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FINAL REPORT OF A MISSION
CARRIED OUT IN
UKRAINE
FROM 24 JUNE TO 04 JULY 2008
IN ORDER TO
EVALUATE THE ANIMAL AND PUBLIC HEALTH CONTROLS OVER THE
PRODUCTION AND PROCESSING OF DAIRY PRODUCTS INTENDED FOR
EXPORT TO THE EU

*Please note that factual errors in the draft report have been corrected in response to comments by the
Competent Authority.*

Executive Summary

The current mission was the first FVO mission to Ukraine to evaluate the official controls over the production and processing of dairy products intended for export to the EU.

The responsibility for official controls in milk is shared between the veterinary and public health authorities, with the latter responsible for coordination. The limits to their respective powers are somewhat unclear. In practice, there was little evidence of co-ordination with large areas of overlapping, leaving some areas uncontrolled. Official sampling and laboratory examination is extensive. There are frequent and documented visits by each competent authority (CA) separately and also joint inspections. The frequency of official controls by the CA for public health is risk-based and there is a permanent veterinary presence in the milk establishments. The quality of the official controls was in principle satisfactory, but varied between the regions. In some regions the official services did not identify serious structural or maintenance deficiencies present in the establishments visited and yet they identified most of them in other regions. Deadlines were set and follow up was in place.

The system is based on the national legislation and there are no specific procedures destined to meet EU requirements. This also includes the certification and approval of establishments, currently not in line with the provisions of Community legislation.

The establishments visited varied between satisfactory (very good structures, maintenance and equipment) and acceptable (old structures and equipment well maintained and being successfully replaced and refurbished). However, in three plants visited, a division in each of them was not acceptable (old structures requiring reconstruction and dilapidated equipment requiring replacement). The food business operators (FBO) in general understood their obligations in relation to food safety, and their own checks were largely satisfactory which were based on the national GOST methods and standards. The general deficiency noted by the mission team was a lack of proper and sufficient storage space for final products, ingredients and packaging material.

There are three different monitoring plans implemented for residues, including the National Residue Control Plan approved by the EU. Use of chloramphenicol and nitrofurans is forbidden in Ukraine since 2002 and action is taken in the case of positive results.

The official laboratories visited were all accredited, participated in ring tests, were properly staffed and their equipment was satisfactory.

The main shortcoming currently is the poor quality of raw milk (with only up to 10 % of milk fulfilling EC microbiological requirements), while the remaining milk had an average total bacterial count of around 300 000-400 000 (CFU/ml). Some establishments have separate production lines for the processing of different standards of milk, but the CA issued no instructions and no strategy was developed to ensure the proper supply of EU compliant milk.

The animal health situation is favourable for brucellosis, foot and mouth disease (FMD) and Rinderpest. In relation to tuberculosis (TB), the instructions for TB are not

completely in compliance with the relevant EU requirements, in particular, in not granting TB free status to herds. It currently cannot be concluded that only milk from officially free TB herds is used for the production of dairy products.

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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Abbreviation	Explanation
CA	Competent Authority
CAP	Chloramphenicol
CCA	Central Competent Authority
CFT	Complement Fixation Test
CIS	Commonwealth of Independent States
CSPHO	Chief Sanitary (Public Health) Officer – (Chief State Sanitary Physician of Ukraine)
CVO	Chief Veterinary Officer - Head of the State Committee of Veterinary Medicine of Ukraine
DSTU	State Standard of Ukraine (GOST based)
DVO/DSO	District Veterinary Office / District Sanitary Office (Sanitary Epidemiological Centre)
ELISA	Enzyme–Linked ImmunoSorbent Assay
EU	European Union
FBO	Food business Operator
FMD	Foot-and-Mouth Disease
FVO	Food and Veterinary Office
GOST	ГОСТ – Государственные Стандарты Technical State standards used in the CIS countries
HACCP	Hazard Analysis Critical Control Points
ISO	International Standardisation Organisation
LPBE	Liquid Phase Blocking ELISA
MCC	Milk Collection Centre (collecting milk from agricultural holdings and /or MCPs)
MCP	Milk Collection Point (collecting milk from household holdings)
MRL	Maximum Residue Limit
NRL	National Reference Laboratory
OIE	

Abbreviation	Explanation
	World Organisation for Animal Health
OV	Official Veterinarian
PCR	Polymerase Chain Reaction
PH	Public Health
RBT	Rose Bengal Test
RMP	Residue Monitoring Plan
RVO/RSO	Regional Veterinary Office/Regional Sanitary Office (Sanitary Epidemiological Centre)
SAT	Serum Agglutination Test
SCC	Somatic Cell Count
TB	Tuberculosis
TBC	Total Bacterial Count
uchastok	The smallest, local unit of the veterinary organisation in Ukraine. Several "uchastok" form a district.
VMP	Veterinary Medicinal Products
WHO	World Health Organisation
WTO	World Trade Organisation

1 INTRODUCTION

The mission took place in Ukraine from 24 June to 4 July 2008. The mission team comprised 4 FVO inspectors from the Food and Veterinary Office (FVO), divided into 2 sub-teams. The mission was undertaken as part of the FVO's planned mission programme. Both teams were accompanied throughout the mission by representatives of the Competent Authorities (CA). An opening meeting was held on 24 June 2008 with both Central Competent Authorities (CCA). At this meeting, the objectives of, and the itinerary for, the mission were confirmed by the inspection team and the action undertaken to develop exports from dairy sector in Ukraine, including the control systems, were described by the CCA.

2 OBJECTIVES OF THE MISSION

The objective of the mission was to evaluate the implementation of official animal and public health controls over the production and processing of dairy products destined for export to the EU, in the framework of Regulations (EC) No 852/2004, No 853/2004, No 854/2004, No 882/2004 of the European Parliament and of the Council and Commission Decision 2004/438/EC.

Competent authorities			Comments
Competent authorities (veterinary and public health)	Central	2	In Headquarters and Central Laboratories in Kiev
	Regional	6	Cerkasskaja, Sumskaja and Cernihovskaja regions
	Districts	6	In district offices, laboratories, and establishments visited
Laboratories			
Public Health laboratories		4	1 Central, 1 Regional and 2 District Public Health Laboratories
Veterinary laboratories		6	1 Central, 1 Regional and 4 District Veterinary Laboratories
<i>Food producing establishments</i>			
Dairy holdings		5	
Milk Collecting Centres / Points		2	
Milk processing plants		4	

3 LEGAL BASIS FOR THE MISSION

The mission was carried out under the general provisions of Community legislation and, in particular Article 46 of Regulation (EC) No 882/2004.

Legal acts quoted in this report are provided in Annex 1 and refer, where applicable, to the last amended version.

4 BACKGROUND

4.1 LIVESTOCK AND PRODUCTION INFORMATION

The livestock population and the number of small private cattle keepers in Ukraine are decreasing. In its reply to the pre-mission questionnaire, the Committee of Veterinary Medicine indicated, that the total number of adult dairy cattle fell from 9 108 000 in 2003 to 6 514 000 by 1 October 2006.

On 1 May 2008, about 1,9 million cattle were kept in “agricultural farms” and 4,1 million cattle in private holdings.

According to data provided to the mission team by the Agency for identification and registration of animals, there were more than 3 000 000 dairy cows registered in 2007, 2 400 000 of them kept in private holdings with 1 or 2 cows. Ukraine produced more than 12 million tonnes milk in 2007.

160 dairies in Ukraine are currently approved by the CCA for export. Dairy products are mainly exported to the Russian Federation and other Commonwealth of Independent States (CIS).

5 MAIN FINDINGS

5.1 LEGISLATION

Three main pieces of legislation are relevant for the scope of the current mission:

The Law of Ukraine on Food safety and quality of 6 IX 2005 No 2809-IV, as amended by 31 V 2007.

The Law of Ukraine on Veterinary Medicine (hereinafter referred to as "the Veterinary Law") of 16 XI 2006 no 3610 as amended by 31 V 2007.

The Law of Ukraine on the Epidemiological Safety of the Population of 24 II 1994 no 4004-XII as amended by 02 XI 2004.

The Law on Food safety and quality identifies the CAs – the Public Health (Sanitary) Service and the Veterinary Service, and describes their respective powers and scope of activity. The other two lay down the conditions for the activities of each of the CAs.

The Law on Food safety and quality also covers the controls along the whole chain of food production and supply; it is based on the principle of risk analysis, requires the FBO to implement the system of own checks based on the Hazard Analysis Critical Control Points (HACCP) principle and provides extensive powers to the official services.

According to the Law on Food safety and quality, the Ministry of Health is responsible for the coordination of other central authorities.

For Animal Health issues, the Veterinary Law lays down the principal conditions for the performance of the veterinary service.

In addition, a number of instructions and technical standards are relevant for the scope of

the mission, see sections 5.3 and 5.4.3.

5.2 COMPETENT AUTHORITIES PERFORMANCE

5.2.1 Organisation of competent authorities

According to national legislation (“Law on safety and quality of food products”) 2 authorities are currently sharing the competencies in the supervision of the milk chain.

The Ministry of Agricultural Policy with its State Committee of Veterinary Medicine (Veterinary Service) is the CCA for animal health of dairy livestock, quality controls of raw milk, its collection and transport, controls on import of raw materials and certification of foodstuffs intended for export. It is also in charge of the daily routine supervision and hygiene requirements for the safety of products in the dairy establishments.

The Ministry of Health with its State Sanitary and Epidemiological Service (hereinafter referred to as the Public Health Service) is the CCA competent for approval and supervision of all food establishments in Ukraine, including dairy sector, and controls over transport of raw milk. Both services have a centralised structure and similar organisation across the country with veterinary and public health executive organisations duplicated at each administrative level, from the centre to regions and districts.

The executive responsibility for the control of the dairy chain mainly rests with the 25 Regions (Oblast), the administrations in 2 cities (Kiev and Sevastopol) and the Autonomous Republic of Crimea. Each Oblast and the Autonomous Republic of Crimea is divided into several Districts (Raions). There are 448 districts in the country. Two main central laboratories are part of the network of the Veterinary Service as National Reference Laboratories (NRLs): the “State Research Institute of Laboratory Diagnostics and Veterinary Expertise” (furthermore The Central Veterinary Institute) in Kiev and the “State Scientific Research Control Institute of Veterinary Drugs and Feed Additives” in Lvov. One central laboratory, the “Institute of Eco-hygiene and Toxicology L.I. Medvev” in Kiev, acts as the NRL of the Public Health Service. Laboratories of both services are present at regional and district level.

Observations:

- Competencies of both Services are not clearly defined in the national legislation: Art. 5.3 of the "Law on Safety and quality of food products" is written in such a way, that it can be understood and that the responsibility of the Veterinary Service is limited to raw materials, in this case, to raw milk. However, Art. 34 states that the Veterinary Service is also in charge of the daily routine supervision and hygiene requirements for the safety of products in dairy establishments.
- No evidence of coordination between both Services was seen by the mission team at central level.
- In one region visited, an annual plan for joint inspections of food establishments (meat, milk and fish) was prepared by the regional Public Health Service. In the other region, no evidence of such a plan could be confirmed. Nevertheless reports

of joint inspections of the milk establishments were seen in all three regions visited.

- It was noted in the establishments visited that an overview of the hygiene conditions and structures was in general not in the reports of each authority, each of them presenting only part of the picture. In some cases essential points were not identified in any report.
- The teams produced a common report for joint inspections but recommendations and follow-up were separate. In the cases examined by the mission team, these reports did not reveal the full picture of the situation in the establishments concerned.

5.2.2 Legal/enforcement powers

According to national legislation (“the Law of Safety and quality of food products” – Art. 10 and 11) the CAs have the right to enter the premises, to take samples, to impose corrective actions within prescribed deadlines and to impose administrative and financial sanctions.

A report should be delivered to the FBO concerned.

Observations:

- There was evidence of financial sanctions imposed in one RVO visited.
- Documented evidence of follow-up of non-compliances including investigation on-the-spot, additional sampling, corrective actions prescribed (temporary closure of the premises if pathogens were detected) was presented at different levels.
- In particular, the mission team examined the action taken in case of detection of chloramphenicol (CAP) by the Central Veterinary Laboratory in the scope of the national residue monitoring plan. In such an event, urgent information was sent to the Regional Veterinary Office (RVO) and from the RVO to the District Veterinary Office (DVO) of origin; examination on the spot was carried out according to Order no 27 of 09 III 2004, with repeated sampling. The holding remained blocked until five consecutive samplings had negative results. In addition, an administrative procedure against the management of the farm was carried out.
- The mission team had no possibility to visit one Milk Collection Point (MCP), which had been selected at short notice. The CA explained that the MCP was open in the morning only and that the person responsible was absent and had the keys.

5.2.3 Supervision of the competent authorities and control systems

A programme of official controls is drafted each year by the Sanitary Service. The frequency is based on risk assessment, according to the Decision of the CVO of 14 II 2008 (high risk 4 times a year, medium risk twice a year, low risk once a year). This programme is updated every year on the basis of results of previous official controls and monitoring programmes, epidemiological parameters (incidence of food-borne diseases

and acute gastro-intestinal illnesses, etc) and possible emerging dangers following RASFF notifications.

The majority of products are classified as high risk in the milk sector.

The Veterinary Service prepares a yearly plan for official controls at every level.

In addition, both services implement an extensive sampling and monitoring plan, with monthly visits to establishments (see 5.6.2).

A representative of the Veterinary Service (Official Veterinarian - OV) is permanently present in milk processing establishments.

Observations:

The risk based classification of the plants had no practical impact on the frequency of official controls. In reality, the number of controls was much higher, due to many additional activities such as ad-hoc controls, joint inspections with the participation of many different authorities and controls in the scope of the preparation for the summer period (compulsory campaign in all the regions).

The mission team was informed about the internal audit system. According to the Veterinary Services, audits of the regional, district and local (uchastok) levels are carried out on a regular basis. Within the regions, the audits of the CAs are performed by RVOs over the DVOs according to an annual plan which foresees the auditing of all DVOs within 5 years. Audits of RVOs by the CCA are carried out only where problems are detected.

In addition the central level carries out audits in 4 regions each year which include checks of the regions own audit performance.

In one RVO visited, the documentation on the audit carried out by the CCA was provided, with a number of deficiencies identified in the report. However, no deadlines for corrective actions were indicated in this report and no evidence of any follow up could be shown.

A similar audit system was described by the Public Health authorities, with audits of all district offices within a period of five years or according to needs. The CAs carry out audits in the regions, and the frequency is risk based.

The mission team was informed that in June 2007 an audit by the regional authorities was carried out in a district responsible for the supervision of one of the milk establishments visited during this mission. On the spot, it was found that this was not a planned audit, but an urgent control due to an outbreak of food poisoning in a canteen in a local factory. Documents provided indicated efficient action taken immediately by the local and regional public health authorities, with deadlines and restrictions, including the temporary closure of the canteen and financial sanctions against the management. Follow-up consisted of repeated inspection.

Except for this there was no other documented evidence of the implementation of a supervisory system of the CA by a higher level.

The mission team was informed that the tasks of the OV permanently present in milk establishments is to supervise the quality of raw material, the general production hygiene and perform the official sampling. In practice, very little evidence of their activity was

seen by the mission team.

5.2.4 Training of staff

Within the structure of the Ministry of Agricultural Policy there is an institute of post-graduate studies. Each veterinarian in the veterinary service has to participate in an "upskilling course" for one month every 5 years.

Officials of the Public Health Service have to have a specialist diploma and the grade of junior expert. One month training is provided in selected Universities every 5 years.

In addition several training courses and seminars were held during the year when training needs were identified pursuant to the specialisation. Furthermore, some officials, in particular, at the laboratories visited attended international seminars elsewhere in the world.

Observations:

- The officials met during the mission were well trained and experienced, and they had a good knowledge of the national legislation. They could demonstrate their participation in the one month training course every five years and other additional training.
- However, although translated versions of the main EU legislation (Regulations (EC) Nos 852/2004, 853/2004, 854/2004, 882/2004 and 1774/2002, and Council Directive 96/22/EC) were available on the website and at RVO/DVO level, staff of both services were not familiar with the requirements laid down in the model certificate for milk and milk-based products to be exported to the EU as provided by Commission Decision 2004/438/EC (the translated version was provided only at the final meeting).
- Both post-graduate and periodic training are general and did not include the EU requirements for the milk sector. Quality and quantity of training provided to officials varied considerably between RVOs visited; in some of them the officials met stated that no specific training (in addition to the general and specialist ones provided every 5 years) was supplied on EU requirements for the milk chain.
- In one RVO visited specific training on EU requirements was organised by the Veterinary Service on 17/06/2008, with 65 representatives from 9 establishments and official services. This was in preparation for the FVO mission. Moreover, meetings took place with inspectors once a year and there was a seminar for inspectors on HACCP-based systems in February 2008. A seminar on control of HACCP-based systems in the same RVO was attended by staff of the PH-CA in 2007.
- In one Region, a Public Health Service official stated that he participated in a training course in an EU Member State. However, he was unable to provide details about the content of the course or in which town the course took place.

5.2.5 Notification procedures of disease outbreaks

Article 42 of the “Law of Ukraine on Veterinary Medicine” obliges animal keepers, FBOs, OVAs and practitioners to report immediately any suspicion of notifiable disease to the official services.

In case of food-borne diseases, under the responsibility of the public health (PH) services, the veterinary service at district level is informed within the commission created at district level to cope with the outbreak, and also by phone.

5.2.6 Approval of dairy plants

Dairy plants for export are approved each year by order of the CVO on the basis of national legislation, and the recommendations of the Regional Chief Veterinary Officers (RCVO) in the regions concerned. According to the CVO Order of 29 February 2008 No 12, 160 dairy establishments in Ukraine have been approved for export to date. The export list is not country-specific: establishments approved for export are allowed to send their product to any country in the world.

Observations

- No evidence was found that EU requirements have been taken into account by the Ukrainian CA when proposing 4 dairy establishments for export to the EU.
- The national approval for export is issued for the whole establishments, although only a part of them is concerned by export.
- In one establishment, where one division was found to be not satisfactory by the mission team (see section 5.5.2, indent relating to the "fourth dairy plant"), the CA have requested a reconstruction of this unit. However, there was no evidence that this unit would be excluded for export pending the deficiencies being addressed. This also concerns separate divisions in other plants, where deficiencies noted by the mission team were not identified by the CA.
- In addition, according to national legislation, separate production units situated in another location are covered by the same approval and, thus, by the export approval. This also concerns Milk Collection Centres (MCCs) and MCP, if owned by the same company. This procedure is contrary to Article 4 of Regulation (EC) No 853/2004.

5.3 ANIMAL HEALTH CONTROLS

The performance of animal health controls is described in different instructions related to the disease concerned.

5.3.1 Holding registration and animal identification

The “Agency for identification and registration of animals” operates at central level since 2005 and recently regional offices are also in use. The database contains a register of both “agricultural farms” and private cattle keepers, or “household holdings” and includes information about the holding number, name and address of holding, the owner, the ear tag number and name of the animal, date of birth, the dam and sire and the passport

number.

Holding registers containing information equivalent to that requested by EU legislation must be kept on the farm.

The birth of an animal must be notified to the database within 7 days and the database will issue the cattle passport. All cattle must be identified with double ear tags before leaving the holding. There are provisions in place for the replacement of lost ear tags.

The system in place for movement control is based on the entry in the cattle passport, a licence for movement and veterinary certification of the health status of the animal (TB, brucellosis, leukosis and leptospirosis testing and anthrax vaccination).

The mission team noted that:

- the holding registers were properly completed and cattle passports were available at the holdings visited.
- Most of the cattle seen were identified with two ear tags. However, some cows were missing both tags. It was explained to the mission team that these animals have lost their tags and the replacements was delayed due to late distribution.
- the lists of the private cattle keepers were available grouped by village at the district veterinary offices visited.

All cattle holdings seen were visited on a regular basis by the OV from district offices and "uchastoks".

5.3.2 Tuberculosis and brucellosis

Tuberculosis

The eradication of tuberculosis is based on the testing of the entire national cattle herd twice a year. In 2007, in total 5 885 118 cattle were intra dermally TB tested. In addition, 2 903 bacteriological examinations and 139 histopathological examinations were carried out (10 of them were positive). 5 796 animals were slaughtered for diagnostic investigation (with lesions found in 473 animals). No compensation is paid to the animal owners for their losses when TB reactors are slaughtered (neither for brucellosis nor FMD).

In the time period from 2004 to 2007, the TB herd* and animal prevalence decreased from 14.6 % to 10.1 % and, respectively from 0.23 % to 0.09 %.

*The number of herds include "agricultural farms" but not private holdings which are several millions.

Table 1: TB prevalence

	Number of herds	Number of TB herds	Herd prevalence	Number of animals	Number of TB animals	Animal prevalence
2004	8 641	1 260	14.6 %	8 147 746	18 667	0.23 %
2005	7 742	1 002	12.9 %	7 524 501	14 627	0.19 %
2006	6 959	787	11.3 %	6 881 747	8 779	0.13 %
2007	6 216	627	10.1 %	5 885 118	5 351	0.09 %

The Ukrainian TB eradication programme deviates from the EU requirements notably:

- Cattle are only to be TB tested from the age of 2 months.
- Goats kept together with cattle are not to be tested. In holdings visited these species were not kept together, however, many examples were seen of sharing municipality grazing areas.
- No measurement of the skin fold before TB testing (and consequently no recording) is required. TB testing is conducted with a jet-injection and not with a TB syringe.
- In a TB free herd, a positive reaction to tuberculin (*M. bovis*) does not lead to the suspension of the herd status and consecutive intradermal TB testing at least 42 days after removal of the reactor(s). Restrictions are applied only after confirmation through bacteriological testing after slaughter.
- Following the national instruction, the milk of reactor animals can be used for human consumption following heat treatment and reactor animals are allowed to remain in the herd provided they are separated. However, whenever checked during the mission, all reactor animals were slaughtered and their milk was not used for human consumption.

In some points the Ukrainian TB eradication programme is stricter than the EU requirements:

- Livestock which is intended to be sold to another holding or brought to this holding is subject to pre-movement TB testing.
- Positive reaction is considered when an increase of 3 mm in the thickness of the skin fold occurs.

After confirmation of TB by laboratory examination the milk of the entire herd may not be used for human consumption but can be used for feeding purposes following heat treatment. The mission team noted that:

- In the DVO visited it could be documented that all eligible cattle were TB tested twice a year.
- In January 2008, one cattle herd tested positive for TB (17 animals positive at single intradermal test, but bacteriologically negative) and was retested in April (3 animals positive at comparative test). Although the results of the bacteriological examination of the latter 3 cases were still pending the CA considered the herd to be TB free

because of the negative bacteriological result of the first testing.

- Bacteriological examinations were only performed in cases of doubt or suspicion. No samples were taken where lesions after slaughter were found.
- Following data from the World Health Organisation (WHO), in Ukraine, TB in humans is increasing with an estimated incidence of about 100 cases per 100 000 people.

Brucellosis

Since 1992, no cases of brucellosis (*B. abortus*) were reported in the Ukraine. The last case of sheep and goat brucellosis (*B. melitensis*) occurred in 2003.

Once a year the entire cattle herd older than one year is serologically tested for brucellosis. In 2007 in total 4 748 218 Rose Bengal Tests (RBT), 1 245 365 Serum Agglutination Tests (SATs), 2 526 412 Complement Fixation Tests (CFT) and 348 ELISA tests were carried out on cattle. The CA explained that in future instead of blood sampling for serology the milk ring test will be used (in 2007, 4 472 tests).

In 2007, in sheep and goats in total 428 342 RBT, 138 077 SAT and 301 847 CFT were carried out; all with negative results.

Cows after abortions are serologically tested twice for brucellosis. In 2007 in total 1 613 cases were examined at regional laboratories (613 after abortion and 1 000 after the birth of still born calves).

The mission team noted that:

- At the district and regional veterinary offices visited it could be demonstrated that all eligible cattle were tested for brucellosis.

5.3.3 Foot-and-Mouth Disease

Foot-and-Mouth Disease (FMD)

Ukraine is recognised by the OIE as “free from FMD without vaccination”. The last reported FMD outbreak was in 1988 and, since 1992, vaccination against FMD has not been performed and animals vaccinated against FMD have not been imported. The CA stated that live cattle were only imported from the EU and Australia.

The only laboratory dealing with FMD diagnostic is, even in the case of an outbreak, the Central Veterinary Institute. There, the mission team was informed that different FMD vaccine strains are held in stock. For detection of the disease an antibody-ELISA is in use with a maximum capacity of 1 000 samples per day. In the near future an antigen-ELISA will also be used with a capacity of 10 samples per day. For the time being no PCR test is available. In the case of a suspicion sample it would be immediately sent to both the OIE reference laboratories in Pirbright/UK and in Vladimir/Russia.

For FMD monitoring in the regions at the borders of the Ukraine, in 2007, 350 blood samples of cattle were taken and examined at the Central Veterinary Institute and it is foreseen that in 2008 1 000 samples taken in the same regions will be tested for FMD.

The mission team received evidence of sufficient training of the official veterinarians within the system described in section 5.2.4.

Rinderpest

Rinderpest was never notified and Ukraine is recognised as free from Rinderpest by the OIE. Within the training system described above lectures on exotic diseases including Rinderpest are provided. No tests for Rinderpest are available for the time being. The CA explained that in the case of a suspicion sample it would be sent to the OIE reference laboratory in Pirbright/UK.

5.4 APPLICATION OF HYGIENE RULES ON DAIRY HOLDINGS AND MILK-COLLECTION CENTRES AND OFFICIAL CONTROLS

Conditions for production of raw milk have been laid down in GOST standard (*Animal and public health instructions for agricultural holdings, 1986*).

5.4.1 Dairy holdings

Observations:

- The health status of supplying farms was satisfactory and all holdings presented annual veterinary cards with confirmation of status regarding TB and brucellosis.
- The premises where animals were kept complied with general hygiene requirements for their operation. Some milk storage rooms were not pest proof, and in the majority of farms the toilets and wash basins were not fitted with hot water and maintenance of milking equipment in one large farm visited was not satisfactory.
- The preparation of udders before milking and the process of milking seen in one private holding was carried out in a hygienic way. However, cows coming in for milking were not always clean.
- The cleaning and disinfection procedures of milking equipment varied depending on the size of the holdings. No disinfection took place at household holdings, only rinsing with water, sometimes with the temperature slightly more than 50° C. The frequency varied from two cycles daily to once a week at holdings where disinfection was used.
- Quality of farm sanitation manuals differed significantly. In general, the practical performance of sanitation was not properly documented.
- Testing of potable water did not fully comply with Annex I of Council Directive 98/83/EC because Enterococci and the majority of chemical parameters were not tested.
- Registers of veterinary treatments were kept, however withdrawal periods for antibiotics were not always documented. The controls of animals treated with antibiotics were not always sufficient. At one agricultural holding the eartag numbers of treated cows were communicated to staff verbally; extra identification means were used at another private holding but were not effective and were invisible).

5.4.2 Milk-collection centres

Two establishments were visited: an MCP, collecting milk from household holdings and an MCC collecting milk from agricultural holdings and from MCPs.

Both facilities visited had an acceptable structure, however the maintenance and hygienic standards of operation were only meeting EU requirements in one of them.

Observations:

- Facilities were not approved as separate food businesses. The CA was not familiar with the relevant EU legislation and stated that separate approval is not necessary if MCPs are covered by general approval given to milk processing establishments that collect milk from these points.
- In the MCC visited, there were no wash basins in rooms where raw milk was handled, most surfaces (floors, walls) were damaged and not easy to clean, drainage was not covered with grids and the disinfection equipment for trucks was rusty. The establishment was not pest proof.
- Concerning personal hygiene, annual medical examinations of staff including examination for tuberculosis were recorded in medical books and protection clothes of staff were clean. However, there were no flushing toilets or wash basins in the MCC and there were no toilets in the MCP.

5.4.3 Criteria for raw milk and controls upon collection

The parameters of raw milk are checked by the FBO every 10 days for each supplier.

A number of GOST / DSTU standards apply for raw milk.

There are four quality standards of raw milk according to DSTU 3662-97. Only the first of them (“extra”) which was introduced in 2007, fulfils EU requirements for Somatic Cell Count (SCC) and Total Bacterial Count (TBC).

Cooling of milk before collection is required by national legislation and the temperature requirement depends on the frequency of collection. (6° C for daily collection and 8° C for collection twice a day). Milk from household holdings need not comply with above temperature requirements if it is delivered to the MCP within two hours of milking.

Observations:

- National legislation does not foresee the calculation of rolling geometrical averages for SCC and TBC and does not specify the responsibility of the FBO for the acceptance of raw milk that does not meet the criteria with regard to SCC and TBC and initiate corrective action. Geometrical averages were not calculated in any of the premises visited by the mission team and action was not taken in the case of high TBC.
- A maximum 10% of raw milk complied with EU microbiological criteria and the average TBC for the majority of milk fell within 300-400 000 CFU per ml in the regions visited. A satisfactory situation was observed regarding SCC where the majority of milk produced showed 200 000–300 000 CFU per ml.
- Only one holding visited supplied raw milk meeting EU microbiological criteria.
- Temperature requirements for the raw milk were not respected on one farm visited,

with daily supply (temperature at collection over 6° C). The temperature measured at arrival in the MCP indicated that the temperature records at farm of origin were not reliable.

- Testing methods based on GOST standards used for the determination of TBC and SCC in raw milk which did not comply with ISO methods and neither have they been validated as possible alternative analytical methods against these standards as required in Annex VI a, Chapter I, Point 2 of Commission Regulation (EC) No 2074/2005.
- The results of raw milk examination were available in large farms only. They are not sent automatically by the FBOs to all producers. According to national legislation the data may be provided to household holdings on request.
- Radiological controls of raw milk is carried out based on Order of the Ministry of Healthcare, no 256 of 3 May 2006. 170 samples of raw milk have been taken at farms in 2008 in the DVO visited. A number of samples complied with annual plan and the level of radioactivity detected was in all samples lower than 20 Bq/l (national limit is 100 Bq/l).

5.4.4 Official controls over the raw milk collection and supply

The Veterinary Service is responsible for controls over production of raw milk. Controls are carried out by the DVO and local OV from the “uchastok”. Frequency of controls is laid down in the Order of Ministry of Agriculture No 99 on the prevention of inhibitors in raw milk from 2004 -2010.

Each dairy holding should be inspected quarterly by the DVO or Local OV from the “uchastok” for husbandry conditions, implementation of national programmes for control of diseases and treatment records.

All animals on dairy holdings must be screened monthly for mastitis and certified as healthy. Different control regimes are in place depending on the size of farms. Currently the majority of them are still OVs but in 4 regions with mountain and remote areas these activities have been delegated to private veterinarians. Controls of MCPs are carried out monthly by district offices.

Observations:

- All holdings visited are subject to regular controls by the veterinary service in order to ensure that the cows comply with the animal health conditions and are not affected with mastitis.
- The Veterinary Services did not take action in case of unsatisfactory bacteriological results in raw milk, in particular TBC. To date, this is considered as a quality rather than a safety issue and there is no procedure in place to follow up unsatisfactory results.
- The Veterinary Services have a procedure in place for action when inhibitors are detected. See section 5.2.2, Observations, third indent.
- Several deficiencies were observed in the administrative procedure, for example the

format of protocols used by district offices was not harmonised, neither were all controls documented nor sanctions used. Deficiencies detected by the mission team in the MCC were not identified in protocols from monthly controls.

5.5 APPLICATION OF HYGIENE RULES ON DAIRY PLANTS AND OFFICIAL CONTROLS

5.5.1 Raw milk quality

In addition to what is mentioned in section 5.4.3, the following observations about the dairy establishments visited were made by the mission team:

- In one establishment, in which the percentage of EU compliant milk (Ukrainian standard “extra”, according to DSTU 3662-97) was 0, the FBO had no knowledge of the EU requirements in this matter. Centrifugation of milk “with 99% efficiency” was proposed as an action to obtain acceptable raw material.
- In two other dairy plants, receiving raw milk, the problem was understood by the FBO. The percentage of EU compliant milk (“extra”) in these plants was 5% and 10% respectively. Both plants had separate reception and processing lines for different categories of milk.
- No instructions were issued by the CAs in relation to the quality of raw milk in establishments proposed for export to the EU.
- The Veterinary Committee informed the mission team that Ukraine has a programme for the improvement of raw milk quality. In particular, in the "Order of Minister of Agricultural Policy and the Ukrainian Academy of Agricultural Sciences, no 886/128 of 10XII2007 on the Frame programme for the development of the dairy industry in Ukraine until 2015”, amongst the main goals of the programme, is “to improve the quality of raw milk originating in industrial farms, to the level of international standards....to comply with the requirements of the WTO and EU". However, no evidence of any implementation of this programme could be provided.

5.5.2 Dairy Plants and official controls

Four establishments proposed by the Veterinary Committee, situated in three different regions and intended to export butter, cheese and dry milk to the EU, were proposed by the CCA.

Observations:

One dairy plant visited presented satisfactory conditions in relation to structure, maintenance, cleanliness, own checks including HACCP, in 2 of the 3 main divisions (cheese and butter). The third division (dry milk) was under reconstruction. The main shortcomings were the lack of sufficient storage space for dry milk, ingredients, and packaging material.

The official controls in this plant may be considered as satisfactory. However, structural deficiencies found by the mission team were not detected by the CA. The shortcoming in relation to the quality of raw material was noted by the CA but the recommendation to improve its quality was not supported by any finding in their report.

Dry milk and butter divisions were visited in the second plant. The first one was found to be satisfactory in terms of structure, maintenance, equipment and cleanliness. In the second one, maintenance deficiencies were found in the butter production room and in the cold stores (40 year old structures poorly maintained). Pest control was not efficient (mice faeces in the packaging material store, despite pest repelling facilities in place). HACCP plan elements selected at random and own checks were found to be satisfactory. The incoming raw milk controls were carried out according to GOST standards and revealed the same shortcomings as mentioned above.

The official controls were satisfactory in terms of official sampling and the large number of laboratory analyses. However, on the spot, despite many documented official controls, none of the CAs involved, including the full-time official veterinarian, had detected maintenance and other deficiencies, including the quality of raw milk, noted by the mission team.

In the third plant which is a stand alone cheese unit approved by the veterinary services under the same number as the parent plant described above but considered to be a different plant by the PH authorities, structure, maintenance and cleanliness were considered to be acceptable, with the following remarks.

The plant was missing the final product storage rooms (construction was already initiated, supposed to be ready in August 2008) and appropriate storage rooms for packaging material, salt and auxiliary equipment (such as cheese maturation shelves, forms and similar). The final products were temporarily stored in chilled containers in the yard, under acceptable hygiene conditions. However, the conditions for the packaging material and salt, kept in a garage, were not acceptable.

The own checks (including sampling of final product) were acceptable.

In relation to the official controls, the situation remains as in the parent company described above. In particular, none of the structural deficiencies noted by the mission team were documented by the CA including deficiencies such as a lack of storage rooms and flaking paint in the ceiling in the main cheese production room, which were well known and widely discussed in the plant.

The approval by the PH authorities, based on the legislation of 2007/2008, has not been granted yet.

The fourth dairy plant visited presented satisfactory (new cheese unit) or acceptable (dry whey unit) structure, equipment and maintenance. The old cheese unit was not acceptable. The CA identified most of the structural deficiencies in this plant. However, correct monitoring of the progress in addressing the recommendations by the FBO (reconstruction or refurbishments of some parts of the establishment) was not present. Deficiencies in relation to the storage of ingredients and packaging material were also found by the mission team, but not by the CA. This plant had 10 % of milk of EU quality originating in two farms constantly supplying this category of milk, and also had a dual technological line for separate processing of different categories of milk.

5.5.3 *Water examination*

The establishments visited had their own water supply (artesian well) or used municipal water, or both. The Sanitary Service is in charge of official water control both in the municipalities and in the establishments. According to national legislation, water has to be checked at district level once a month for bacteriological indicators and once every 3 months for physical and chemical indicators. In addition, the establishments take own samples in the scope of the own checks programme.

Observations:

- In all the establishments visited comprehensive sampling plans and water distribution plans were available when requested,
- The frequency of sampling was extensive. In one establishment, 4 samples from different points, according to the rolling scheme were taken 4 times per year. In another plant, 9 points were examined monthly for physico-chemical and bacteriological parameters.
- Water was examined according to GOST 2874-82 “Drinking water”, which requires different bacteriological and chemical parameters than those in Annex I of Council Directive 98/83/EC. In particular, total bacterial count is checked as well as the Coliforms, but not Enterococci.

5.6 OFFICIAL LABORATORIES

Both Public Health and Veterinary Services have an extensive network of official laboratories located at district and regional levels and cities of particular importance (Kiev and Sevastopol).

5.6.1 *Animal health controls*

The network of veterinary laboratories is composed of the Central State Laboratory of Veterinary Medicine in Kiev, 24 regional, 3 town laboratories and 396 district state laboratories. All laboratories are licensed to work with microorganisms of II-IV pathogen groups. All laboratories have been accredited according to the Law of Ukraine on metrology and the Central Veterinary Laboratory in Kiev and 14 regional laboratories have also been accredited according to ISO 17025 by the Ukrainian Accreditation Agency. According to Veterinary Law, the central laboratory is responsible for the approval of all regional and district laboratories for tasks required in the context of national monitoring programmes and also auditing of 24 regional laboratories. Every year, a minimum of 4 regional laboratories are selected for the audit, regional laboratories organise audits of all district laboratories annually.

Observations:

- The laboratories visited were sufficiently staffed and audited according to the annual plan. Work was well organised and time between reception of samples – analyses – report of results was documented and did not show any unjustifiable delays. The results were available on time in the supervising laboratory.

- Some inconsistencies in the operation of district laboratories were noted, for example, the use of different standards, percentage of positive reactions after RBT, system for filing of laboratory results. In one district laboratory deficiencies concerning the testing of abortions and keeping records were detected by regional laboratory during annual audit but no corrective action took place afterwards.
- In one district laboratory the testing of abortions and blood coming from household holdings for brucellosis was carried out only with RBT. Parallel CFT was not performed as prescribed in the national instruction.
- The central laboratory in Kiev provided the mission team with figures of positive RBT results after RBT per region. In 2007, 113 cases of positive RBT or PA were detected coming from 8 regions, all of them concluded after CFT as a false positive. In last 2 years these reactions were detected in the same regions. During visits to 2 district laboratories located in 2 different regions a similar situation was observed. In one, where laboratory practices were inadequate positive results of the RBT never occurred, in another RBT positive reactions from household holdings were documented.
- All district laboratories visited participated in ring tests organised by regional laboratories annually. However, the organisation of these tests by regional laboratories was not standardised and documentation relevant to these tests was not always complete in district laboratories.
- No deficiencies have been detected in laboratory analyses of samples from slaughtered TB reagents in connection with confirmation of a disease. In 2007, almost 3 000 bacteriological tests were carried out and in about 10% of samples delivered after slaughter of TB reactors *M. Bovis* was detected.

5.6.2 *Public health controls*

Public Health Service Laboratory Network:

With Decision No 43 of 28/12/2007 “on criteria for risk analysis” the frequency for sampling of processed products (microbiological and physical-chemicals parameters) is set at once a month.

A national plan for monitoring and control of processed foodstuffs (microbiology, residues and contaminants) is prepared annually and implemented by the public health services including the organisation of information meetings, training and general instructions.

Observations:

- The frequency of sampling for radionuclide, which is theoretically set at once a month, is now performed twice a year; however, in one regional veterinary office visited, frequency was once a quarter. The national limits in the national legislation are much lower than those set in the Community legislation.

Veterinary Service Laboratory Network:

The network is responsible for analyses of raw materials, products of animal origin and feedstuffs.

According to the Veterinary Law, all the laboratories of the network have to be accredited by the National Accreditation Agency of Ukraine, or a foreign accreditation authority .

In addition to the National Residues Monitoring Plan approved by Commission Decision 2004/432/EC and to the routine screening test conducted by in-house laboratories of dairies, three other monitoring programmes are in place and implemented by the Veterinary Service:

- A General National Plan for Food Safety is approved every year and monitors residues and contaminants in foodstuffs, including microbiology and radionuclides.
- A national programme in order to enforce the ban on the use of CAP on farms in order to detect the presence of residues in raw milk and milk-based products.
- An additional programme of analyses and monitoring for purposes of certification of foodstuffs intended for export, in which heavy metals, mycotoxins and antibiotics must be checked.

Observations:

- The results of these programmes were presented to the mission team and showed a percentage of positive results for antibiotics (CAP included) of around 0,18% for tests conducted in in-house laboratories of dairies (467 out of 248 356), and of 0,05% for CAP in the national monitoring plan (68 out of 122 442). Positive results are identified in two Regions, namely Odessa and the Autonomous Republic of Crimea), indicating local favourable conditions for illegal use of CAP and no respect of the prescribed withdrawal period for other VMPs.
- Every consignment intended for export is tested for several contaminants and residues, including CAP and radionuclides: evidence was seen by the mission team that when the result was positive for CAP, the pre-certificate has not been issued.
- The proficiency test was organised in 2007 between the NRL and 29 other laboratories, and another was organised with 4 accredited laboratories for the analyses for CAP in milk powder: in this latter 2 had satisfactory results and the results of the other 2 were considered to be not fully satisfactory, but still accepted without further investigation.
- Evidence of the training of specialists for the NRL was provided and a twinning project for the training of 100 analysts in EU laboratories is on-going.

In-house laboratory facilities at the dairy plants

Approval of milk processing establishments also covers in-house laboratories.

Such laboratories evaluate the quality parameters, temperature at arrival and also, every ten days, TBC, SCC and inhibitory substances.

Observations:

- Rapid screening tests are used for the detection of antibiotics on samples from raw milk coming from individual big farms and from bulk milk of MCCs, and not from individual holdings as foreseen by Annex III, Section IX, Chapter I – III of Regulation (EC) No 853/2004.

5.7 OFFICIAL CERTIFICATION

The Veterinary Service is in charge of certification for export. The certificate for a consignment is issued by the OV of the establishment or by the DVO. According to national legislation, the model of the certificate is called “Form no 2”, i.e. a national internal movement certificate for raw materials or products, indicating that the consignment originates from a district not under veterinary restrictions. This certificate can only be issued, if the FBO provides satisfactory results of laboratory examination, from an official laboratory where the consignment is analysed under a number of parameters, including bacteriological (S.aureus, E.Coli, Listeria monocytogenes and Salmonella), pesticides and radiological. The number of the laboratory result is indicated in the “Form No 2”, which accompanies the consignment to the border. An international certificate is issued at the Border Inspection Post.

Observation

- Examples were seen of the export certificates in which the international or final certificate contained information not present in the internal certificate or Form No 2.

6 CONCLUSIONS

6.1 LEGISLATION

The Ukrainian legal framework ensures that the level of food safety is similar to that required by the relevant EU legislation. However, several technical aspects such as approval of establishments, certification procedures, TB testing, quality of raw milk and water testing are not in line with the EU legislation.

6.2 COMPETENT AUTHORITIES PERFORMANCE

Both the Veterinary and Sanitary services have extensive powers and resources and have many experienced and motivated staff. However, their resources are not always used effectively.

Due to the unclear division of tasks between both Services, gaps and overlapping are present in the field. The mission team could not find any evidence of coordination of tasks of both services at central level. Despite frequent documented controls by both services in some establishments visited, neither service was in a position to identify essential deficiencies, even in the case of joint inspections.

No deadlines were set up and no follow up took place in the only region where an audit had been carried out by the CCA.

Approval of establishments for export is carried out on the basis of national legislation but requirements are not equivalent to Art. 4 of Regulation (EC) No 853/2004. Establishments are considered as whole entities, even if they consist of units in different locations. Divisions with non-satisfactory structure and maintenance are allowed to

export without addressing the deficiencies, even if these deficiencies were identified by the CA and corrective action requested.

With one exception, the officials involved in the supervision of milk establishments proposed for export to the EU have not received specific training related to the EU requirements for the control and production of milk products.

6.3 ANIMAL HEALTH CONTROLS

The Ukrainian system of holding registration, animal identification and movement control is satisfactory. There is a TB eradication programme in place which is however, not fully in compliance with the relevant EU requirements particularly regarding the granting of TB status of herds, the use of reactor milk, the TB testing procedures. TB in cattle is decreasing.

TB in humans presents a severe problem in the Ukraine and TB infection from humans to cattle and vice versa may contribute to the still high TB incidence in both cattle and humans.

The brucellosis situation is favourable. There is a monitoring programme for brucellosis in place which ensures that brucellosis can be detected. The Ukrainian veterinary service is prepared to diagnose FMD and to combat FMD and Rinderpest.

Concerning the animal health attestation of the certificate provided by Commission Decision 2004/438/EC, it can be concluded that:

- Animals whose milk is intended for the production of milk products for export are under the control of the veterinary service.
- Only milk from brucellosis free herds is used for the production of dairy products.
- Milk intended for the production of milk products for export is not coming from cows belonging to holdings which were under restrictions due to FMD and Rinderpest.

However, it cannot be ensured that only milk from officially TB free herds is used for the production of dairy products.

6.4 APPLICATION OF HYGIENE RULES ON DAIRY HOLDINGS AND MILK-COLLECTION CENTRES AND OFFICIAL CONTROLS

Raw milk comes from registered and checked holdings meeting hygienic conditions laid down in Annex III, Section IX, Chapter I of Regulation (EC) No 853/2004. Animals were in a good state of health and belonged to herds which were free of tuberculosis and brucellosis; however national legislation still allows the processing of milk after boiling at the farm from TB reactors.

Due to deficiencies noted at holdings and the MCP it cannot be ensured that raw milk was always obtained, collected, cooled, stored and transported in accordance with the specific hygienic conditions laid down in Annex III, Section IX, Chapter I of Regulation EC (No) 853/2004 and that compliance with these criteria was verified during official controls.

National criteria for acceptance of raw milk differs from Annex III, Section IX, Chapter I of Regulation (EC) No 853/2004. 95—100% of raw milk supplied to milk processing plants visited did not meet the EU TBC requirements and no action was taken by the FBO or the CA. Improvement of raw milk quality to meet EU requirements, recognised at the level of the Ministry of Agriculture, has not been practically implemented.

6.5 APPLICATION OF HYGIENE RULES ON DAIRY PLANTS AND OFFICIAL CONTROLS

The establishments visited and separate units within them varied between satisfactory (very good structures, maintenance and equipment) and acceptable (old structures and equipment well maintained and being successfully replaced and refurbished). However, in 3 plants visited, a division in each of them could not be accepted (old structures and equipment going beyond the point of maintenance). The FBO in general understood their obligations in relation to food safety. The general deficiency noted by the mission team was lack of sufficient storage space for final products, ingredients and packaging material.

The quality of the official controls was in principle satisfactory, but varied between the regions. Gaps and overlapping between the services involved were found in all cases. In some establishments none of the official services identified serious structural or maintenance deficiencies, in others they identified most of them, deadlines were set and follow up was in place. Concerning the OV permanently present in the dairy establishments, little evidence of their contribution to ensuring compliance with the requirements was seen.

The parameters for water examination in dairy holdings and dairy establishments proposed for export to the EU do not comply with those requested by Annex I of Council Directive 98/83/2C.

6.6 OFFICIAL LABORATORIES

Extensive laboratory network of official laboratories is subject to regular auditing. Resources are available to carry out all the necessary laboratory analyses of tuberculosis and brucellosis as required by Council Directive 64/432/EEC. However, national laboratory standards used for brucellosis detection were not always enforced and the organisation of comparative tests was not harmonised between the different regions.

The results of residue monitoring programmes show some use of antibiotics including CAP, in particular in 2 regions, namely Odessa and Crimea, which indicates local favourable conditions there.

6.7 OFFICIAL CERTIFICATION

Under the current system, the export certificate is issued by an official who has no access to full information required by the certificate, contrary to Art. 3 of Council Directive 96/93/EC.

6.8 OVERALL CONCLUSION

The situation is in principle satisfactory with the exception of the following issues: coordination of the CAs, approval and certification procedures, some aspects of water testing and TB testing and control. The main shortcoming is the quality of raw milk with only 5 to 10 % of milk of EU eligible quality available. The Ukrainian authorities stated they were confident they would be in compliance with the EU requirements within a short time.

7 CLOSING MEETING

A final meeting was held on 4 July 2008 with representatives of the both CCA. At this meeting, the mission team presented the main findings and preliminary conclusions of the mission. The CCA did not express any major disagreement with the the findings and preliminary conclusions, with the exception of the remarks on the instruction for TB testing. They informed the mission team of a number of measures which will be taken in response to the issues identified during the mission.

8 RECOMMENDATIONS

An action plan describing the action taken or planned in response to the recommendations of this report and setting out a time table, and a description of the actions taken to correct the deficiencies found should be presented to the Commission within 25 working days of receipt of the report.

No.	Recommendation
1	To improve coordination between both Competent Authorities in order to ensure, that the official controls in the establishments proposed for approval for export to the EU (hereinafter referred to as “export establishments”) fully comply with the requirements of Art. 4 of Regulation (EC) No 882/2004.
2	To put in place procedures in order to ensure, that the raw milk supplied to export establishments fully complies with Annex III, section IX, Chapter I, part III of Regulation (EC) No 853/2004.
3	The CA to put in place monitoring procedures in conformity with Annex IV of Regulation (EC) No 854/2004 in order to ensure, that the controls of raw milk supplied to export establishments comply with Annex III, section IX, Chapter I , part III of Regulation (EC) No 853/2004.
4	To bring TB testing and the eradication programme on holdings supplying milk for EU export in line with the requirements of Annex I of Council Directive 64/432/EEC.

No.	Recommendation
5	To put in place procedures in order to ensure, that the approval of export establishments, including milk collection centres and milk collection points, complies with the requirements of Art. 4 of Regulation (EC) No 853/2004 and Art. 3 of Regulation (EC) No 854/2004.
6	To amend the certification procedures in order in to ensure, that the certifying officer has full knowledge about the consignment, as requested in Art. 3 of Council Directive 96/93/EC.
7	To correct deficiencies found by the mission team in the establishments visited, including milk collection centres and milk collection points to ensure that similar deficiencies are corrected in all establishments the Competent Authorities might wish to propose for export to the EU.
8	To provide the officials involved in official controls of export establishments with appropriate training related to EU requirements for the import of dairy products from third countries.
9	To adapt the water examination procedures in export establishments in order to ensure that the parameters requested by Annex I of Council Directive 98/83/EC are examined.
10	To take action in order to prevent illegal use of antibiotics, including chloramphenicol, in animal husbandry, as requested in Art. 54 of Regulation (EC) No 882/2004, in particular in regions with a high level of non conformities.
11	To ensure that the national laboratory standards for brucellosis detection are enforced in all regions and the organisation of comparative tests is harmonised between the different regions and to ensure that the laboratories are designated in conformity with Art. 12 of Regulation (EC) No 882/2004.

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/ap/ap_ukraine_7901_2008.pdf

ANNEX 1 - LIST OF LEGISLATION REFERENCED IN THE REPORT

Reference	OJ Ref.	Detail
Directive 64/432/EEC	OJ 121, 29.7.1964, p. 1977–2012	Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine
Directive 91/68/EEC	OJ L 46, 19.2.1991, p. 19–36	Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals
Directive 92/119/EEC	OJ L 62, 15.3.1993, p. 69–85	Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease
Directive 96/22/EC	OJ L 125, 23.5.1996, p. 3–9	Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of β -agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
Directive 96/23/EC	OJ L 125, 23.5.1996, p. 10–32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
Directive 96/93/EC	OJ L 13, 16.1.1997, p. 28–30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
Directive 97/78/EC	OJ L 24, 30.1.1998, p. 9–30	Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries
Directive 98/83/EC	OJ L 330, 5.12.1998, p. 32–54	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
Directive 2001/82/EC	OJ L 311, 28.11.2001, p. 1–66	Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products
Directive 2002/99/EC	OJ L 18, 23.1.2003, p. 11–20	Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption

Reference	OJ Ref.	Detail
Directive 2003/85/EC	OJ L 306, 22.11.2003, p. 1–87	Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC
Directive 2004/41/EC	OJ L 157, 30.04.2004, p.33 corrected and re-published in OJ L 195, 02.06.2004, p. 12	Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC
Regulation (EC) No 2377/90	OJ L 224, 18.8.1990, p. 1–8	Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin
Regulation (EC) No 178/2002	OJ L 31, 1.2.2002, p. 1–24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Regulation (EC) No 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Regulation (EC) No 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Regulation (EC) No 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin

Reference	OJ Ref.	Detail
	re-published in OJ L 226, 25.6.2004, p. 83	intended for human consumption
Regulation (EC) No 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 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
Regulation (EC) No 2073/2005	OJ L 338, 22.12.2005, p. 1–26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
Regulation (EC) No 2076/2005	OJ L 338, 22.12.2005, p. 83–88	Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
Decision 2004/432/EC	OJ L 154, 30.4.2004, p. 44–50, corrected and re-published in OJ L 189, 27.5.2004, p. 33	2004/432/EC: Commission Decision of 29 April 2004 on the approval of residue monitoring plans submitted by third countries in accordance with Council Directive 96/23/EC
Decision 2004/438/EC	OJ L 154, 30.4.2004, p. 72–92, corrected and re-published in OJ L 92, 12.4.2005, p. 47	Commission Decision 2004/438/EC of 29 April 2004 laying down animal and public health and veterinary certifications conditions for introduction in the Community of heat-treated milk, milk-based products and raw milk intended for human consumption