding global principle as expressed in relevant WTO and Codex Alimentarius Commission provisions is that “such systems should be no more restrictive of trade than is necessary to achieve the required level of protection”.

⁴ According to the Institute of Economics and Forecasts of the National Academy of Science of Ukraine, Ukraine showed a trade deficit of agricultural products with the EU equal to \$86,5 million in 2005, while rebounding to a \$59.4 million trade surplus in 2006 and \$231,8 million in 2007.

This report provides an overview of the main legal, regulatory, and institutional bottlenecks adversely affecting the food safety system in Ukraine, as a way to raise awareness among policymakers and all relevant stakeholders about the need to reform the current system and harmonize it with international best practices. The report also identifies a set of policy recommendations (section 5) with the goal of creating a common policy dialogue platform among all relevant policymakers. The main findings presented here result from extensive legal review and economic analysis of both food safety regulations and the agribusiness sector in Ukraine, field interviews with private businesses, and consultations with relevant government institutions and business associations over the period of November 2008 to March 2009.

Overall, the main characteristics of the Ukrainian food safety regulatory system include:

- **Fragmented and contradictory primary and secondary legislation (for details see sections 3.1 and 3.2, and Annexes 1 and 2);**
- **Numerous and outdated overly-prescriptive mandatory *product-focused* standards (GOST and DSTU)⁵ and other requirements (for example, it is necessary to comply with up to 94 mandatory standards to produce cottage cheese or up to 177 standards for ice-cream (see section 4.1));**
- **Little appropriate communication or coordination between food safety government agencies, resulting in scattered and overlapping competencies, redundant inspections, and overall inefficient control. This affects the viability and competitiveness of food-related businesses, which have to deal with the State Committee of Ukraine for Technical Regulations and Consumer Policy (DSSU), the State Sanitary and Epidemiological Service (SES) under the Ministry of Health Care, the State Committee of Veterinary Medicine, and the Ministry of Agrarian Policy, which often control the same parameters (see section 3.3);**
- **Control of safety based mainly on pervasive sample collection, compulsory certification, and frequent on-site inspections (for example around 94 percent of food processing businesses were inspected at least once in 2008 – see section 4.3) instead of a comprehensive and robust risk based control system of the production process (such as HACCP);**
- **The testing laboratories based on outdated Soviet-type product standards (GOST/ DSTU) do not meet the requirements of the European Union and other industrial countries. For example, approximately only 1.5 percent of all laboratories in Ukraine are accredited under ISO 17025 (see section 4.1);**
- **Lack of traceability. The absence of a well-functioning traceability system does not enable prompt recall of unsafe products nor identification and sanctioning of non-compliant producers for alleged food safety violations;**

⁵ GOST (Gosudarstvennyi Standard – State Standard) is a pre-1991 standard used in the former Soviet Union and refers to a set of technical standards maintained by the Euro-Asian Council for Standardization, Metrology and Certification (EASC), a regional standards organization operating under the auspices of the Commonwealth of Independent States (CIS). DSTU (Derzhavnyi Standart Ukrainy – State Standard of Ukraine) is the official standard that is being developed and used in Ukraine since independence.

As a result, the costs to producers are heavy. The dairy sub-sector is an important case in point (and illustration of the need for reform in all other sub-sectors such as meat, grain, or vegetables) since it has a strong potential for post-crisis recovery and growth, but is constrained by an unnecessary burdensome and outdated regulatory framework. As an illustration of the overall regulatory burden, a preliminary review of food safety regulation in the dairy sub-sector carried out by the IFC⁶ reveals that on average a typical milk processing value chain (“from farm to fork”) needs to:

- **comply with a up to of 120 permits, authorizations, and other regulatory requirements;**
- **comply on average with up to 50 mandatory standards (GOST and DSTU) for each dairy product;**
- **comply with up to 51 orders and mandatory guidelines from the Ministry of Health Care and other supervision agencies for each dairy product;**
- **comply with a around 110 prescribed testing methods, in spite of the fact that 63 percent of them are not in line with international standards;**
- **receive repeated and overlapping inspections from several inspecting agencies;**

For example, in 2006 one-fourth of food services and one-third of manufacturing enterprises spent \$3,000 and \$8,000 on mandatory product certification procedures⁷. This is in contrast with the experience of advanced economies, which has shown that necessary and adequate levels of safety can be achieved without restrictive, inflexible, and highly administrative processes that negatively affect the competitiveness of the private sector and impose costly barriers to trade.

⁶ A comprehensive list of food safety regulation in the dairy sector is available upon request and will be published in a forthcoming (2009) report of the IFC assessing the overall administrative burden and economic impact of food safety regulation on dairy businesses in Ukraine. The figures presented in this section and throughout the paper are based on preliminary findings of the legal, regulatory, and field-based review conducted by IFC in preparation of the forthcoming report on dairy. Some variations with the figures may occur in the forthcoming published report. However, IFC has taken all care to make sure that they accurately reflect the overall regulatory framework on food safety in Ukraine in 2009.

⁷ Source: IFC Technical Regulations Survey, 2007.

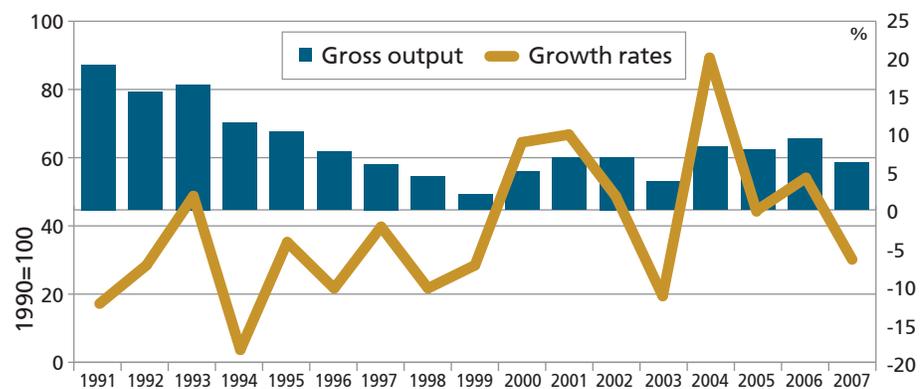


2

Ukraine's Agricultural Potential, Weak Investment Climate, and Need to Reform Food Safety Regulation⁸

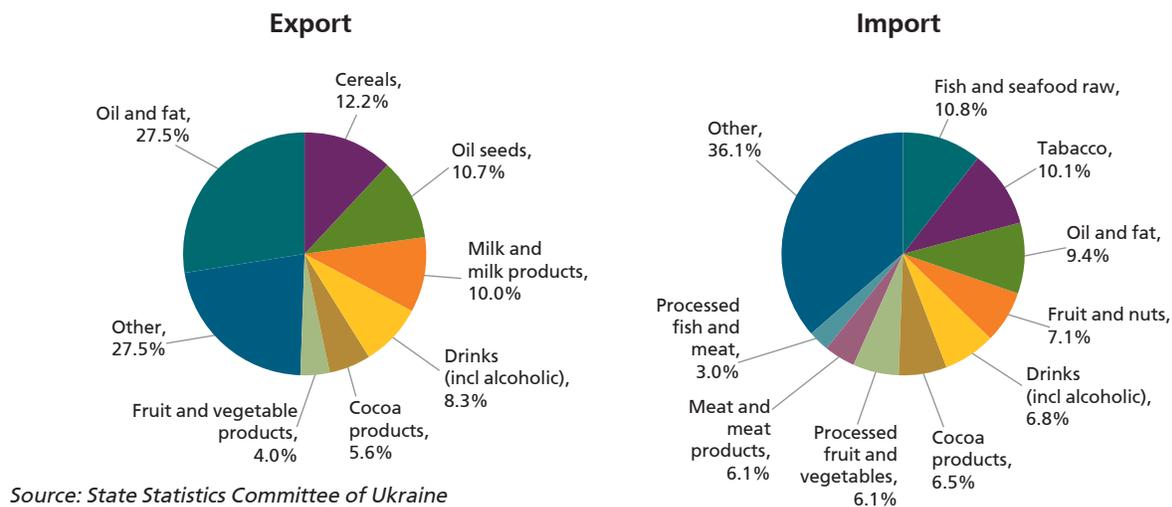
Though Ukraine has the potential to become one of the world's major food producers, the average growth rate of agricultural output for the last fifteen years was minus 3 percent per year. The major impediments for the development of the sector include the lack of efficiency of markets for agri-products, the monopoly of large traders, the poor quality of food products compared to European and international food safety regulations, the inefficient subsidizing system, and the absence of a land market in combination with a moratorium on agriculture land sales.

Figure 1 – Gross Agriculture Output and Growth Rates 1991–2007



Source: State Statistics Committee of Ukraine

⁸Data on agriculture and food processing sector are based on the following sources: "Trade Sustainability Impact Assessment for the FTA between the EU and Ukraine within the Enhanced Agreement", Final Report, European Commission, DG-Trade, December 2007, and "Market Study Food Sectors in Ukraine", Report prepared by Tebodin Consultants & Engineers for the Embassy of the Kingdom of the Netherlands in Ukraine, May 2008.

Figure 2 – Structure of Foreign Trade of Agricultural and Food Products from Ukraine in 2007

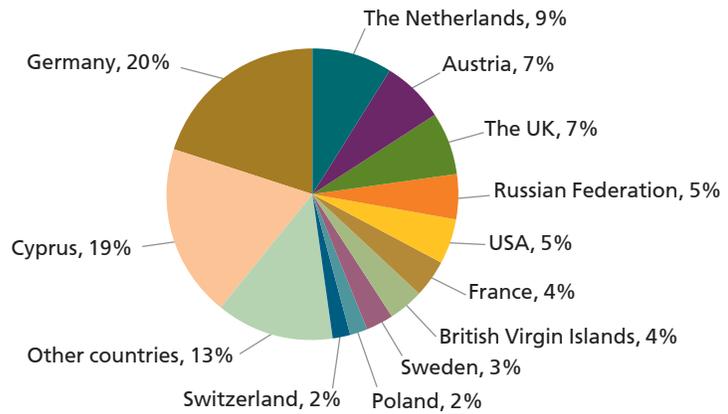
Although performance of agriculture was rather weak, a large part of the Ukrainian labor force is still engaged in agricultural production which means changes in this sector have significant (social) impact effects. The sector officially employs over 4.2 million people, which is close to 20 percent of the employed population. Unofficially, the sector probably employs a much larger share of the working population, as approximately 10.7 million people within the economically active age (2008) reside in rural areas. The main output is created from grain, crops and vegetables in crop production plus meat in animal production. The majority of output is produced by the private sector as more than 60 percent of agricultural production is supplied by rural households.

Agricultural external trade decreased substantially during the initial transition phase. Despite a slow recovery in more recent years, exports still amount to less than 25 percent of gross output, while the total volume of food exports constitutes a mere 13 percent of merchandise exports in 2007. Agricultural exports to the EU increased by 25 percent in 2005 with grain being the main export item, while agricultural imports from the EU increased by 43.5 percent.

In 2005, Ukraine became a net importer of agricultural products from the EU and fully rebounded only recently in terms of net agricultural exports. The main reasons for this were on the one hand increased domestic demand and on the other hand limited competitiveness of Ukrainian goods, the failure to comply with international quality and safety standards (SPS), and existing legal and practical barriers to trade.

Agriculture in Ukraine remains one of the sectors where the investment potential is not yet completely realized. Based on the data of the State Statistic Committee (October 1, 2008), \$2.6 billion (7 percent of total FDI in Ukraine) has been invested in the agricultural sector of Ukraine since 1992. \$1.7 billion of this amount was invested in food processing and \$893 million in agriculture. The biggest investors in the agro-industrial complex of Ukraine are from: Cyprus, UK, Netherlands, Austria, Denmark, Germany (all EU members). Other smaller investors are from U.S., Canada, and CIS countries.

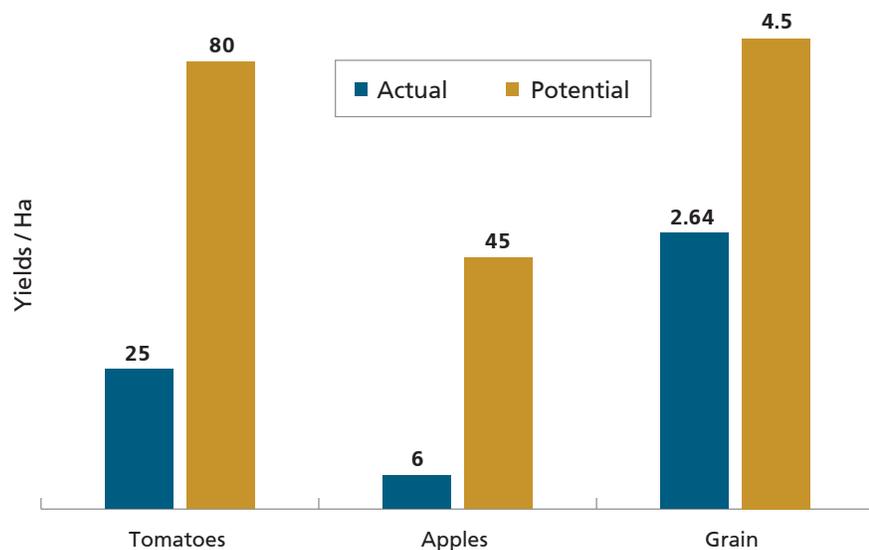
Figure 3 – Share of FDI by Country of Origin into Ukraine in 2007



Source: State Statistics Committee of Ukraine

The inflow of FDI remains below its potential primarily because both prospective and established foreign investors choose to delay additional investment as a consequence of the weak investment climate⁹ and high cost of doing business in Ukraine, which ranks 145th out of 181 economies on the overall “ease of doing business” indicator of the World Bank’s Doing Business 2009 report. The regulatory and investment climate constraints on FDI and overall private sector investment in agribusiness also adversely affects the productivity of the sector, which remains below its potential and leaves room for significant improvements as shown by a IFC’s recent study of the vegetable and grain sectors in Ukraine (see figure 4).

Figure 4 – Potential Productivity Gains in Agriculture in Ukraine



Source: IFC 2008

⁹ “Market Study Food Sectors in Ukraine,” report prepared by Tebodin consultants & engineers for the Embassy of the Kingdom of the Netherlands in Ukraine, May 2008.

At the same time, Ukraine has recently completed its lengthy negotiations on WTO accession, and has entered into negotiations with the EU on a free trade agreement (FTA). While this represents an unprecedented opportunity to fulfill the productivity, investment, and export potential of agribusiness in Ukraine, the extent to which the sector benefits from WTO membership and an FTA with the EU hinges on its ability to comply with international food safety standards.

For example, Ukraine is currently only able to export most livestock products (meat, milk products) to mainly CIS (with Russia importing the lion's share) or African countries. In this respect, the ban on Ukrainian meat, eggs, fish, cheese, milk, and butter imposed by Russia in mid-January 2006 provides an illustration of the need to access new export markets. If food product safety and quality do not comply with market requirements and internationally recognized guidelines and standards, the result will be poor safety of food products for domestic consumers, and inability to access high-quality-high-price foreign (and domestic) markets.

Currently, Ukraine continues to use food safety regulations inherited from the Soviet Union¹⁰, which are not WTO compliant nor recognized by leading economies. Continued reliance on outdated food safety regulations severely undermines Ukraine's export potential and competitiveness in agriculture and food production, and, most importantly, jeopardizes the public health and safety of the population. It does so by imposing unnecessary costs on businesses and duplicating regulatory requirements that can amount to up to 6 percent of the value of production (Ukrainian mandatory import-export regulation alone – see box).

According to the Ukrainian Law on Safety and Quality of Food Products, food products, food processing equipment, raw materials for food industry and related materials may not be imported into Ukraine or produced, supplied for sale, sold, or used otherwise before their quality and safety have been approved by appropriate documents. These documents are:

- a declaration of conformity issued by the producer for every consignment of food products, raw materials for food industry and related materials;
- a certificate of conformity or a certificate of acceptance of a foreign certificate, issued by an accredited authority for food products intended for sale on a domestic market, or for domestically produced food products to be exported from Ukraine;
- a positive conclusion of the State Sanitary – Epidemiological Expertise, a state registration certificate or a hygiene certificate;
- veterinary documents for food products of animal origin;
- a certificate of quality and a quarantine permit for grain, fruit, and vegetables.

Suppliers of food products for Ukrainian retail are responsible for providing the above-mentioned documents.

¹⁰ Mostly consists of GOST (Gosudarstvennyi Standard – State Standard) and GOST-based national standards as well as other obsolete normative acts which regulate sanitary and phyto-sanitary norms and rules. GOST is a pre-1991 standard used in the former Soviet Union and refers to a set of technical standards maintained by the Euro-Asian Council for Standardization, Metrology and Certification (EASCC), a regional standards organization operating under the auspices of the Commonwealth of Independent States (CIS). Note that in the EU standards are being applied to the testing methods only – see Directive 1992/46 on milk, for instance.

At the same time, reliance on a post-Soviet type food safety control system, which imposes a heavy regulatory and compliance burden on businesses (for example, a typical dairy processor needs to obtain a minimum of 120 authorizations), has not helped prevent food-related diseases and poisonings. Annually, the Ministry of Health Care of Ukraine (MHC) registers approximately 1,500 food-related poisonings with about 70 percent attributed to factory produced food products¹¹.

Currently, the scale of food safety norms violations throughout the entire production and supply chain in Ukraine is massive while food safety control is ineffective, costly, and burdensome.

The Sanitary and Epidemiological Service (SES) of the Ministry of Health Care of Ukraine in 2007 conducted 661,726 audits of food processing facilities, trade outlets, and food service establishments. Examinations conducted by SES in **dairy enterprises alone** revealed non-compliance with the existing norms in 10.4 percent of cases. The vast majority of such violations were related to nonconformance to very complex, prescriptive, and often outdated sanitary norms and hygienic rules dating back to Soviet times; meanwhile, some existing pathogens were not detected since there is no norm or recognized methodology to check them. This leads to a paradoxical situation of high-intensity controls (with associated administrative burdens for businesses) that fail to detect potentially dangerous food safety violations.

Implementation of the international best practices in food safety regulations would ensure higher safety of products and thus increase consumer confidence. **It is therefore imperative for Ukraine to proceed expeditiously to a substantial reform of the food safety regulatory system according to international best practice standards, norms, and principles (see section 2.2), by piloting the reform initiative in a specific, yet significant, agribusiness sub-sector such as dairy.**

¹¹ According to IFC consultations held in the summer of 2008, the situation is especially troubling with the increasing number of enteric infections in children. The number of registered cases of enteric infections in children increased from 541 per 100,000 in 2002 to 768 per 100,000 in 2005 or by 43 percent.

2.1. Relieving Businesses from Unnecessary Regulatory Burdens in a Time of Crisis: the Case of the Dairy Sub-Sector

In view of the current global financial crisis, and of its adverse effects on the productive base of the Ukrainian economy, it is crucial to relieve Ukrainian businesses (especially in strategic sectors such as agribusiness) from unnecessary regulatory and administrative burdens and reform the sectoral regulatory framework in preparation for recovery. The dairy sub-sector is an important case in point (and illustration of the need for reform in other sub-sectors such as meat, grain, or vegetables) since it has strong potential for post-crisis recovery and growth, but is constrained by an unnecessary burdensome and outdated regulatory framework.

In fact, dairy is one of the strategically important sectors for Ukrainian food industry in consideration of the following:

- **Favorable natural and climatic conditions for milk cattle breeding;**
- **Growth of milk products consumption on both local and foreign markets in the long run;**
- **Highly attractive sector for investors: new construction and reconstruction projects underway, although the pace of investment has slowed down due to the persisting uncertainty of the investment climate and regulatory environment;**
- **Total market turnover of \$2.7 billion in 2007;**
- **The largest food and beverage sub-sector in Ukraine in terms of volume (15 percent of the total) in 2008;**
- **Leading exporter of milk products – took fifth place in 2006 among world leading exporters of milk products after New Zealand, the EU, Australia, and Argentina¹²;**
- **Leading exporter of condensed milk, cheese, and butter;**
- **At the same time, Ukrainian dairy exports are primarily concentrated in former CIS countries (57.7 percent of exports, including Russia with 38.4 percent), Algeria (13.4 percent), and few other Asian and African countries (17.6 percent), while exports to EU and other advanced economies total to a mere 11.6 percent;**

¹² The most popular dairy products for export are cheese, condensed milk, and butter. The main importers of Ukrainian milk products are Russia, Belarus, and Algeria. Due to the embargo on export to Russia, exports were partly redirected to Asian and African countries. The export of milk products in 2006 decreased by 34 percent in volume and by 40 percent in money terms compared to the previous year. In 2007 the situation improved slightly: exports grew by 4 percent in volume terms and by 71 percent in money terms compared to 2006. The dramatic increase in value can be attributed to the increase of world prices for dairy products. The volume increase of export in 2007 was mainly due to new markets for buttermilk, curd, yoghurt, kefir, and whey. In 2008 Ukrainian dairy export grew further by 7 percent in value terms and only by 8 percent in money terms compared to 2007: the increase was almost exclusively due to the lifting of the ban on exports of Ukrainian cheese to Russia. In 2007 milk and cream were mainly exported to Azerbaijan (55 percent), Moldova (28 percent), and Georgia (16 percent). Dried milk products and condensed milk were exported to more than 63 countries. The main importers in 2007 were Algeria (28 percent), Russia (8 percent), China (7 percent), Japan (5 percent), Turkey (5 percent), and Kazakhstan (5 percent). Export of cheese is one of the main Ukrainian exports after dried milk products and condensed milk. After the decrease of cheese export by 58 percent in 2006, the year 2007 was marked with 26 percent growth; however the indicator of 2007 is only 53 percent of the number of tons which have been exported in 2005. Cheese is exported to 15 countries, among them Russia, Kazakhstan, Moldova, Belarus, the United States, and Armenia. To the EU, Ukrainian cheese is exported only as a raw material for production of processed cheese. Exports of casein decreased in 2007 by 40 percent in value terms (while increased by 14 percent in money terms in comparison with 2006). Casein is mainly exported to EU countries: Germany (51 percent), the Netherlands (23 percent), and Poland (10 percent). The most valuable milk exports in 2007 remain milk and cream (48.4 percent in value terms and 43.8 percent in money terms) and cheese and cottage cheese (32.9 percent in value terms and 40.7 percent in money terms).



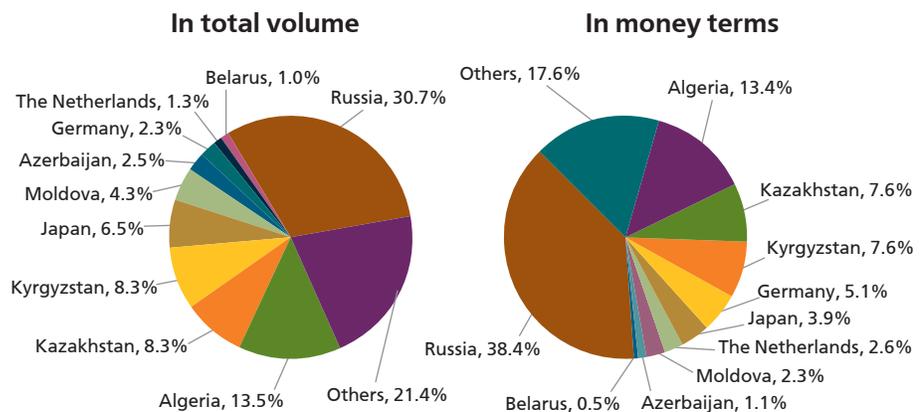
- Also, the product mix of dairy exports to EU and other advanced economies remains limited to casein, dry milk powder, and other intermediate inputs for industrial use with low value-added. The export potential of high value-added high-end final products, such as milk, cream, cheese, or cottage cheese remains largely untapped due to the lack of compliance with EU and international food safety standards.

Dairy Export of Ukraine in 2007–2008 (\$ thousands)

Products	2007	2008	Top-three countries–importers in 2008
Milk	2,765	13,632	Kazakhstan, Azerbaijan, Moldova
Condensed milk	290,320	207,897	Russia, Kazakhstan, Algeria
Sour milk products	978	1,342	Moldova, Kazakhstan, Azerbaijan,
Whey	18,991	7,694	Belarus, Japan, Pakistan
Butter	10,909	19,598	Kazakhstan, Azerbaijan, Moldova
Cheese	269,671	402,589	Russia, Kazakhstan, Moldova
Ice-cream	3,102	3,619	Moldova, Russia, Israel
Casein	6,6511	65,929	Germany, Poland, USA
Total	663,247	722,300	

Source: State Statistics Committee of Ukraine

Figure 5 – Ukrainian Dairy Export Markets in 2007



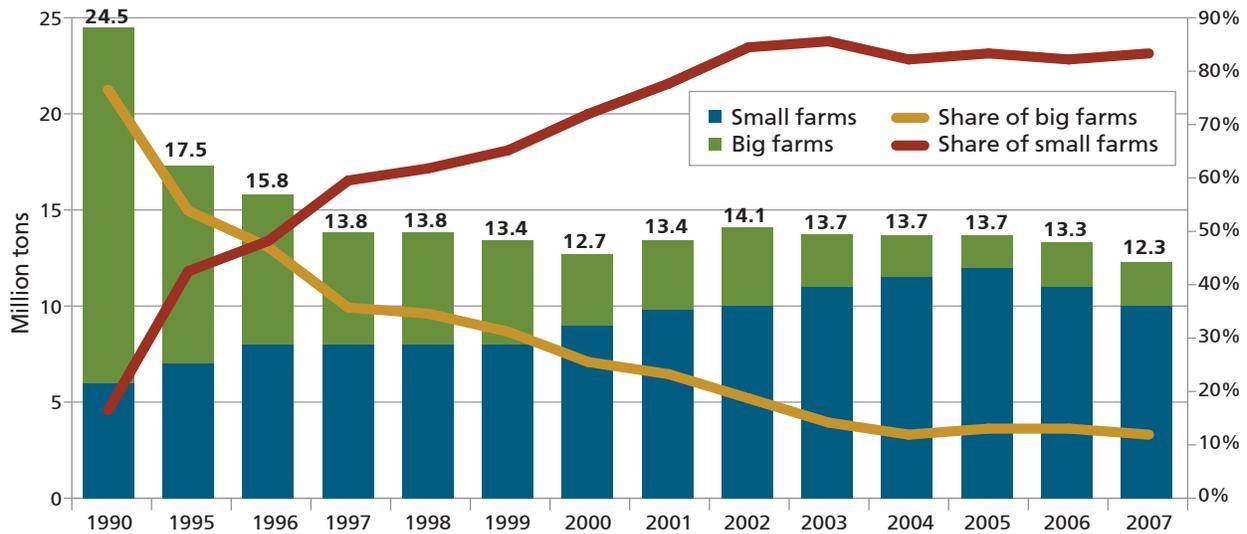
Source: State Statistics Committee of Ukraine

In short, the potential of the sector remains largely unexploited¹³ primarily as a consequence of poor quality and limited supply of raw milk¹⁴ and an inability to comply with international food safety

¹³ For example, in terms of productivity the average milk yield per one cow in the big farms amounted to 3,293 kg in 2007, which represented a 10.4 percent increase than in 2006. While the average productivity has been constantly growing over the past few years, it remains well below the average productivity in advanced economies (for example, Australia 5,000 kg, EU average 5,886 kg, U.S. 9,165 kg per cow per year), thus confirming the existence of a large untapped productivity improvement potential.

¹⁴ Over the past five years the number of cattle has significantly decreased. For example, in 2008 there were 28 percent less heads than in 2003. In 2008, the negative trend in milk production continued to affect the dairy sector: the total volume of raw milk produced in Ukraine has further decreased by 4 percent compared to 2007. Source: State Statistics Committee of Ukraine, <http://www.ukrstat.gov.ua>

Figure 6 – Milk Production in Ukraine



Source: State Statistics Committee of Ukraine

standards. The capacity of the existing more than 300 milk-processing plants considerably exceeds the supply capabilities of small farms and households (see figure 6 below) that provide 82 percent of raw milk, raising significant milk safety and quality concerns.

In 2007, 7,138 enterprises and farms produced raw milk in Ukraine, and over half of these owned less than 100 cattle.¹⁵ These small enterprises and household farms are often unsophisticated when it comes to farming practices.

Poor quality of raw milk creates serious challenges for processors to ensure that their end-products pose minimal health risk when consumed; the government must develop the proper mechanisms for oversight. International best practices in food safety are therefore critical for Ukraine's dairy sector, and the inability to reform the system restrains its future growth and export potential.

This is particularly relevant also in consideration of the heavy regulatory burden imposed by the existing food safety system on dairy businesses. An ongoing review of food safety regulations in dairy carried out by the IFC reveals that on average a typical milk processing value chain ("from farm to fork") needs to:

- comply up to 120 permits, authorizations, and other regulatory requirements;

- comply on average with up to 50 mandatory standards (GOST and DSTU) for each dairy product;
- comply with up to 51 orders and mandatory guidelines from the Ministry of Health Care and other supervision agencies for each dairy product;
- comply with around 110 prescribed testing methods, in spite of the fact that 63 percent of them are not in line with international standards;
- receive repeated and overlapping inspections from several different inspecting agencies.

The burden associated with such regulatory requirements adds significant costs to the already financially distressed dairy sector, which is experiencing a significant reduction of global demand and drop in prices in the key U.S. and EU markets¹⁶ (in the U.S., prices of dairy products have declined by about 40 percent in the first months of 2009)¹⁷, and is expected to rebound not earlier than 2010. With slowing global demand, significant reduction of profit margins, and increasing international competition, it becomes therefore even more critical to release dairy producers from additional administrative burdens and costly procedures to empower the sector to rebound faster from the current global economic slowdown.

¹⁵ State Statistics Committee of Ukraine, Agricultural Statistics Yearbook, 2007.

¹⁶ "Future directions in EU dairy policy: Implications for EU dairy exports." March 2009. DG for Agriculture and Rural Development. European Commission.

¹⁷ According to the American Farm Bureau Federation: Special Dairy Market Update, February 10, 2009.

2.2. International Principles of Effective and Efficient Food Safety Regulations



The experience of other countries has shown that necessary and adequate levels of food products safety can be achieved without restrictive, inflexible, and highly administrative processes that negatively affect the competitiveness of the private sector and impose costly barriers to trade.

In response to food scandals, increased demand for securing food safety and WTO principles on transparency, many countries have reassessed their food safety systems and made various reforms. Widely accepted international trends in managing food safety measures comprise the following principles:

- **Food safety management has shifted from end-of-pipe controls, imposed by government, to prevention throughout the food supply chain.** Basic responsibility for food safety compliance has shifted to the private sector, with the government taking on advisory, oversight, and rulemaking roles. The main principle: “Operators on the food market are in the best position to develop a safe system for food product supply and ensure the safety of the products they supply, therefore the responsibility for food safety should be borne by them”.
- **Risk analysis and assessment of costs and benefits are the main building blocks of food safety policymaking** that includes risk assessment, risk communication, and risk management. EU law uses risk analysis to balance efficiency while protecting human life, health, and consumer interests, including fair practices in food trade, protection of animal health and welfare, plant health, and the environment.
- **Integral approach “from farm to fork” to food safety controls.** For example, EU members are in the process of creating or have already created either single controlling bodies or integrated food control systems over the whole production chain in accordance with the “farm to fork” principle, starting from field and finishing with retail trade.

The General Food Law (Regulation EC 178/2002) which is in effect in the EU since 2002 sets out the general principles and procedures for assuring food safety. Within the framework of this law the European Food Safety Authority (EFSA) was set up. This organization started to work in 2003, focusing on the evaluation of risks and scientific consultations on food safety.

- **EU approach to food safety control is risk-based** and employs mainly general “horizontal” legislation covering common aspects of foodstuffs, such as food additives, labeling and hygiene, as well as some “vertical” legislation, where necessary, applicable only to specific products, such as milk, meat, and poultry. This scheme introduces norms only so far as necessary for safety, making it more cost effective and business-friendly.

- **Regulatory impact analysis**, i.e. assessment of costs and benefits of new regulations that allows for mutually beneficial policymaking and management in food safety and agricultural health for three key players: consumers, private enterprises and government.
- According to best practices commonly applied in OECD countries and in the EU, **food products do not require certification at all**¹⁸. Certification is used almost exclusively for the purpose of export-import operations (only if this is required by the importing country).

In general, there is no ideal system which would be completely acceptable to all countries. Each country should conduct institutional reform in accordance with its own unique political and historical context. For example, during the past few years most of the EU countries reformed national directorates of food safety with different functions and objectives according to the context.

Poland

The structure and organization of official control as well as legislation is now undergoing reform. To align relevant procedures with EU procedures, Poland has adopted a new law on food products. Additional reform is implemented in the system of monitoring and supervision to formalize official control over food products. Poland intends to set up a single agency modeled along the Food Standards Agency in the United Kingdom (set up in the UK in 2000). The united system of control over food products will operate under the Ministry of Health Care.

In addition, the manufacturers themselves control food quality and safety by introducing such quality systems as ISO, HACCP, and GMP (good manufacturing practice). Encouragement to introduce quality management systems which regulate the entire manufacturing process is a much more effective way of assuring quality of food at all stages of its production (raw materials, manufacture, packaging) than the certification of finished products, which does not justify its effectiveness.

In some countries, the mandate is limited to evaluating risks and providing advice to governments, while in others the mandate includes the notification of risks and the execution of statutory provisions governing the control of food products. A common trait of all these institutional set ups (see box above) is that the reform allowed companies to achieve higher safety standards at less cost while ensuring their effective and efficient control.

¹⁸ Of course, the EU and EU member states have hygiene regulations and food safety requirements. They also have strict consumer information rules forcing producers and sellers to provide all essential details on the product, and preventing abusive marketing. They do not, on the other hand, prescribe to producers what recipe they should use.

3

Assessing Ukraine's Regulatory System on Food Safety



3.1. The Legal Framework

The overall legal framework on food safety in Ukraine is composed of a series of fragmented and often overlapping laws (see Annex 1), which have stratified over time since the break-up of the USSR. Overall, the legal framework on food safety controls presents the following critical issues:

- The legislation concerning food safety is contradictory and not systematic, contains regulatory gaps and lacks of effective enforcement mechanisms. This also restrains the process of harmonization with EU food legislation (see Annex 2);
- International best practices in food safety management (such as HACCP), although mentioned in several pieces of legislation, have no effective mechanism of implementation in practice. For example, while Ukraine has included references to HACCP in various legislation, in reality state officials are not sufficiently trained to inspect compliance with food safety systems such as HACCP, and cannot adequately judge whether an appropriate food safety system is in place;
- Ukrainian food safety legislation is not in line with the international WTO commitments undertaken by Ukraine (see Annex 5). This could potentially lead to appeals by member states of WTO to the Dispute Settlement Body of the WTO and result in the imposition of sanctions;
- In spite of the proliferation of laws related to food safety issues since the end of the Soviet era, the organizational and legislative foundations of the state regulation on food safety and quality has not experienced any substantial process of harmonization with globally accepted best practices and remains oriented on socialist economic principles;

Ukrainian food safety legislation is full of internal inconsistencies as well as non-compliant with the EU norms. For instance, paragraph 2 of Part 1 of Article 14 of the Law on Consumer Rights Protection No 1023-XII from May 12, 1991, says: “Failure to provide standard documentation or regulations specifying compulsory requirements for products which may do harm to the well-being or health of consumers, the environment, or property, shall result in immediate ban on the production or sale of such products by executive authorities in charge of consumer protection.” In practice this means that all standards are de-facto mandatory and are not in line with international agreements. Therefore Ukraine should adopt and implement the Good Practice Code on standard development and implementation in accordance to the WTO TBT Agreement which stipulates that all standards should be *voluntary*.

3.2. Overview of the Food Safety Regulatory System

A cursory review of the food safety regulatory system in Ukraine shows that most food sanitary measures have not been revised since the breakup of the Soviet Union in 1991. The Medical and Biological Requirements and Sanitary Norms of Quality of Raw Food Materials and Food Products (SANPIN) is the base by-law document in regulating food safety, approved by the USSR Ministry of Health Care on August 1, 1989. It divides all food products into nine major categories, establishing a set of nutritional¹⁹ and safety²⁰ norms for each product category.

In addition to the SANPIN regulations, the other key pieces of regulation indirectly affecting food safety²¹ in Ukraine include the 15,000 mandatory product standards (old Soviet GOST standards adopted before 1991 and Ukrainian state standards (DSTU) adopted after 1991) administered by the State Committee for Technical Regulations and Consumer Policy²², veterinary²³ regulation administered by the State Committee of Veterinary Medicine, phytosanitary measures²⁴ administered by the State Plant Quarantine Service, and many other regulations and standards that must be observed by market operators.

The main characteristics of Ukraine’s food safety regulatory system include:

- **Outdated overly-prescriptive mandatory product-focused standards and other requirements which, for example, may dictate a specific recipe, type of equipment, or material to use;**
- **Control of safety based mainly on testing samples (i.e. compulsory certification) instead of a comprehensive and robust risk based management system (such as HACCP);**
- **Lack of traceability.**

These characteristics create problems not only for safety and competitiveness of the end-product, but also for innovation and efficiency of the productive process. Moreover, responsibility for food safety controls is spread over many agencies.

¹⁹ Content of protein, energy, carbohydrates, vitamins, micro elements, etc

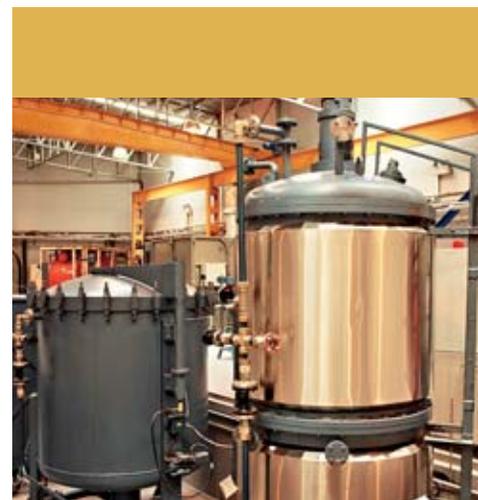
²⁰ Maximum residue levels (MRLs) for heavy metals, micotoxins, antibiotics, hormones, pesticides and microbiological limits.

²¹ Ukrainian Law on Safety and Quality of Food Products №771/97-BP from December 23, 1997, as amended by Ukrainian Law on Changing the Law of Ukraine on the Safety and Quality of Food Products No 2809-IV from September 6, 2005; Ukrainian Law on Ensuring Sanitary and Epidemic Safety of the Population №4004-XII from February 24, 1994.

²² Decree of Cabinet of Ministers of Ukraine on State Surveillance of Conformity with Standards, Norms, Rules and Responsibility in Case Violation № 30-93 from April 8, 1993; Law on Standardization № 2408-III from May 17, 2001; Law on Ukraine on standards, technical regulations and conformity assessment procedures № 3164-IV from December 1, 2005.

²³ Ukrainian Law on Veterinary Medicine №2498-XII from June 25, 1992, and amendments (see box on page 10).

²⁴ Ukrainian Law on Plant Quarantine №3348-XII from June 30, 1993, and amendments (see box on page 10; Ukrainian Law on Seeds and Planting Materials №411-IV, from December 26, 2002.



3.3. Institutional Structure of Food Safety Control System in Ukraine

The following executive authorities are involved in assuring the safety control of domestically produced and imported food products, and animal and plant health control issues (see chart below and Annex 4 for full analysis):

- **The Ministry of Health Care– The State Sanitary and Epidemiological Services**
- **The Ministry of Agrarian Policy:**
 - **The State Committee of Veterinary Medicine (which has an autonomous status)**
 - **The Central State Inspection on Quarantine of Plants**
- **The State Committee for Technical Regulations and Consumer Policy (DSSU)**
- **The Ministry of Environmental and Natural Resources – The State Ecological Inspection Services**

Overall, the system of state control of food safety in Ukraine can be characterized in the following ways:

- **No clear organizational structure** at the national level (due to duplication of functions by the controlling bodies),
- **No proper planning system** that makes impossible evaluate efficiency and results,
- **Excessive administrative burdens** on business as a consequence of redundancy and lack of coordination among controlling agencies.

There is little appropriate communication or coordination between food safety government agencies, resulting in redundant inspections and overall inefficient control. This affects the viability and competitiveness of food-related businesses, especially those that deal with products of animal origin. Such businesses are often inspected multiple times by the State Standards Committee, the Ministry of Health Care and the Ministry of Agriculture, which all control the same parameters.

The “command-and-control” legacy of the Soviet legal system on food safety translates into stringent and pervasive obligations for businesses, while it does not entail any accountability or transparency mechanisms for state controlling bodies. The lack of accountability of regulatory bodies in turn impairs the ability of both producers and consumer groups to advocate for the modernization of regulatory practices.

In addition, the performance measurement criteria of state controlling bodies on food safety lean towards a rigid “command-and-control” system of inspections. As a matter of fact, the prevailing criteria for evaluation of controlling bodies are the number of inspections and the amount of penalties gathered, rather than indicators, which define and ensure the level of food products safety (for example, the number of food borne diseases). This is also misleading for consumers who consequently (and erroneously) tend to believe that stricter controls and a higher number of inspections is associated with a higher level of food safety.

Unfortunately, all attempts to streamline and increase coordination among controlling agencies during the last 15 years have failed and even led to increased fragmentation. This was most likely due to the influence of strong vested interests within each controlling agency that have undermined the various attempts to improve inter-agency coordination.

In order to proceed with its Euro-integration ambitions, and to facilitate local food processors to export to the EU, Ukraine must harmonize and reform the state food control system aiming at conformity with the EU (see box below for EU food control system characteristics).



Food Safety Governance Structure in Ukraine



Best international practices

Germany

There is one agency controlling food products: the Federal Ministry of Consumer Rights Protection, Provisions and Agriculture. The Ministry's departments are charged with functional duties covering specific areas, such as food and industrial products, products of plant protection, veterinary medicine, and genetic engineering.

The Federal Institute of Risk Evaluation is a scientific establishment that draws up expert reports on food product safety and protection of consumer health on the basis of international scientific criteria of evaluation.

Belgium

The Belgian Food Agency provides an illustration of how it is possible to reorganize a multi-agency, poorly coordinated food safety control system into a coherent food control system that ensures efficient, purposeful, and coordinated supervision through clear communication between all competent control services. In the past, different agencies, including the Ministry of Agriculture and the General Food Inspection, each had their own inspection and control services. This structure did not lead to an effective, efficient, yet business-friendly, food control system, so the Belgian government decided to integrate all the control services into one Federal Agency for the safety of the food chain: the Belgian Food Agency. The Food Agency integrates all control and inspection services of the food chain, from farm to table, in one single administrative organization.

Estonia

The only state agency responsible for food safety is the Veterinary-Food Department under the Agrarian Ministry. The main functional duties of the Department are control over the execution of legislation such as veterinary medicine, food safety, and market regulation.

4

Critical Areas of Food Safety Reform: Outdated *de facto* Mandatory Product Standards, Mandatory Certification, and Inspections



Three critical areas in need of reform of the Ukrainian food safety system relate to the existence and enforcement of outdated standards from the Soviet era, the regulatory practice of mandatory certification of the majority of food products, and a pervasive and complex system of inspections. This is also confirmed by the ongoing regulatory review of the dairy sector conducted by the IFC, according to which **each dairy product has to comply with an average of 50 state standards (GOST/ DSTU), the mandatory certification** of food products (27 product categories) has been identified by food processors among the most burdensome regulations, and continuous inspections from several state control agencies hinder regular business operations.

4.1. The Food Safety Product Standards

The use of standards in assuring the marketing of safe and high quality consumer products has long been a tradition in Ukraine and other Commonwealth of Independent States (CIS) countries. This importance is demonstrated by the long-standing dedication to both the development and the enforcement policy of national standards, particularly for the safety and quality of food for human consumption. The GOST/ DSTU system of standards inherited after the break-up of the Soviet Union consists of thousands of standards, which are a mixture of technical prescriptions, quality parameters, agricultural health standards, and safety standards.

Most of the health and safety standards are implicit and not based on transparent scientific criteria. Sometimes food safety requirements are lower than those of the Codex Alimentarius and other international and EU standards. GOST/ DSTU standards in general form an obstacle for market access as they are not recognized in market economies. For example, to export to the EU, Ukrainian **food producers have to comply with a double layer of product regulation**: first they have to comply with the Ukrainian mandatory standards and specifications (on average 50 Soviet-type GOST/ DSTU standards for each dairy product) which are not recognized by the EU or any other significant international markets, and second they also have to comply with EU technical standards which can add up to **14 percent of production costs** of agricultural products and **10.4 percent of production costs** of food processed products, imposing a significant squeeze on margins.

In this respect, the full harmonization of Ukrainian product regulations with the WTO commitments would lead to a **30 percent reduction of standardization costs** for agricultural and food products, while the cost reduction would amount to up to 50 percent in the case of product standards harmonization under a EU-Ukraine Extended Free Trade Agreement.²⁵ Furthermore, outdated GOST/DSTU standards reduce competitiveness in exports because they give little flexibility to producers to follow market trends and consumer taste (i.e., quality specifications are subject to regulatory control), and involve extensive inspections throughout the production and trade channels.

Approximately 19,000 effective standards were adopted prior to 1992 (GOSTs) out of which 10.3 percent were considered as harmonized by March 2006. Recent reports from the DSSU suggest that a total of 5,571 standards were harmonized with ISO and EU standards by the end of 2008. Around 3,222 GOSTs developed before 1992 have been abolished during the past two years. However, in spite of these advances in the process of modernizing of product standards, the regulatory burden of the GOST/DSTU system remains high especially in the dairy sector, where businesses have to comply with hundreds of GOST/ DSTU standards to produce dairy products (for example, it is necessary to comply with up to 94 mandatory standards to produce cottage cheese or with up to 177 standards for ice-cream).

Overall, the lack of compliance with international standards of food products safety, and the slow harmonization of the GOST/ DSTU standards and their mandatory status are in contradiction with WTO and other legally binding international commitments made by Ukraine²⁶ and adversely affects private sector development by creating the following barriers:

Barriers to international trade

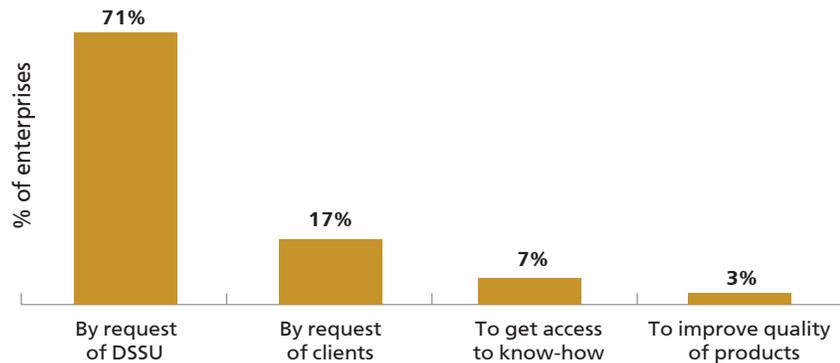
- **The GOST/DSTU system of standards is not recognized in OECD markets and restricts the acceptability of Ukrainian products in non-GOST/DSTU markets.**
- **The testing laboratories based on GOST/DSTU standards cannot meet the requirements of the European Union and other industrial countries. This is because the absence of quality management systems, such as the facilities, equipment, and analytical methods were designed to meet the inspection and certification requirements of the GOST/DSTU system (approximately 1.5 percent of all laboratories are accredited under ISO 17025).**

²⁵ Estimated cost reductions based on "Trade Sustainability Impact Assessment for the FTA between the EU and Ukraine within the Enhanced Agreement", Final Report, European Commission, DG-Trade, December 2007.

²⁶ As stated in EU-Ukraine Action Plan approved by the Cabinet of Ministers of Ukraine in December 2005, Ukraine took commitments for voluntary use of standards (sub-point 6 of point 2.3.1. Movements of goods; Standards, technical regulations and conformity assessment).

Barriers to innovation

- The rigidity of the GOST/DSTU standards system thwarts product and process innovation since it requires difficult-to-obtain approvals of new standards.
- Extremely constraining standards are, in practice, not enforceable, and only result in “unofficial solutions,” barriers to innovation, and the entry of new actors on the market – consumers do not get any benefit from these standards.
- No distinction between technical regulations addressing food safety issues, which are mandatory, and voluntary product standards that deal with quality.

Figure 7 – Reasons for Adopting Food Product Standards in 2008

Source: IFC Ukraine Business Enabling Environment Survey 2009²⁷

Costs for businesses

- The Ukrainian system of standardization and certification entails high transaction costs for businesses (see above – harmonization with WTO and EU regulation would lead to up to 50 percent reduction of standardization costs) due to
 - large number of mandatory requirements;
 - excessive multiple inspections by various segmented government agencies and laboratory tests for certifications or approvals all along the various phases of the chain without a risk-oriented approach.

²⁷ These figures are based on preliminary findings of the survey conducted in 2009. Some variations with the figures may occur in the published report, based on the above survey (September 2009). However, IFC has taken all care to make sure that they accurately reflect the trends of the business environment in 2008.

Dairy producers speak:

“Even when products are to be exported and the destination country doesn’t require certain tests to be done, Ukrainian producers must still perform all tests required in Ukraine for the exported product. For example, for selling hard cheese in Ukraine it is necessary to provide the results of a test on copper, but in Russia such tests are not required. Nevertheless, in order to export hard cheese from Ukraine to Russia, Ukrainian cheese producer must provide DSSU with the results of copper tests done exclusively in one of the DSSU-affiliated laboratories within the UkrSEPRO system.”

IFC staff interview with dairy producer

- **The rigidity of the GOST /DSTU standards gives supervisory agencies great discretionary power in checking conformity of products. This leads to a high level of ambiguity in enforcing regulations and provides ample room for administrative rent seeking.**

4.2. Mandatory Certification of Food Products

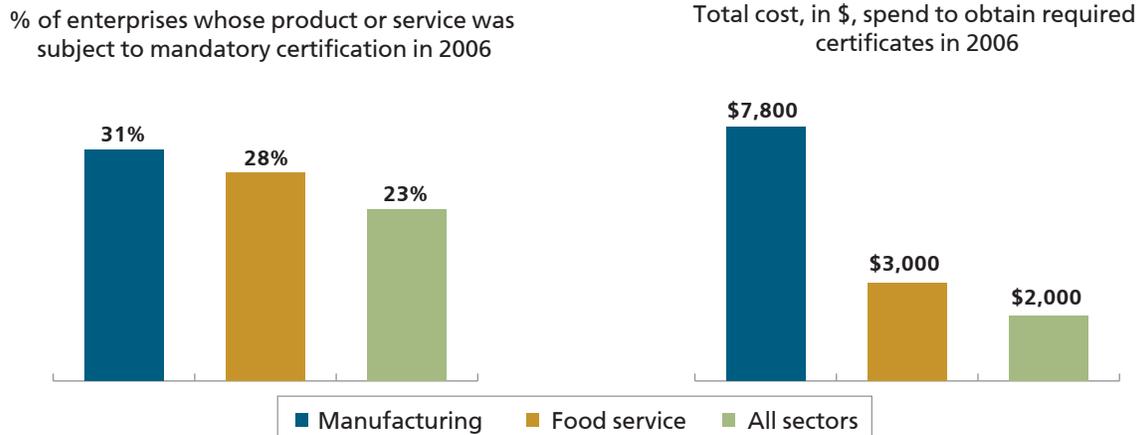
In contrast with the western certification practices where most producers of food products voluntarily certify the quality and safety of their products through independent non-governmental organizations, in Ukraine most food products must undergo mandatory certification and receive respective conclusions. In particular, the required certification process always involves a minimum of two state entities: the Ministry of Health Care and DSSU. This is an expensive and lengthy process which adds to the price of goods and services offered by producers, since each type of food product needs to obtain and renew a Certificate of Compliance on a regular basis. As an illustration, the certificate of compliance for each dairy product needs to be renewed every six months, and the renewal process requires on average 10 days of two dedicated administrative and technical staff of the company to prepare the necessary documentation and follow the administrative procedure, with an average total waiting time of five weeks and a minimum fee of approximately 10,000 Ukrainian hryvnias (\$1,298)²⁸. This certification is not recognized outside CIS countries and thus companies must undergo product food safety testing according to EU legislation or requirements of other countries in order to access other markets.

Likewise, any Ukrainian company willing to use European technology in Ukraine must present the equipment/machinery to the laboratory of DSSU as a prerequisite to receive a certificate for its use. This is a certification that has no meaning in Europe; it raises the price of the goods to be produced because, literally, every nook and cranny must be checked and certified. Not surprisingly, this cumbersome barrier to entry does not sit favorably with foreign companies.



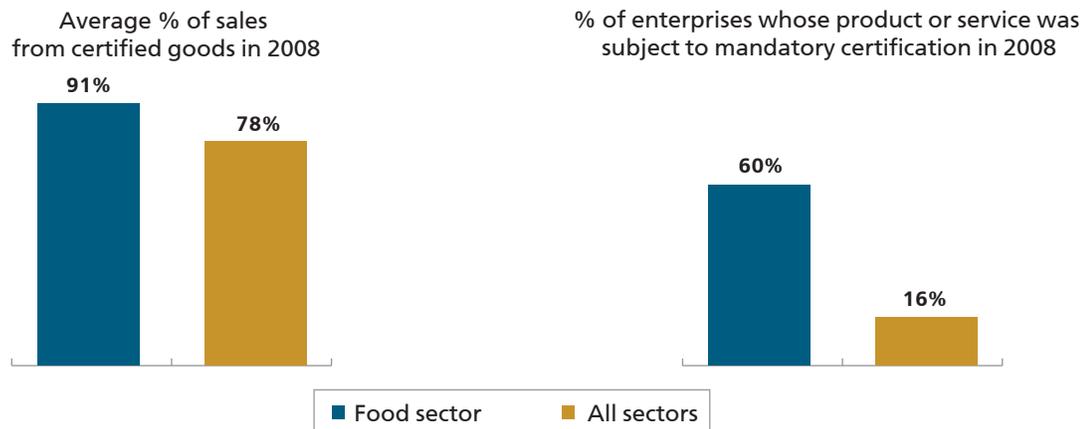
²⁸ Based on the official exchange rate \$1 = 7.70 Ukrainian hryvnias established by the National Bank of Ukraine as of March 2009.

Figure 9 – In 2006 One in Four Food Service and One in Three Manufacturing Enterprises Spent \$3,000 and \$8,000 on Mandatory Certification Procedures



Source: IFC Technical Regulations Survey, 2007³⁰

Figure 10 – Coverage of Mandatory Certification and Share of Sales Coming from Goods that were Subject to Mandatory Certification in 2008



Source: IFC Ukraine Business Enabling Environment Survey, 2009³¹

Additional problems with mandatory certification relate to the following two issues:

1. There is the List of products subject to mandatory certification in Ukraine approved by the Order of DSSU #28 issued in Feb. 2005. This list includes cheese and butter, margarine, water, spirits, candy, coffee, tea, fish, and meat products. Taking into consideration that after WTO ac-

cession all imported food products are formally not subject to mandatory certification (the WTO commitments of Ukraine) this order creates a paradoxical situation in which the country grants foreign producers more favorable conditions through regulations than domestic entrepreneurs. Therefore, full cancellation of mandatory certification requirement for domestic products must be a high priority.

³⁰ Food service companies include restaurants, catering services, and food retail.

³¹ These figures are based on preliminary findings of the survey conducted in 2009. Some variations with the figures may occur in the published report, based on the above survey (September 2009). However, IFC has taken all care to make sure that they accurately reflect the trends of the business environment in 2008.

2. Mandatory certification does not ensure market protection from low quality and hazardous products. According to a DSSU Activity Report for the first half of 2008, published on the official website in August 2008, there were 2,285 tons of various food products inspected, out of which 1,074 tons (47 percent) of food products were removed from the consumer market based on inspections results³². **Potentially unsafe products are thus removed not at the stage of certification, when harm can be prevented, but when they have already reached the market.**

This is in contrast with the fact that there is no mandatory certification of food products in EU countries. This does not mean that over 450 million EU nationals consume low-quality or dangerous products. On the contrary, EU food safety helps to make sure that for all food products, appropriate controls are in place at all steps of the chain and that products conform to traceability requirements. While allowing for innovation, the quality of consumer goods is assured. The key is that the entire system relies primarily on making sure that businesses have appropriate internal control and management mechanisms for verification of compliance with safety requirements. At the same time, the implementation of a well-functioning traceability system enables prompt recall of unsafe products and the identification and sanction of non-compliant producers for alleged food safety violations.

4.3. The Food Control System: Inspections

Inspections in food safety industry in Ukraine have all the systemic weaknesses inherent to the general design of state control over businesses. In short, while the existing system of government control is very burdensome and complex, it does not ensure a high level of safety. As a matter of fact, inspections are carried out on a massive scale. In 2008, control authorities inspected nearly 94 percent of food processing companies in Ukraine.

A preliminary analysis suggests that the following factors are the main causes of the massive scale, high frequency, and inefficiency of the food safety related inspections system in Ukraine:

1. **Control authorities do not use risk-based criteria in planning and prescribing inspections.** At present the frequency of government inspections in the Ukrainian food processing industry in practice is not usually based on risk categories assigned to this type of businesses. Despite the fact that the Sanitary and Epidemiological Service³³ (SES) of the Ministry of Health Care and the State Veterinary Committee have introduced risk-criteria, their actual implementation is still very slow.



³² DSSU press-release as of August 15, 2008, http://www.dssu.gov.ua/control/uk/publish/category/system?cat_id=109544

³³ SES authorities introduced risk criteria in February 2008, through a Decision of the Chief Health-Officer which was not in line with the legal procedure stipulated in the Ukrainian Law on Main Provisions of State Surveillance (Control) in Business Entities, № 877-V from April 5, 2007.

2. **The legislation does not contain key provisions that are important for creating a solid legal foundation for government control measures.** In particular it lacks:

- **a detailed description of the rationale for inspections and clear procedures for pre-scribing and conducting them.** This is in spite of some preliminary progress with the adoption of the Framework Law on Controls No 877 IV from April 5, 2007, which mandated the introduction of risk categories by January 1, 2008, yet has remained ineffective pending the approval of the relevant decrees for implementation;
- **a clear definition of the rights and responsibilities of officials conducting inspections.** The existing legal framework does not address the issue of the rights and liability of inspectors for abuse of law.

Food producers speak:

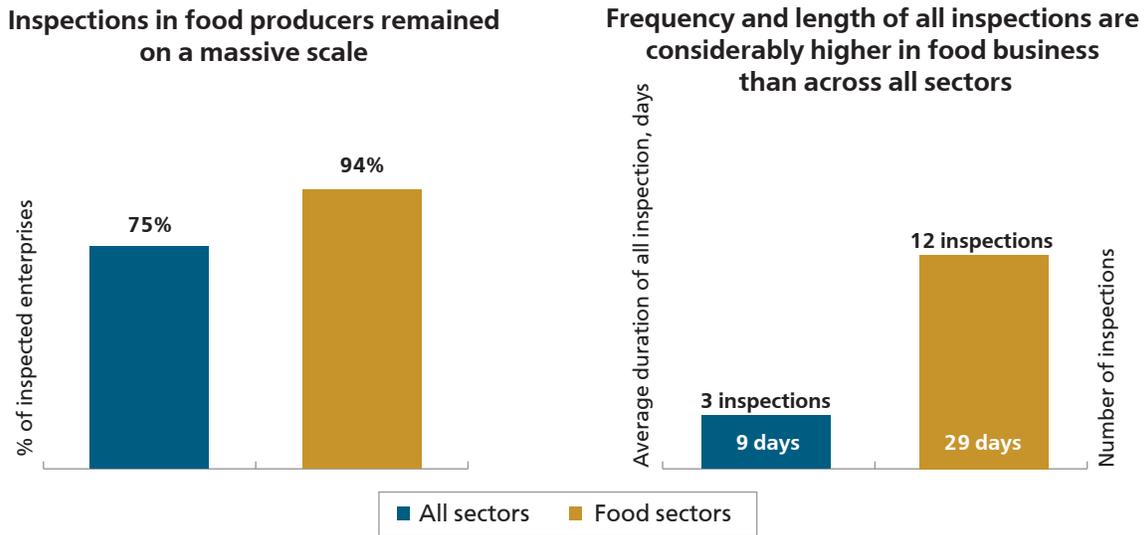
“SES and the consumer protection authorities are both allowed to take the same samples for testing. They come, independently of each other, and take the same products. The products often come from the same batch or the same manufacturer. And both run the same tests, as well. They both appear to be justified in what they do, but I am the one who has to pay for all that....”

IFC staff interview with food producer

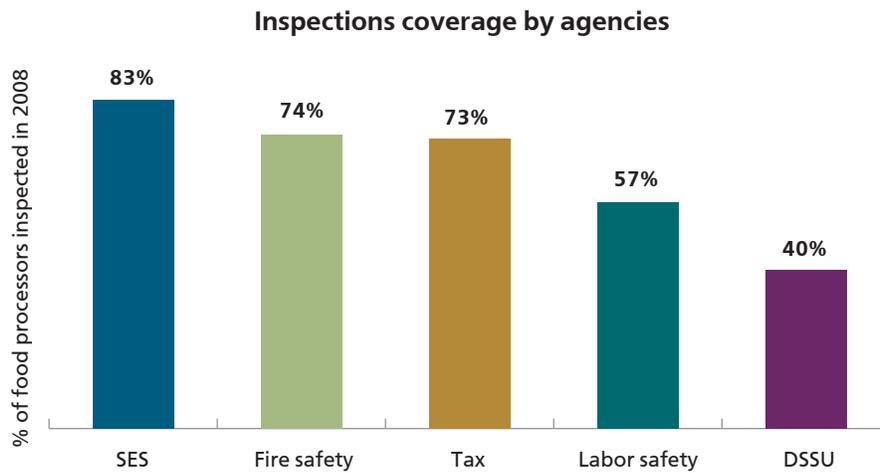
- **a clear division of responsibilities and coordination between inspecting authorities.** There is redundancy and duplication of effort between control authorities owing to lack of communication channels and coordination. The legislation mandates for the duplication of controls by different regulatory authorities on the same product specifications at different stages of the production process. As a result, businesses are often inspected or assessed by more than one agency for the same subject.
3. **The performance evaluation criteria for control agencies have long been based on the number of inspections and the amount of fines collected, rather than on indicators, which define and ensure the level of food products safety, for example the number of food borne diseases.**

Government control is especially burdensome for food processors. As shown in figure 11, food industry development is constrained by an overload of controls, whereas the food sector is particularly affected by DSSU inspections (75 percent of businesses were inspected at least once in 2006).

Figure 11 – Inspections in Food Producers Remained on a Massive Scale in 2008



Authorities that Conducted the Highest Number of Inspections for Food Producers in 2008



Source: IFC Ukraine Business Enabling Environment Survey 2009³⁴

³⁴ These figures are based on preliminary findings of the survey conducted in 2009. Some variations with the figures may occur in the published report, based on the above survey (September 2009). However, IFC has taken all care to make sure that they accurately reflect the trends of the business environment in 2008.

Internal reports produced by DSSU have proven that inspections mostly reveal petty issues; in fact, the vast majority of cases of noncompliance with norms and mandatory requirements have nothing to do with product safety. Almost the same situation persists with other inspectorates responsible for foodstuffs – the Ministry of Health Care and the Veterinary Committee.

According to data obtained in the course of inspections conducted by DSSU authorities in the first half of 2007, the majority of all reported cases of non-compliance related to petty administrative issues, such as lack of appropriate documentation (29-62 percent) and/or product information (20-62 percent).

DSSU press releases of March 13, 2007; June 1, 2007; May 4, 2007.

The need to improve efficiency of the system of government control is indisputable and should include at least three crucial components:

- 1. development of prudent risk criteria for inspection system**
- 2. standard procedure for conducting inspections and presenting findings**
- 3. checklists to be used by inspectors**

Sound and efficient inspections in manufacturing should be complemented by rapid alert system and clear responsibility of producers for the production and sale of unsafe products.

5

Conclusions and Recommendations



In view of the current global financial crisis, and of its adverse effects on the productive base of the Ukrainian economy, Ukrainian food producers must be relieved of unnecessary regulatory and administrative burdens. These producers already face diminished demand for their products, increased competition from foreign producers, and lower prices. The case for harmonization with international best practices is clear. A change in focus from product-specific standards to a risk-based control system based on internationally-accepted food safety management systems would relieve Ukrainian producers of burdensome requirements and costs, thus allowing their products to become more competitive in the domestic and export markets. More important, however, will be the resulting decline in food-borne illnesses and the long-term positive impact on public health in Ukraine.

Recommendations for Policy Makers

1 Establish an Integrated Food Control System or Only One Food Control Agency in Accordance with International Best Practices

Problem Statement

Three state executive bodies, the Ministry of Health Care (Sanitary-Epidemiological Service), the Ministry of Agrarian Policy (State Committee of Veterinary Medicine and State Plant Quarantine Service) and the State Committee for Technical Regulation and Consumer Policy (DSSU) are responsible for the control of safety and quality of foodstuff and food primary production in Ukraine, that in turn results in:

- duplication of functions;
- creation of additional burdens for the enterprises (financial and administrative);
- inefficient use of budgetary funds.

Moreover, the state control system is not sufficiently based on risk assessment, and therefore not science-based, not well prioritized nor targeted.

Current Regulation

At least four Ukrainian laws and one Government Decree determine powers of three Government bodies and procedures of food and agricultural raw materials control:

- Ukrainian Law on Safety and Quality of Food Products No 2809-IV from September 6, 2005;
- Ukrainian Law on Consumer Rights Protection No 3161-IV from December 1, 2005;
- Ukrainian Law on Ensuring the Sanitary and Epidemiological Welfare of the Population No 4004-XII from February 24, 1994;
- Ukrainian Law on Veterinary Medicine No 361-V from November 16, 2006;
- Decree of Cabinet of Ministers of Ukraine on State Surveillance of Conformity with Standards, Norms, Rules and Responsibility in Case Violation No 30-93 from April 8, 1993.

Relevant WTO and Codex Alimentarius Commission (CAC) Provisions

CAC/GL 20

Paragraph 10.

“Inspection and certification systems should have adequate means to perform their task. In the choice of inspection and certification systems, there should be regard to costs to consumers and to the costs in money and time to the affected food industry and government consulting with interested bodies as appropriate. Such systems should be no more restrictive of trade than is necessary in order to achieve the required level of protection”.

Measures Required

To establish a single food control agency or to organize an integrated food control system, taking into account provisions of Regulation (EC) 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules and Commission decision of 21 May 2007 on guidelines to assist Member States in preparing the single integrated multi-annual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council (2007/363/EC).

The above mentioned should be done through amendments to a number of laws of Ukraine (see column “Current Regulation”).

2 Abolish Mandatory Certification of Food Products

Problem Statement

The system of mandatory certification of foodstuff and food primary production, designed in developed economies as a market mechanism, has become an instrument of state control in Ukraine. The system carries out the certification almost exclusively through monopolized structures (the Centers of Standardization, Metrology and Certification of Derzspozivstandard).

Current Regulation

Current Ukrainian legislation contains obligatory provisions for food business operators to certify their products:

- Ukrainian Law on Consumer Rights Protection No 3161-IV from December 1, 2005;
- Ukrainian Law on Ensuring the Sanitary and Epidemiological Welfare of the Population No 4004-XII from February 24, 1994;
- Decree of Cabinet of Ministers of Ukraine on Standardization and Certification No 46-93 from May 10, 1993;
- Derzspozivstandard Order No28 from February 1, 2005.

Relevant WTO and Codex Alimentarius Commission (CAC) Provisions

Working Party Report on the Accession of Ukraine to the World Trade Organization. WT/ACC/Ukr/152. January 25, 2008

Paragraph 313.

"The representative of Ukraine confirmed that Article 5 of the Law on Safety and Quality of Food Products clearly gave the veterinary service and the sanitary service authority over all imported food products and specified that these products were subject to veterinary and/or sanitary examination by these two authorities. Further, he again confirmed that the State Standards Committee was not authorized to impose mandatory requirements on the import of food and agricultural products, and that the State Standards Committee would not regulate the import of such products from WTO Members or require imports to comply with voluntary standards from the date of accession. He further confirmed that, nevertheless, the Ukraine Derzspozhivstandart would adopt an Order, effective by the date of accession, removing any authority for the State Standards Committee to require testing or certification of any imported food product. As a result, imported food products would be subject to testing and certification only by the sanitary service or veterinary service, as appropriate".

Measures Required

1. Delete provisions regarding mandatory certification of food in the listed laws of Ukraine and Government Decree.
2. Eliminate the part of the Derzspozivstandard Order which establishes the list of food products subject to mandatory certification.
3. Avoid different approaches regarding standards between domestic and imported products.

3 Move Away from Obsolete Mandatory Standards and Harmonize Regulations According to WTO Commitments

Problem Statement

The present compendium of standards is a mixture of technical prescriptions, quality parameters, and safety standards. These standards are mandatory documents by which characteristics of products become subject to the system of regulatory control. This is in direct contradiction with the principles and definitions of the WTO TBT Agreement which clearly distinguishes between technical regulations and standards, and also Ukrainian WTO obligations.

Current Regulation

1. Ukrainian Law on Safety and Quality of Food Products No 2809-IV from September 6, 2005 gives the definition of a standard as a document whose provisions are mandatory.
2. Final provisions of the Ukrainian Law on Standardization No 2408-III from May 17, 2001 determine that: "requirements of state and other standards, which are mandatory for fulfillment, are in force until adoption of technical regulations and other normative acts, that regulate these issues".

Relevant WTO and Codex Alimentarius Commission (CAC) Provisions

Working Party Report on the Accession of Ukraine to the World Trade Organization. WT/ACC/Ukr/152. January 25, 2008

Paragraph 299.

"The representative of Ukraine confirmed that from the date of accession, all existing national and regional standards would be voluntary, except those referred to or set out in technical regulations intended inter alia to protect national security interests, prevent deceptive practices, protect the life and health of people, animals or plants, as well as protect the environment".

Measures Required

As part of the WTO accession process and plans of integration into the EU, Ukraine will have to fulfill a major commitment under the TBT Agreement to move from a system of mandatory standards to a system of mandatory technical regulations and voluntary standards, and to harmonize its SPS measures with international and EU standards.

This should be done through:

- rigorous observance of Paragraph 299 of the "Working Party Report on the Accession of Ukraine to the World Trade Organization. WT/ACC/Ukr/152. January 25, 2008";
- removal of food from the final provisions of Ukrainian Law on Standardization No 2408-III from May 17, 2001 – since the Ukrainian Law on Safety and Quality of Food Products No 2809-IV from September 6, 2005 regulates issues concerning implementation of standards for food;
- elimination of divergence between terms "standard" in the Ukrainian Law on Safety and Quality of Food Products and definition of this term in accordance with the WTO TBT Agreement.

4 Harmonize Regulations on “Novel” Food with the Provisions of the Ukrainian Law on Food Safety and Quality of Food Products

Problem Statement

In spite of the relatively clear definition of term “novel food” given by the Ukrainian Law on Safety and Quality of Food Products, the Ministry of Health Care carries out state sanitary and epidemiological expertise of all new foodstuffs independently of whether these products are novel or new.

This practice not only contradicts the provisions of the above law, but also creates unnecessary trade barriers. Indeed all food operators should pass state sanitary and epidemiological expertise for a new foodstuff which is made using ingredients having a history of safe use and with application of production processes which also have a history of safe use.

Current Regulation

1. Ukrainian Law on Safety and Quality of Food Products No 2809-IV from September 6, 2005 provides an exhaustive list of the types of food products that are subject to state sanitary and epidemiological expertise:
 - novel food;
 - food for special dietary purposes, functional food, food supplements, food additives, flavourings.
2. Order of Ministry of Health Care on Approval of Temporal Order for Conducting State Sanitary And Epidemiological Expertise No 247 from October 9, 2000 .

Relevant WTO and Codex Alimentarius Commission (CAC) Provisions

SPS Agreement. Article 2. Basic Rights And Obligations

Paragraph 2.

“Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal, or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.”

Measures Required

To amend the Order of Ministry of Health Care on Approval of Temporal Order for Conducting State Sanitary And Epidemiological Expertise No 247 from October 9, 2000 . The aim of these amendments is to bring this Order in conformity with Ukrainian Law on Safety and Quality of Food Products No 2809-IV from September 6, 2009 that provides an exhaustive list of the types of food products that are subject to state sanitary and epidemiological expertise:

- novel food;
- food for special dietary purposes, functional food, food supplements, food additives, flavorings.

5 Harmonize Regulations on Permitted Food Additives, Flavorings, Levels of Contaminants, Pesticides, and Veterinary Drug and Pesticide Residues in Line with International Standards and WTO Commitments

Problem Statement

No updated lists of permitted food additives, flavorings, levels of contaminants, pesticides and veterinary drugs residues exist.

Current lists are out-dated (for example, the list of maximum levels of contaminants was approved almost 20 years ago). A list of approximately 300 permitted food additives exists but this list does not include limits and foodstuff where these additives can be used; therefore, it is impossible for food operators to use. A list of permitted flavouring substances also does not exist.

Current Regulation

1. Cabinet of Ministers of Ukraine Resolution on Approved List Of Food Additives That Are Permitted For Use In Foodstuffs No 12 from January 4, 1999.
2. Ministry of Health Care of USSR on Medical, Biological Requirements and Sanitary Norms of Quality of Foodstuffs And Primary Production No 5061-89 from August 1, 1989.

Relevant WTO and Codex Alimentarius Commission (CAC) Provisions

SPS Agreement. Annex C. Control, Inspection And Approval Procedures.

“Where an importing Member operates a system for the approval of the use of food additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs which prohibits or restricts access to its domestic markets for products based on the absence of an approval, the importing Member shall consider the use of a relevant international standard as the basis for access until a final determination is made”.

Measures Required

To approve an order of Ministry of Health Care which permits use of relevant international standards³⁵ as the basis for access to Ukrainian market until the following lists will be approved:

- permitted food additives with limits and foodstuff where these additives can be used;
- list of permitted flavouring substances;
- residue limits of pesticides;
- residue limits of veterinary drugs;
- maximum levels of toxins and other contaminants.

³⁵ These international standards include:

- (a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
- (b) for animal health and zoonosis, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;
- (c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention;
- (d) for food additives, the EU Community legislation on food additives consists of the following Regulations:
 - Regulation (EC) 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.
 - Regulation (EC) 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.



Annexes

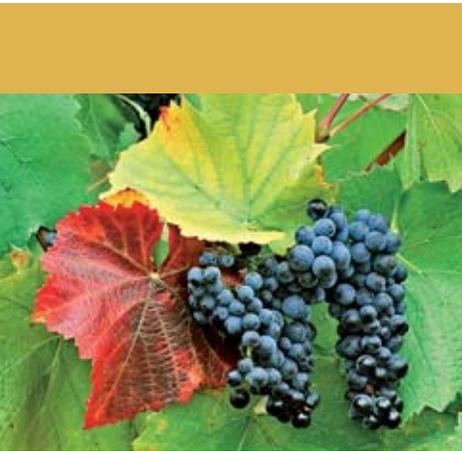
Annex 1. Principal Legislative Acts Regulating Ukrainian Food Industry

- The Ukrainian Law on Quality and Safety of Food Products №771/97-BP from December 23, 1997 as amended by Ukrainian Law on Changing the Law of Ukraine on the Safety and Quality of Food Products No 2809-IV on September 6, 2005,
- The Ukrainian Law on Ensuring Sanitary and Epidemic Safety of the Population №4004-XII from February 24, 1994
- The Ukrainian Law on Milk and Milk Products № 1870-IV from June 24, 2004
- The Ukrainian Law on Child Nutrition №142-V from September 14, 2006
- The Ukrainian Law on Veterinary Medicine №2498-XII from June 25, 1992
- The Ukrainian Law on Plant Quarantine №3348-XII from June 30, 1993
- The Ukrainian Law on Seeds and Planting Materials №411-IV from December 26, 2002

- The Ukrainian Law on Protection of Rights for Plant Varieties №3116-XII from April 21, 1993
- The Ukrainian Law on Consumer Rights Protection №1023-XII from May 12, 1991 as amended by the Ukrainian Law on Consumer Rights Protection No 3161-IV from December 1, 2005
- The Ukrainian Law on Standardization №2408-III from May 17, 2001
- The Ukrainian Law on Conformity Assessment №2406-III from May 17, 2001
- The Ukrainian Law on Accreditation of Bodies of Conformity Assessment №2407-III from May 17, 2001
- The Ukrainian Law on Pesticides and Agrochemicals №87\95-BP from March 2, 1995
- Decree of Cabinet of Ministers of Ukraine on Standardization and Certification №46 from May 10, 1993
- The Ukrainian Law on Regulation of Imports of Agricultural Products №468\97-BP from July 17, 1997
- Order of Governmental Committee on Standardization and Certification on Rules of Obligatory Foodstuff Certification №333 from June 2, 1997
- Resolution of The Ukrainian Parliament on Main aspects of National Policy of Ukraine for the Environmental Protection and Usage of Natural Resources No. 188/98-BP from March 5, 1998.

Annex 2: Comparative Analysis of Ukrainian Food Safety Legislation and EU Legislation

This annex provides a comparative legal analysis of the Law on Quality and Safety of Foodstuffs from December 23, 1997³⁶, a central piece of Ukrainian legislation on food safety, with the EU legislation³⁷ on the subject to provide an overview of the main gaps and challenges in the process of harmonization. In this respect, it is important to point to the following critical issues:



1. Inconsistent and unclear legal text within different pieces of Ukrainian legislation, and between Ukraine and the EU framework and national legislations. For example, the terms “unsafe”, “dangerous”, or “low quality” and “hazard” are used in different pieces of Ukrainian legislation, presumably interchangeably. In addition, multiple references to “quality” in Ukrainian legislation (70 mentions in the Law on Quality and Safety of Foodstuffs alone), in light of international best practices which regard quality standards as optional, will pose problems for participation in international trade.
2. Despite adopting the EU’s food safety framework, Ukraine has not included certain essential elements. Four critical items that are lacking:
 - harmonization of secondary regulations to the principle of transfer of primary responsibility for food safety to the food business operator (in spite of the amendments to the Law on Quality and Safety of Foodstuffs of 2005),
 - a risk-based approach to food safety controls,
 - meaningful reference to traceability, and
 - clear civil and penal liability for producers of unsafe products.

In addition, even if these items were adopted into domestic legislation, the proper implementation of traceability in food processing would require substantial financial and human resources. In addition, it will be a challenge to “change the mindset” of both state officials and businesses to accept the concept of transferring responsibility for food safety from the state to businesses, in spite of the amendments to the the Law on Quality and Safety of Foodstuffs adopted in 2005 that point in this direction.

³⁶ Amended by the Ukrainian Law on Changing the Law of Ukraine on Safety and Quality of Food Products No 2809-IV from September 6, 2005.

³⁷ Key EU legislation include the following:

- Regulation (EC) No 178/2002: general food law, EFSA
- Regulation (EC) No 882/2004: official controls
- Regulation (EC) No 852/2004: the hygiene of foodstuffs
- Regulation (EC) No 853/2004: the hygiene of foods of animal origin
- Regulation (EC) No 854/2004: official controls on products of animal origin
- Regulation (EC) No 1881/2006: maximum levels for contaminants in foodstuffs
- Regulation (EEC) No 2377/90: maximum residue levels (MRLs) for veterinary medicines
- Directive 96/22/EC: prohibition on certain substances
- Directive 96/23/EC: monitoring of substances and residues
- Directive 91/414/EC: pesticides
- Regulation (EC) No 396/2005: MRLs for pesticides
- Regulation (EC) No 258/97: novel food
- Regulation (EC) No 1333/2008: food additives
- Directive 2000/13/EC: labeling of food

3. Legislation mandates for the duplication of controls and inspections by different regulatory authorities on the same product specifications at different stages of the production process.

In general, compared to the sector-focused legislation and multiple agencies with overlapping functions in Ukraine, the EU approach to food safety control is risk-based³⁸ and employs mainly general “horizontal” legislation covering common aspects of foodstuffs, such as additives, labeling and hygiene, as well as some “vertical” legislation, where necessary, applicable only to specific products, such as cocoa and chocolate products, sugars, honey, fruit juices, and fruit jams. This scheme regulates and prescribes norms only so far as necessary for safety, making it more cost effective and business-friendly than Ukrainian legislation. In addition, in the EU, a producer is given the primary responsibility for safety, using tools such as traceability and HACCP. The producer has the flexibility to design a process to control and check quality and safety within the framework of the legislation that is effective for the particular business and promotes safe output³⁹.

Main principles of EU food legislation

- Integral approach “from farm to fork”
- Traceability of feed, animals and food
- Application the methodology of risk analysis (includes risk assessment, risk communication and risk management)
- Application of the precautionary principle, if justified
- Integrated system of control or one government institution responsible for organization of control over legislation fulfillment under “farm to fork” principle”

In contrast, Ukrainian regulations are focused on compliance with the *de facto* mandatory standards (state standards of Ukraine) rather than product safety. The respective characteristics above are seen throughout EU and Ukrainian legislation, and can be generalized as follows:

EU MODEL	UKRAINIAN MODEL	COMMENTS
Mostly goal and end-product oriented	Requirements for premises and equipment	The quality and safety of the end product is ensured through prescriptive process requirements
Flexibility in process design	Prescriptive requirements	Without flexibility in process, innovation and advances in technology cannot be introduced efficiently.
Risk-based food safety requirements Focus of control is over final output	Food safety is an expected indirect outcome achieved through following the detailed norms	In reality, the norms may not achieve food safety, and certainly do not do it efficiently.
Traceability	Lack of traceability	Overlapping functions and lack of inter-agency coordination make traceability difficult to implement

³⁸ EU law uses risk analysis to balance efficiency while protecting human life, health and consumer interests, including fair practices in food trade, protection of animal health and welfare, plant health and the environment.

³⁹ Recent legislation is introducing compulsory food safety management procedures, which underscores the importance of systems like HACCP

Furthermore, a more detailed comparative legal analysis between the two food safety legislations points to the following key differences:

Ukrainian Legislation and implementation practice	EU Legislation and implementation practice
<p>1 No organizational and financial foundation for conducting thorough research in the field of food safety and nutrition in place.</p>	<p>The legislative background is created for ensuring scientifically proven information for decision-makers in the sphere of food legislation.</p>
<p>2 Ukrainian food law is by nature using the principle of “presumption of guilt”, granting the state controlling institutions the authority to decide whether a specific enterprise has violated the norms and apply penalties or another type of sanctions.</p>	<p>Norms are stipulated with the objective of balancing the need for consumer protection and for maintaining a business friendly regulatory environment. Example: the principle of due diligence, which is used in the legislation of the Great Britain. According to this principle the operator could be freed from the responsibility if s/he can prove that s/he did everything that s/he could to fulfill what the law prescribes.</p>
<p>3 No clear division of authority between the controlling institutions. No unified food controlling body or integrated food control system established.</p> <p>There are no clear mechanisms or principles to manage coordination among the various regulatory bodies at the national level.</p>	<p>EU member states are in the process of creating or have already created either single controlling bodies or integrated control systems over the whole product chain in accordance to the “farm to fork” principle, starting from field and finishing on the stage of retail trade.</p> <p>EU Regulation #882/2004 of European Parliament and Councils issued April 29, 2004 stipulates clear principles and mechanisms of national food products control system.</p>
<p>4 The number of administrative services (which businesses are required to obtain in order to comply with the law and inspections requirements) is constantly increasing.</p>	<p>As a rule, operators pay themselves only for those types of administrative services which are not related to the vast majority of operators on the food market. For example for executing additional measures of official control in the case of legislative violations found while performing routine official controlling procedure.</p>
<p>5 There is no systemic or transparent mechanism to assess the impact and/or revise the food safety law/s in Ukrainian legislation.</p>	<p>There is a legislative foundation for the systemic review of food safety legislation, also through broad-based consultation.</p>

Ukrainian Legislation and implementation practice	EU Legislation and implementation practice
<p>6 Normative documentation has to be approved for any sort of product which is to be produced in a series.</p>	<p>Approval of normative documents and the permit obtained for placement on the market the product which could be qualified as “novel”.</p> <p>In the EU not more than several dozens of “novel” products are registered annually.</p>
<p>7 Periodical mandatory certification (and re-certification) of products.</p>	<p>Certification is used almost exclusively for the purpose of export-import operations (only if this is required by the importing country).</p>
<p>8 Veterinary certification is required for all types of products of animal origin (including processed types previously inspected).</p>	<p>Mandatory inspection of all live animals before slaughter and of carcasses after slaughter. The veterinary document is normally not required for processed products for internal market.</p>
<p>9 Each ingredient/part of a product should be accompanied by all certifications and mandatory documents. This entails an exponential increase of administrative documents that need to be produced at the various stages of the value chain.</p>	<p>For EU internal market transactions there is no duplication of documentation along the various stages of the value chain. In some cases paper documents are not required at all.</p>
<p>10 The controlling function is performed by two or, in the case of products of an animal origin, three controlling bodies which check the same product requirements.</p>	<p>The official control of a specific business operator is performed usually by one controlling body. In some cases, other controlling bodies are involved for different and non-overlapping legal requirements.</p>
<p>11 There is no national plan of controls of food safety with annual reporting by public authorities.</p>	<p>National plan of control of food safety is formulated by controlling body/bodies and it is accompanied by annual report on performance.</p>
<p>12 Only a limited number of testing laboratories operate according to the ISO 17025 standard, although Ukraine adopted a state standard which is equivalent to the ISO 17025 standard.</p>	<p>All testing laboratories that perform testing for official control purposes should comply with the ISO 17025 standard.</p>

Annex 3: General Functions of Controlling Bodies for Safety and Quality of Food and Foodstuffs

Type of economic activity or place of its fulfillment	Ministry of Health Care (SES) ³⁹	Ministry of Agrarian Policy (Vet) ⁴⁰	State Committee on Technical Regulations and Consumer Policy (DSSU) bodies ⁴¹
1. Import			
• Unprocessed food products of animal origin		+	+ (Certification)
• Food products	+	+	+ (Certification)
• Plant products		+	+ (Certification)
2. Development of new products			
• Food products of non-animal origin	+ (sanitary - hygiene expertise and documentation validation)		+ approval of documentation
• Food products of animal origin	+ (sanitary - hygiene expertise and documentation validation)	+	+ approval of documentation
3. Processing			
• Unprocessed food products of animal origin		+	+ (Certification and inspections)
• Food products	+	+	+ (Certification and inspections)
• Plant products	+	+	+ (Certification and inspections)
4. Wholesale and storage			
			Inspections
• Unprocessed food products of animal origin		+	+
• Food products	+	+	+
• Plant products	+	+	+
5. Retail trade and public catering			
			Consumer protection
• Unprocessed food products of animal origin		+	+
• Food products	+	+	+
• Plant products	+	+	+
6. Agro industrial markets			
			Consumer protection (except for control for natural persons)
• Unprocessed food products of animal origin		+	+
• Food products	+	+	+
• Plant products		+	+

⁴⁰ In accordance with the Ukrainian Law on Safety and Quality of Food Product №771/97-BP from December 23, 1997, as amended by the Ukrainian Law on Changing the Law of Ukraine on Safety and Quality of Food Products No 2809-IV from September 6, 2005.

⁴¹ In accordance to the Order of Ministry of Agrarian Policy №310 from May 8, 2007 and Ukrainian Law on Quality and Safety of Foodstuffs №771/97-BP from December 23, 1997, as amended by the Ukrainian Law on Changing the Law of Ukraine on Safety and Quality of Food Products No 2809-IV from September 6, 2005.

⁴² In accordance to the Decree of KМУ «On a state supervision after observance of standards, norms and rules ta responsibility for their violation», adopted April of 8, 1993 №30-93, " Statute on the State Committee of Ukraine is on questions of the technical adjusting and consumer policy", adopted Decree of President №225/2003 of 18 March 2003

Annex 4. Institutional Structure of State Regulators in Food Industry of Ukraine

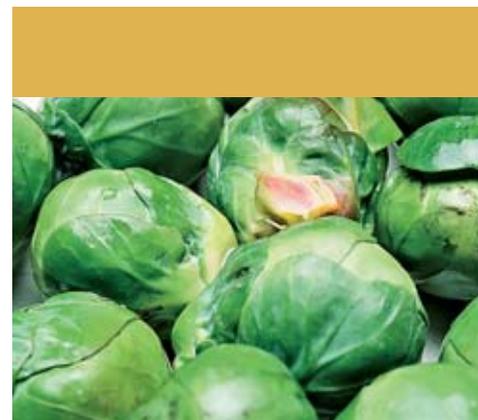
1. MINISTRY OF HEALTH CARE OF UKRAINE

- The Ministry of Health Care of Ukraine (MHC) is the primary executive body responsible for protecting public health. The State Sanitary and Epidemiological Service (SES) under MHC is in particular responsible for the state control over the following food products and facilities of their manufacture and/or circulation:
 - all food products for special dietetic consumption;
 - all functional food products; and
 - all food products, except (i) unprocessed food products of animal origin at the facilities of their manufacture; and (ii) all plant products, agricultural produce and unprocessed food products of animal origin sold on the agricultural food markets, which is supervised by the State Committee of Veterinary Medicine (Veterinary Service) under Ministry of Agrarian Policy of Ukraine.
- Issue operation permits for facilities engaged in the manufacture of food products under its control and for facilities engaged in introducing food products into circulation and keep registers of such operation permits.
- Exercise standard and extensive sanitary border control over imported or exported shipments of food products under the control of the sanitary service;
- Conduct sanitary-epidemiological surveillance: identification of hazardous foods, identification and tracking of causes of food borne diseases, and the development of early warning systems for outbreaks and food contamination.
- Take measures to eliminate violations of the law and to bring to responsibility those guilty of such violations.

In addition, the main Food Law⁴³ has introduced provisions for sanitary and veterinary inspectors to implement and exercise state supervision over the introduction of HACCP-based systems by food manufacturers. This provision represents, in principle, an important change in the role of the state and private sector in ensuring food safety, and clearly aims to model the provisions of Regulation (EC) No 178/2002⁴⁴. However, a move from the current inspection model based primarily on end-

⁴³ The Ukrainian Law on Safety and Quality of Food Product №771/97-BP from December 23, 1997, as amended by the Ukrainian Law on Changing the Law of Ukraine on Safety and Quality of Food Products No 2809-IV from September 6, 2005;

⁴⁴ While the New Food Law includes a number of definitions and provisions that are clearly modeled on some of the definitions and provisions in the EC Food and Feed Law, it omits in the rational, definitions, and other key terms, objectives and provisions that are necessary to achieve a close alignment with the EC Food and Feed Law. Regulation (EC) No 178/2002, Paragraph 19 clearly states the intention of the legislation with regard to the primary responsibility of food business operators regarding food safety: "A food business operator is best placed to devise a safe system for supplying food and ensuring that the food it supplies is safe; thus, it should have primary legal responsibility for ensuring food safety". Article 17 then enforces this by clearly delineating this responsibility: "Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met". The inclusion of this legal requirement of food business operators in the framework legislation constitutes a significant change in the intention of EC Food and Feed Law. It now confers a joint responsibility for ensuring food safety on the food business operators (through the design and implementation of HACCP) and the state authorities (through the enforcement of controls). Prior to this, in some EU countries, the state control authorities had the primary responsibility for ensuring food safety. This change in intention is not reflected in the New Food Law and arguably this requirement is an ineluctable feature of EC Food and Feed Law.



product testing towards a more audit-based approach raises a number of concerns given the lack of awareness of HACCP principles in the country, both among officials and private sector.

The MHC employs about 60,000 people nationwide of which about 10,000 employees work in labs. The SES food inspectors are sanitary doctors and have a background in medicine (they do not follow the full medical curriculum, but have some medical knowledge along with training in technology of food production).

To perform its state monitoring function, the Sanitary Service has a total of 770 laboratories throughout Ukraine. The entire infrastructure consists of the following institutions:

- The Medved L.I. National Institute of Ecohygiene
- The Marzeev Institute of Hygiene, Academy of Medical Sciences of Ukraine
- The Central Sanitary and Epidemiology Station (SES)
- 25 oblast laboratories
- 475 rural SES
- 91 SES in the towns not divided into districts
- 81 district SES in the cities
- 14 SES in the cities with districts
- The Central SES for Water Transport
- 3 SES of basins
- 14 SES of ports
- The Central SES for Air Transport
- The Central SES for Railway Transport
- 6 SES at the railway stations
- 49 SES of the railway lines and
- 8 SES of specialized medical and sanitary units.

The present funding of laboratories comes from both budget allocations and revenues earned from testing food products for imports into Ukraine and, to a lesser extent, exports from Ukraine. Though the main Food Law partially delineates responsibilities for food safety control in the country, both the laboratories (Central and Oblast) of the Sanitary and Veterinary Services compete for the testing of imported food products (there is also competition from the DSSU food laboratories, the L.I. Medved Institute, Laboratory for Quality and Safety of Agricultural Products of the National Agricultural University of Ukraine (LQSAP) and private laboratories). Local governments can also mandate funding for laboratories and their improvement.

2. MINISTRY OF AGRARIAN POLICY OF UKRAINE

The Ministry of Agrarian Policy of Ukraine (MAP) is the principal governmental agency responsible for implementing the state agricultural policy, state governance in agricultural, horticultural, viticulture, food industry, fisheries and agricultural processing sectors (Regulations of the MAP of Ukraine, Presidential Decree of June 7, 2000 No 772/2000).

The State Committee of Veterinary Medicine of Ukraine

The mandate and responsibilities of the State Committee of Veterinary Medicine⁴⁵ of Ukraine (Veterinary Service) that operates under MAP, include:

Exercise state veterinary-sanitary control and supervision at the facilities for production of animals, unprocessed food products of animal origin and circulation of agricultural produce, and issue corresponding veterinary documents certifying their veterinary-sanitary condition;

Exercise state control over the manufacture and finished products at meat processing, fishing, fish processing and dairy enterprises that use unprocessed food products of animal origin as raw materials, and at enterprises of bulk storage of unprocessed food products of animal origin;

Exercise state supervision over the introduction of HACCP and identical systems of ensuring quality and safety used by manufactures of food products under the control of the veterinary service;

Issue operation permits for operators of facilities engaged in the manufacture of food products under the control of the veterinary sector and keep registers of such operation permits;

Issue international veterinary certificates for food products under the control of the veterinary service;

Exercise standard and extensive veterinary border control over imported, transit, and exported shipments of food products under the control of the veterinary service;

Conduct epizootic and, when necessary, take part in sanitary-epidemiological investigations to detect the causes and conditions resulting in the circulation of food products hazardous or unfit for consumption, the emergence and spread of infectious diseases through food products under the control of the veterinary service.

The Central State Laboratory of Veterinary Medicine (CSLVM) is the main executing laboratory of the Veterinary Service. CSLVM tests the quality and safety of food products of animal origin, vegetables and animal feed for over 360 parameters in more than 20 areas, such as: microbiology, chemo-toxicology, radiology, ichthyopathology, parasitology, etc.

⁴⁵ The State Committee of Veterinary Medicine has been established as an independent body by the Decree of the Cabinet of Ministers of Ukraine # 1075 of 30 August 2007. Previously, it was a department under the Ministry of Agrarian Policy according to the decree of the Cabinet of Ministers of Ukraine #1648 from 3 November 2000.

Comparative analysis of VET authority functions

In Ukraine	In EU countries
Veterinary certification is required for all types of products of animal origin (including processed types previously inspected).	The veterinary document is normally not required for processed products for internal market.
Each ingredient/part of a product should be accompanied by all certifications and mandatory documents. This entails an exponential increase of administrative documents that need to be produced at the various stages of the value chain.	For EU internal market transactions there is no duplication of documentation along the various stages of the value chain. In some cases paper-documents are not required at all.

State Plant Quarantine Service

The State Plant Quarantine Service⁴⁶ (SPQS), which operates under MAP authority, is responsible for the plant health measures related to production, movement and trade in plant-origin products. The SPQS operates 27 quarantine laboratories that conduct phytosanitary examinations of agricultural produce. Although Ukraine became a signatory to the International Plant Protection Convention (IPPC) in May 2006, the country had followed its obligations under the IPPC before signing the Convention. The List of regulated pests (Art. VII.2i) was provided to IPPC in January 2005. The SPQS constantly assesses phytosanitary risks in cooperation with the Ukrainian Academy of Agricultural Sciences and its research institutes.

3. STATE COMMITTEE OF UKRAINE FOR TECHNICAL REGULATION AND CONSUMER POLICY

The State Committee of Ukraine for Technical Regulation and Consumer Policy (DSSU) is the state authority that is responsible simultaneously for development and approval of standards, including food standards, issuing certificates, conducting inspections of producers, and ensuring market surveillance and protection of consumer rights⁴⁷.

This confusion of functions, including the bundling together in one agency of functions of a commercial nature (certification) with state supervision functions, combined with the fact that the same organization provides certification services and appoints other certification bodies, means that there are considerable sources of conflicts of interest and of excessively discretionary powers. Moreover, many of these functions overlap in respect to certain kinds of products with other government authorities, such as the Sanitary and Epidemiological Service, the State Committee for Veterinary Medicine, and others. This reduces the effectiveness of supervision by creating confusion and conflicting requirements, is inefficient from the perspective of allocation of scarce state resources, and creates an undue burden on businesses.

⁴⁶ According to the new Law of Ukraine 3369-IV "On Introduction of Changes to the Law of Ukraine on Plant Quarantine" of January 19, 2006 that was prepared and adopted in line with Ukraine's commitments under the SPS Agreement.

⁴⁷ According to Statute of the Committee, approved by Decree of the President of Ukraine, March 18, 2003 #225/2003, and further regulated by a range of laws.

To organize development of national standards and to conduct standardization activities in conformity with international practice, Ukraine became a member of ISO, IEC (the International Electrotechnical Commission), and OIML (the International Organization of Legal Metrology). In its WTO accession talks, Ukraine committed to use the Code of Good Practice of Development, Adoption and Application of Standards within the framework of the WTO TBT Agreement. On March 1, 2006, the Cabinet of Ministers of Ukraine adopted the State Program on Standardization for 2006-2010 by its Resolution # 229. The purpose of this Program was to assure development of the national standards system in compliance with the WTO TBT Agreement and harmonization with EU standardization system, but progress has been limited so far.

The DSSU system includes three research and scientific centres, 28 regional centres for standardization, metrology and certification, and 27 territorial departments for consumer rights protection. The Committee has a network of 107 accredited product certifying bodies and six accredited certifying bodies for quality management systems, as well as 780 testing laboratories throughout Ukraine.

4. MINISTRY OF ENVIRONMENTAL PROTECTION AND NATURAL RESOURCES OF UKRAINE

The Ministry of Environmental Protection and Natural Resources of Ukraine (MEPNR) through the State Ecological Inspection is responsible for radiological and environmental control. The environmental protection functions of national, regional and local agencies are set forth by the Resolution of The Ukrainian Parliament on Main aspects of National Policy of Ukraine for the Environmental Protection and Usage of Natural Resources No. 188/98-BP from March 5, 1998.

The Ministry must conduct environmental control at customs entry points in accordance with the Regulation of the Cabinet of Ministers of Ukraine on Ecological Control at Customs Border Entry Points of Ukraine from March 20, 1995

Environmental control is conducted in accordance with the MEPNR Decree on Ecological Control at Customs Border Entry Points and Within the Area of Responsibility of Customs Offices and Regional Customs Offices No 204 from September 8, 1999.

5. STATE CUSTOMS SERVICE OF UKRAINE

The State Customs Service of Ukraine is not a food safety regulatory agency. It has its own laboratory services division to control compliance of importers and exporters with Harmonized System (HS) Classification. The provisions on the State Customs Service of Ukraine were approved by the Presidential Decree of August 24, 2000 No 1022/2000 (amended). According to these provisions, the main tasks of the State Customs Service are: support of implementation of the state policy in the customs sector; protection of economic interests of Ukraine; control over adherence of the Ukrainian customs legislation; using means of tariff and non-tariff regulation.

Food and agricultural products can be imported or exported only through designated border points where appropriate control agencies have their officers. The Order of the Cabinet of Ministers of Ukraine No 365-r from June 16, 2003 approved the list of border crossing points for food and agricultural products.

6. NATIONAL COMMISSION OF UKRAINE FOR THE CODEX ALIMENTARIUS

The National Commission of Ukraine for the Codex Alimentarius (hereafter the Commission) was established in 1999 to fulfill coordinating functions in establishing of norms, regulations and standards in foodstuffs by their quality and safety indicators, as well as to support fulfillment of FAO/WHO membership commitments of Ukraine. The original Codex Commission, however, was not active. On July 3, 2006, the Cabinet of Ministers of Ukraine issued Resolution # 903 on Matters of the National Commission for the Codex Alimentarius of Ukraine in accordance with the Law on Quality and Safety of Foodstuffs. According to the regulations, the Commission must meet at least once every four months. Since its inception in July 2006, however, the Commission was conveyed very few times to discuss compliance of Ukraine's existing food safety standards with those of Codex Alimentarius and adoption of the appropriate national standards.

The main Food Law makes provisions for a more active and relevant role of the Commission in the national food safety system. Article 8 sets out its functions and responsibilities. Clause 4 outlines the tasks of the Commission which include a responsibility to provide scientific advice and technical support in the areas of risk assessment, risk analysis and risk management. This is similar to a key task of the European Food Safety Authority (EFSA) as outlined in Article 23 of Regulation (EC) 178/2002.

However despite legislative provisions and due to regulatory and budget constraints, the National Commission of Ukraine for the Codex Alimentarius needs to work through the existing food safety agencies to implement food safety standards, guidelines and codes of practices. Clauses 1 and 3 of the new Food Law stipulate the responsibility of the Commission to advise the Chief State Sanitary Doctor and the Chief State Veterinary Inspector on SPS measures. Clause 4 requires the Commission to coordinate the harmonization of Ukrainian SPS measures with international norms and standards and introduce new measures where necessary. These responsibilities are similar to the responsibilities of the food safety agencies in EU member states (except that in the EU these agencies are harmonizing EC Food and Feed Law with national food legislation). This clause is in close approximation to the EC legislation in this area in EU Food and Feed Law. Articles 6 and 7 stipulate that the sanitary service and the veterinary service should take part in the work of the Commission but there is no provision on the structure of the Commission or in regard to its governance structure. No wonder that in practice the Commission remains a weak institution.

7. NATIONAL ACCREDITATION AGENCY OF UKRAINE

The National Accreditation Agency of Ukraine (NAAU) is set to play a major role in ensuring that Ukraine's laboratories and certification agencies are recognized abroad by the EU and other countries. Accreditation is at the heart of the SPS infrastructure and is one step towards establishing internationally recognized facilities in Ukraine. NAAU is not a signatory of the European Cooperation for Accreditation Multilateral Agreement (EA MLA). This implies that certification, testing, and inspection of products by bodies accredited in Ukraine are not accepted abroad, requiring the re-examination of these goods by a foreign laboratory or certification body.

Moreover, Ukraine is not a member of the International Accreditation Forum (IAF) or a full member of the International Laboratory Accreditation Cooperation (ILAC – it became only Affiliate but not full member in September 2004), the two principal international organizations for accreditation. Membership in these organizations enhances an accreditation body's prospect for gaining international credibility. To join the IAF or ILAC, accreditation bodies must demonstrate

that they operate at high international standards in areas covering operations, quality management systems, personnel, and equipment.

To date, 351 organizations have been accredited by NAAU; testing laboratories account for most of these accreditations (272). Out of them, only 25 laboratories have been accredited by ISO/IEC 17025⁴⁸. Only two additional laboratories have been accredited by international accreditation bodies: CSVML accredited by DAP (Germany), and the DSSU Kyiv Laboratory by LATAK (Latvia). Ukraine has accredited fewer organizations than many of its neighbours; for example, there are 480 accredited labs in Poland⁴⁹.

8. FOOD SAFETY AUDIT PROVIDERS

Currently in Ukraine less than 2 percent of food industry enterprises are HACCP certified. This low percentage of HACCP certified businesses undermines the export potential of the food processing sector, and it is mostly attributable to supply-side bottlenecks as the quality of food safety audit service providers varies from local “expert” opinions to certification service providers in line with European Standards.

This also means that there is room for growth in the industry if supported with appropriate awareness-building campaigns targeting all stakeholders and proper legislative support which would include clear implementation mechanism.

Unfortunately, at present the infrastructure for HACCP implementation remains rather weak since there is a limited number of companies offering audit and the proficiency of domestic providers is often questionable.

All organizations that provide HACCP implementation and audit services in Ukraine can be divided into three groups:

1. prominent international companies (SGS, TUV etc.) that offer full-scale services including consulting, training, testing, risk management, inspections, and certification according to international standards, that is highly credible within the EU and other developed economies;
2. domestic consultants (about 15 firms): some of these companies are solid enough and have reportedly sufficient qualifications and experience, yet smaller local players offer similar consultancy in lesser scale as they may not properly understand food safety concepts, such as HACCP, and thus their services are inferior;
3. DSSU certification bodies, which offer HACCP in its own version adopted as DSTU 4661 national standard, sometimes using official status of the standard and various ways of influence producers as “competitive advantage” to other service providers. To date, 74 enterprises obtained HACCP certificates from the state bodies and 8 were certified by ISO 22000⁵⁰. The key problem of DSSU bodies is the lack of properly trained personnel and poor follow-up capacities to ensure HACCP is completely introduced and sustained.

⁴⁸ Source: official data from NAAU, <http://www.naa.u.org.ua> as of 12.03.2009

⁴⁹ Assessment of the Ukrainian quality infrastructure: challenges imposed by the WTO and commitments to EU accession. Frota, M.N., Racine, J.L., Blanc, F., Rodrigues, P., Ibragimov, S., Torkhov, D. & Osavolyuk, S. IFC. Kyiv, 2008

⁵⁰ Official information of DSSU, <http://www.dssu.gov.ua/document/123486/Станом090210.pdf>.

By the beginning of 2009, DSSU certification bodies have issued 1353 certificates for quality management systems according to ISO 9001, ISO 14001, ISO 18001, ISO 22000 and “integrated quality systems,” whereas overall 2,453 Ukrainian enterprises have been certified by these international standards (including those who used services of independent certifiers) – still an extremely small number, one of the lowest rates across the region.

Official information of DSSU, <http://www.dssu.gov.ua/document/123486/Станом090210.pdf>.

9. TESTING LABORATORIES

There are many (about 2,600) official food testing laboratories in Ukraine, but their overall effectiveness and credibility is low as they are poorly equipped and staffed with under-qualified personnel in the majority of cases. As a consequence, laboratory testing of food products has become in some cases just a nominal mandatory procedure to obtain the necessary documentation to state that a product is safe without any actual testing of the product. This also implies that the majority of Ukrainian testing laboratories are not internationally recognized by trading partners and entrepreneurs willing to export have to test their products again in the importing country (which doubles the administrative burden of exporting).

Currently, around 2,600 laboratories are authorized to do testing for the purpose of government control in Ukraine. The jurisdiction split is shown in the table below:

State committee of veterinary medicine of Ukraine	Ministry of Health Care of Ukraine	Plant Quarantine service of the Ministry of Agrarian Policy National Accreditation Agency of Ukraine	DSSU
<ul style="list-style-type: none"> • Central laboratory of veterinary medicine • 25 oblast laboratories of veterinary medicine • 2 city laboratories in Kyiv and Sevastopol • 425 regional laboratories • 1347 laboratories on agro markets 	<ul style="list-style-type: none"> • Laboratory of the Medved L.I. National Institute of Ecohygiene • Central SES in Kyiv • 472 rural laboratories • 91 city laboratories • 81 region laboratories • Laboratory for Water Transport • 3 laboratories of basins • 14 port laboratories • Central SES for Air Transport • Central SES for Railway Transport • 6 SES at the railway stations • 49 SES of the railway lines 	27 laboratories	35 laboratories

All the laboratories listed in the box above are engaged in the control measures performed by the Ministry of Agrarian Policy, Ministry of Health Care, State Committee of Veterinary Medicine and DSSU. This unfortunately leads to a duplication of the testing procedures by the very same laboratories which in most of the cases repeat the same test for all the different ministries/agencies to which they are accountable.

Interestingly, the total number of official laboratories in Ukraine is in excess to EU countries. For instance in Great Britain there are approximately 160 official laboratories⁵¹ for 60 million people, in Ukraine there are over 2,600 for less than 50 million people. More importantly, according to the data on the official web-site of National agency of accreditation of Ukraine (<http://www.naaau.org.ua>), out of the total number of laboratories only 38 are accredited in accordance to ISO 17025 (as of October 12, 2007) which constitutes only 1.5 percent of the total number. At the same time, in accordance with EU Regulation #882/2004 issued April 29, 2004 on official control, only accredited under ISO 17025 or analogous laboratories are eligible to do official testing for controlling purposes. As a result, scarce resources are spread throughout at least 10 times as many laboratories, while the number of laboratories which are compliant with modern requirements is far too small.

This cursory overview of the food testing infrastructure in Ukraine suggests that the need for reorganization of the laboratory network is evident. Unfortunately, it is currently prevented by the following factors:

1. Impossibility to properly fund the upgrading of all laboratories either from the state budget or from other sources;
2. As a consequence of the first point, impossibility to supply all the laboratories with necessary equipment and qualified personnel (which affects results of testing and credibility);
3. Lack of planning and coordination at the national level, and funding the upgrading of the laboratories is the responsibility of each separate ministry/agency that controls them. This also makes it almost impossible to enforce consistent practices and principles of food safety control techniques within such scattered and financially uncoordinated system;

Increasing network efficiency, reducing the sheer number of testing laboratories, and increasing the specialization of laboratories are three of the priorities of the needed reorganization of the food safety testing infrastructure in Ukraine.

⁵¹ More detailed information could be obtained at (<http://www.food.gov.uk/enforcement/foodsampling/foodcontrollabs>, <http://www.defra.gov.uk/corporate/vla/aboutus/locations.htm>).

Annex 5. WTO Commitments: Issues of Non-Compliance in Ukraine

THE SANITARY AND PHYTOSANITARY MEASURES (SPS) AGREEMENT

Commitments undertaken in the framework of the SPS Agreement

- Paragraph №313 Of the WP Report (1): "... the Ukraine Derzhspozhivstandart would adopt an Order, effective by the date of accession, removing any authority for the State Standards Committee to require testing or certification of any imported food product. As a result, imported food products would be subject to testing and certification only by the sanitary service or veterinary service, as appropriate."
- Paragraph №325 Of the WP Report (1): "Measures offering higher protection than the Codex would be replaced by Codex standards, or a risk assessment would be undertaken to justify them. Measures that existed in Ukraine but were not in the Codex would be eliminated, or a risk assessment would be undertaken to justify them.";
- Paragraph №327 Of the WP Report (1): "Ukraine would apply all its sanitary and phytosanitary measures in conformity with the requirements of the WTO Agreement, including the Agreements on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and Import Licensing Procedures, without recourse to any transitional arrangements."

The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) sets out the basic rules for food safety and animal and plant health standards and is the main legally binding act in this sphere for WTO members.

Paragraph 2 of Article 2 of the Agreement stipulates, that: "Members shall ensure that any sanitary and phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence..."

One of the key international documents of SPS agreement is the **Codex Alimentarius**, a series of food standards and related texts created jointly by FAO and WHO regulating the following topics: food standards for commodities; codes of hygienic or technological practice; use of pesticides; limits for pesticide residues; guidelines for contaminants; food additives evaluated; and use of veterinary drugs.

Ukraine joined FAO in 2003 and Codex Alimentarius Commission in 2004. The **National Commission on the Codex Alimentarius** (see section 4.1.6.) was established in 1999 (on a voluntary basis), with the mandate of playing a coordinating role in the area of norm setting, regulation and standardization of foodstuffs according to clear quality and safety indicators, as well as monitoring of compliance with FAO/WHO membership commitments of Ukraine.

While in advanced economies this type of Commission constitutes the public-private dialogue platform where private business and state authorities jointly set standards, unfortunately so far the Ukrainian National Commission on the Codex Alimentarius has not been able to play this role.



A cursory overview of the other institutions engaged on SPS issues shows that the Ministries of Health Care and Foreign Affairs have been included into the list of the central executive authorities responsible for compliance with the commitments resulting from Ukraine's membership in international organizations, by the Resolution of the Cabinet of Ministers of Ukraine (CMU) No.1145 of 24 July 2003. These ministries are responsible for the fulfillment of the commitments of Ukraine related to the Codex Alimentarius Commission membership. At the same time, the Ministry of Agricultural Policy and State Committee for Technical Regulation and Consumer Policy have an overlapping competence on some of the key issues under the mandate of the Commission and this raises some concerns over ongoing and potential conflicts between the different institutions. Overcoming such conflicts of competence and ensuring Ukraine's effective membership in the Codex Alimentarius Commission will bring the country closer to international standards of food safety.

TECHNICAL BARRIERS TO TRADE AGREEMENT (TBT)

Commitments undertaken in the framework of the TBT Agreement

Paragraph №299 Of the WP Report (1): "...from the date of accession, all existing national and regional standards would be voluntary, except those referred to or set out in technical regulations intended inter alia to protect national security interests, prevent deceptive practices, protect the life and health of people, animals or plants, as well as protect the environment. Ukraine shall ensure that by 30 December 2011, all of its technical regulations use relevant international standards as a basis".

Paragraph №300 Of the WP Report (1): "notwithstanding the timetable outlined in document WT/ACC/UKR/129, Ukraine would comply with all provisions of the TBT Agreement and would abide by the provisions of the Code of Good Practice for the Preparation, Adoption and Application of Standards (i.e., Annex 3 to the TBT Agreement) as of the date of accession without recourse to any transitional arrangements".

Paragraph №301 Of the WP Report (1): "that from the date of accession, Ukraine would not use standards, technical regulations or conformity assessment procedures in a manner that would be restrictive to international trade, prohibitive to imports, and discriminatory of individual exporters and suppliers, and that Ukraine would ensure that standards and technical regulations apply equally and in a non-discriminatory fashion to domestic products and to products imported from WTO Members, CIS countries and non-CIS countries alike. In addition, from the date of accession, Ukraine would prepare, adopt, and apply standards and technical regulations only in conformity with the TBT Agreement."

WTO Members are obliged to comply with the provisions of the **Code of Good Practice for the Preparation, Adoption and Application of Standards**⁵², even when their national standardization bodies have not accepted such provisions. This is not the case in Ukraine where DSSU (Derzhspozhivstandard) continues to enforce product standards not in line with the Code of Good Practice.

⁵² Article 4 of the Agreement reads: "The obligations of Members with respect to compliance of standardizing bodies with the provisions of the Code of Good Practice shall apply irrespective of whether or not a standardizing body has accepted the Code of Good Practice".

Annex 3 of the Agreement (**Code of Good Practice**) stipulates that “where international standards exist or their completion is imminent, the standardizing body shall use them, or the relevant parts of them, as a basis for the standards it develops...”.

Despite the provision of paragraph I of the Code “*Wherever appropriate, the standardizing body shall specify standards based on product requirements in terms of performance rather than design or descriptive characteristics*”, Ukraine continues to require mandatory certification for a number of lower risk products. This constitutes a violation of the WTO TBT Agreement principles of proportionality and restricts trade.

Other issues on certification in Ukraine that contradict the WTO TBT Agreement are the following:

- Onerous pre-market, third party certification, in areas generally not subject to such procedures (i.e. foodstuffs), combined with an under-developed post-market surveillance system, and model of individual importer approval, which is used instead of product-type approval, with no possibility of granting an approval for the whole life-span of a product, result in long time delays and unnecessary costs for companies.
- Ukrainian certification procedures often lack transparency and the fees requested for conformity assessment are not always proportional to the services rendered⁵³.
- An important component of the TBT Agreement is the obligation to provide public information about the standards being developed and regulations being introduced. This should compel public authorities to inform the public about the introduction of a new obligation and to allow time for discussion among interested stakeholders⁵⁴. Unfortunately this practice is mostly disregarded in Ukraine, with the exception of DSSU that publishes standards under development and already developed standards on its website.
- A key institutional problem is the fact that there is an obvious concentration of all regulatory functions (standardization, metrology, conformity assessment, market-surveillance, consumer rights protection) in one regulatory body – DSSU. This concentration is contrary to international good practice, which usually mandates a clear division of labor between the regulatory authority, which is the government institution responsible for development or adoption of regulations, and the executive regulatory authority, which is the government institution responsible for regulation enforcement. As a general principle, no single body can be responsible for risk assessment, risk management, and risk communication.

⁵³ This is in breach of GATT Agreement Article VIII, which states:

- 1.(a) All fees and charges of whatever character (other than import and export duties and other than taxes within the purview of Article III) imposed by contracting parties on or in connection with importation or exportation shall be limited in amount to the approximate cost of services rendered and shall not represent an indirect protection to domestic products or a taxation of imports or exports for fiscal purposes.
4. The provisions of this Article shall extend to fees, charges, formalities and requirements imposed by governmental authorities in connection with importation and exportation, including those relating to:
 - (f) documents, documentation and certification;
 - (g) analysis and inspection; and
 - (h) quarantine, sanitation and fumigation.

⁵⁴ Among others it is stated in the Article 10 of the Agreement “Information About Technical Regulations, Standards and Conformity Assessment Procedures”. Article applies to legislative or regulatory changes, which in Ukraine are often published very late.