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Directorate F - Food and Veterinary Office

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FINAL REPORT OF A MISSION CARRIED OUT IN THE RUSSIAN FEDERATION FROM 24 JUNE TO 04 JULY 2008 IN ORDER TO EVALUATE THE OPERATION OF CONTROLS OVER THE PRODUCTION OF MILK, HEAT-TREATED MILK AND MILK -BASED PRODUCTS DESTINED FOR EXPORT TO THE EUROPEAN UNION

Please note that factual errors in the draft report have been corrected. Clarifications provided by the Competent Authority are included in endnotes.

Executive Summary

The competent authorities (CAs) have sufficient legal and enforcement powers and staff numbers. However, the responsibilities of the CA in the area of food safety in relation to the milk products destined for EU export were not always clearly defined and were overlapping in certain areas.

Although the staff met who were responsible for the controls of dairy establishments were well aware of the national requirements, the training provided in relation to EU approval of dairy establishments and their controls has been insufficient.

The control system in place, for dairy establishments manufacturing dairy products destined for the EU market, does not provide verification that specific EU requirements have been taken into account (lack of procedures for separating EU/non EU production, use of raw materials and raw milk which are non EU eligible). Additional controls and procedures for milk and milk products destined for export to the EU were insufficient and the EU requirements for these products were not fully met.

The laboratory services operating under the Ministry of Health and Social Development (MHSD) and the Ministry of Agriculture (MA) functioned, in general, adequately and efforts have been made to upgrade the equipment.

Some deficiencies were noted in the implementation of the legislation on bovine tuberculosis and brucellosis.

The general and specific hygiene requirements were met in relation to the facilities and production lines destined for the manufacturing of possible EU export products. The heat-treatment of products which were destined for EU export was in compliance with Article 2, point 3 of Commission Decision 2004/438/EC. Production control programmes based on HACCP principles and traceability systems were available in all establishments visited. However, some deficiencies were identified.

The testing system for the detection of inhibitory substances in raw milk was functioning adequately in most aspects and comprised testing of milk also at holding level. However, no separate criteria has been established for raw milk destined for possible EU export production and the methods used for somatic cell count and total plate count have not been validated against the Community reference methods.

The application and control of hygiene rules was satisfactory in relation to most aspects at the dairy holdings visited.

Although no evidence of prescription or use of chloramphenicol, furazolidon and nitrofurans was available on the holdings visited, these substances are not prohibited to be used for livestock. However, the Russian veterinary law prohibits the use of milk for human consumption which originates from sick or treated animals.

The procedure in place for certification does not take into account the relevant Community requirements as specified in Council Directive 96/93/EC and Decision 2004/438/EC. The internal certificates used do not provide sufficient information to support several of the statements in the export certificates as laid down in Decision 2004/438/EC. Some other deficiencies in relation to certification were identified including the certification of dairy products for transit through EU.

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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Abbreviation	Explanation
CA	Competent Authority(ies)
CCA	Central Competent Authority(ies)
EBL	Enzootic Bovine Leucosis
EU	European Union
FBO	Food Business Operator
FMD	Foot and Mouth Disease
FVO	Food and Veterinary Office
GOST-Standard	Technical Standard
HACCP	Hazard Analysis Critical Control Points
MA	Ministry of Agriculture
MEDT	Ministry of Economic Development and Trade
MHSD	Ministry of Health and Social Development
OIE	International Animal Health Office
OV	Official Veterinarian
PCP	Production Control Programme
RCA	Regional Competent Authority(ies)
Rospotrebnazor	Federal Service for the Protection of Consumer Rights and Human Well-Being
Rosselkhodnazor	Federal Service for Veterinary and Phytosanitary Surveillance
RU	Russian Federation
SCC	Somatic Cell Count
SVS	State Veterinary Service
TB	Bovine tuberculosis
TPC	Total Plate Count

1 INTRODUCTION

The mission took place in the Russian Federation (RU) from 24 June to 4 July 2008. The mission was undertaken as part of the Food and Veterinary Office's (FVO) planned mission programme.

The mission team comprised four inspectors from the FVO divided into two sub-teams. Both mission teams were accompanied during the mission by representatives of the central competent authorities (CCAs); the Ministry of Economic Development and Trade (MEDT), the Federal Service for Veterinary and Phytosanitary Surveillance "*Rosselhodnadzor*", the Federal Service for the Protection of Consumer Rights and Human Well-Being "*Rospotrebnadzo*r" and/or the regional Competent Authorities (RCAs) representing "*Rosselkhodnazor*" and "*Rospodtrebnazor*".

An opening meeting was held on 24 June 2008 with the CCA. At this meeting the inspection team confirmed the objectives and itinerary of the mission and additional information required for the satisfactory completion of the mission was presented.

2 OBJECTIVES OF THE MISSION

The objectives of the mission were to assess the adequacy of guarantees given by the CAs of the RU for the export of milk and milk-based products to the European Union (EU). In addition the mission team also assessed the measures taken by the CAs to address the recommendations of the FVO report DG(SANCO)/7188/2004. This report is available on the Health and Consumer Directorate General web-site at: http://ec.europa.eu/comm/food/fvo/index_en.htm

The mission team did, in particular:

- Assess the controls in place over the production of milk and milk-based products intended for export to the EU; and
- Review the systems for certification of milk and milk-based products in relation to the requirements of Directive 96/93/EC.

In pursuit of these objectives, the following sites were visited:

Central competent authorities	1	Opening and closing meeting
Regional competent authorities	3	
Local competent authorities	1	
Dairy establishments	7	
Livestock holdings	5	Bovine dairy holdings
Milk collection centre	1	
Custom control point	1	
Official laboratories	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 of the European Parliament and of the Council.

References to Community Legislation relevant to this report are listed in the Annex.

4 BACKGROUND

In 2004, an FVO mission took place in the RU in order to evaluate the operation of controls over the production of milk and milk-based products and meat products. This mission followed a request from the CAs of RU in relation to export of milk and meat products to the EU. The mission report DG(SANCO)/7188/2004 included the following recommendation to the CAs of the RU: to provide the Commission Services with an action plan containing satisfactory guarantees to address the findings and deficiencies identified in the report. The answer of the CAs of RU, comprising the measures taken in relation to this recommendation, was evaluated and was deemed to have not been addressed in a satisfactory way as specified in the following points:

- The CAs of RU did not provide guarantees on how to carry out the controls in relation to EU requirements i.e. separate production of EU export products from EU eligible material and production for the domestic or other export markets. The only guarantees were provided by the dairy industry.

- Horizontal issues as listed below were not addressed:
  - Requirements related to raw material for production;
  - EU eligibility of the establishments which deliver to or store goods of EU approved establishments;
  - Obligation to apply Hazard Analysis Critical Control Point (HACCP) based principles;
  - Requirements related to animal identification and traceability of animal products; and
  - Lack of guarantees to prohibit the use of chloramphenicol and furazolidone for veterinary treatment of livestock, of which products might potentially enter the production chain of milk and milk products destined for EU export.

5 MAIN FINDINGS

5.1 LEGISLATION

The main legislation regulating the production of milk and milk-based products has been listed in the earlier report DG(SANCO/7188/2004. The legislation comprises the Veterinary law, the Law on Food Quality and Safety, the Law on Sanitary-Epidemiological Well Being of the Population and the Law on Safeguarding Rights of legal Persons and Individual Entrepreneurs in the Process of State Control Inspections.

New federal legislation comprising detailed technical rules and requirements for milk and milk products was published on 20 June 2008 (Federal Law No 88-F3).

A draft federal law "On the recording of animals and products of animal origin and introduction of changes into some legislative acts of the Russian Federation" was received. This legislation will establish rules for the identification of all types of animals, identification of products, the accompanying documents, the registration in a central database, transitional provisions and responsibilities in case of violation of the law.

The Russian legislative requirements in relation to milk and milk products differ from the Community requirements (see Chapters 5.4.2 and 5.4.3).

5.2 COMPETENT AUTHORITIES

5.2.1 Organisation and co-ordination of Competent Authorities

The basic structure of the different CAs responsible for the control of the production of milk and milk products has been described in the earlier FVO report. Since then some

changes have occurred in the organisation and co-ordination of the CAs.

The State Veterinary Service (SVS) within the Ministry of Agriculture (MA) is responsible for the drafting of legislation and the organisation of preventive measures and also the prevention of epizootic diseases (for example, preparation of animal disease monitoring programmes and vaccination programmes). The SVS has its respective units in the regional departments (83) and at territorial level (60). In addition, it has units at local level (veterinary stations).

Rosselhodnadzor, operating under the MA is in charge of the implementation of controls and supervision of veterinary and phytosanitary protection, including zoonoses, quarantine, use of pesticides and agricultural chemicals.

In the area of food safety, the responsibility is shared between *Rosselhodnadzor* and *Rospotrebnadzor*, which is operating under the Ministry of Health and Social Development (MHSD). *Rosselhodnadzor* is carrying out controls on raw materials (for example, raw milk) and foodstuffs of animal origin which haven't undergone heat-treatment. *Rospotrebnadzor* is carrying out controls on raw materials and final products which have undergone a heat-treatment. *Rospotrebnadzor* has 90 territorial offices within the RU.

The MEDT is a federal executive body which areas of competence include, *inter alia*, the organisation and co-ordination of bilateral and multilateral economic and trade relations.

The State Committee for Standardisation and Metrology, responsible for the accreditation of laboratories, is under the responsibility of the Ministry of Industry and Energy.

The following shortcomings were identified in relation to the responsibilities of the CAs:

- The responsibilities of *Rosselhodnadzor* and *Rospodtrebnazor* in the area of food safety for EU exports were not always clearly defined and were overlapping in certain areas, leading sometimes to a situation where neither of the 2 CAs wanted to take up responsibility for the specific controls required for dairy products destined for EU export (for example, testing of potable water for additional parameters).
- Little evidence was seen of information flow in relation to the EU export approvals/procedure between the different CAs.

5.2.2 Legal/enforcement powers

The Veterinary Law provides the SVS and *Rosselkhodnazor with* enforcement powers, including sanctions, to ensure that animal products comply with the veterinary rules. The Federal Law on the Quality and Safety of Food Products and the Decision of the RU No 987 of 21 December 2000, comprise rules on the state supervision and control in the field of securing quality and safety of food products and provides enforcement powers in relation to the safety and quality of foodstuffs.

Both laws comprise administrative sanctions (warnings and fines).

Evidence of legal and enforcement powers was available. Documentation was seen on the use of sanctions (for example, issuing of fines).

5.2.3 Staff performing official controls

The staff met, employed by *Rosselhoznadzor* and *Rozpotrebnadzor*, were dedicated to their job and well aware of the national requirements.

However, the following deficiencies were identified:

- Most of the staff met who were responsible for the controls of EU export establishments had insufficient knowledge of specific EU requirements.
- No evidence of training given to the staff by the CCA on specific EU requirements was provided to the mission team.

5.2.4 Resources

Sufficient resources (facilities, vehicles, computers etc.) were available in the regions and districts visited.

5.2.5 Official control systems

Supervision (control) over all foodstuff producers operating in the Russian foodstuff market, milk and dairy products included and among others export products to the European Union, is carried out according to the legislation of RU.

The CCA of *Rosselhoznadzor* had issued special instructions on 3 October 2006 on how to proceed with EU approval and controls of the dairy establishments approved for EU export of milk and milk products (see 5.2.6.).

Establishments and dairy holdings are subject to routine audits carried out by the RCA. In addition, each establishment visited had a full-time OV permanently present who was responsible for daily supervision.

The CAs of *Rosselhoznadzor* and *Rozpotrebnadzor* carry out routine audits which take place every second year. If infringements in relation to legislation on food safety are detected in the framework of these controls the FBO is given binding instructions to rectify the situation. If the instructions are not followed, the case is referred to the court. The court can decide to suspend or ban activity of the FBO not following the instructions. Additional, off-schedule checks are carried out if goods of inferior quality are detected, within the follow-up of non-compliances or following consumers' complaints. In the case of infringement of requirements of the Russian legislation the FBO or legal entity can be held responsible according to the criminal or civil law or in relation to administrative procedures, depending on degree of adverse consequences of the offence.

According to articles 27 and 28 of the Federal Law from 02.01.2000 № 29-FZ "Quality and safety of foodstuff" the FBOs and the legal entities manufacturing and placing on the market foodstuffs, food material and products are responsible for the infringement of requirements concerning the food production turnover.

Detailed audit reports were available in all establishments visited and included non-compliances detected and deadlines for corrective actions.

The officials responsible for the controls of EU export establishments had the Food Hygiene Package available in the Russian language in the establishments visited.

The CCA of *Rosselkhodnazor* stated that they have an inspection unit at CCA level which carries out audits on a wide range of topics in the territorial entities. However, no supporting documentation of these audits was provided to the mission team.

The following deficiencies were identified:

- The instructions of 3 October 2006 on EU approvals and controls were only available for the mission team in some of the establishments visited.
- The CCAs had not established control and verification procedures which would take into account the Community specific requirements for milk and milk products.
- Although some of the EU approval reports mentioned that the establishment was operating in accordance with EU requirements, this was in reality not the case (for example, Community requirements in relation to source and compliance of ingredients, raw milk quality, and testing of water were not followed).
- Significant deficiencies identified by the mission team were not reported in the official control reports.

5.2.6 Approval of establishments

The approval procedure for the national market is described in the earlier FVO report DG(SANCO)7188-2004).

On 3 October 2006, the CCA of *Rosselhoznadzor* issued special instructions on the procedure to follow for obtaining EU approval of the dairy establishments, from that date onwards.

The procedure starts with the written request sent by the Food Business Operator (FBO) to the CCA *Rosselkhodnazor*. After this, the CCA sends an order to the territorial *Rosselkhodnazor* services to inspect the establishment within a certain deadline. The RCAs draft an audit plan, which includes a reference to Community legislation (food hygiene package) for the recently approved establishments. The audit is then carried out and a report is drafted. If shortcomings are found, the FBO is requested to take corrective actions and the establishment is re-inspected. When the plant has reached compliance, the RCA informs the CCA, who then assigns an EU-approval number to the establishment and requests the Commission Services to add it to the EU listing of approved establishments from which Member States are allowed to import milk and milk-based products. No document stating its EU-compliance is issued to the establishment.

Evidence was available in all establishments visited that inspections by the RCA had taken place before the EU export approval. Reports of these inspections were available and presented to the mission team.

However, some deficiencies were identified:

- In 3 establishments the CA could not demonstrate their awareness of the instructions sent out by the CCA in relation to EU approvals.
- The reports of the Russian CAs on premises approved to export to the EU before

2008 did not include a statement on whether the establishment was in compliance with the Community requirements or not.

- During the pre-EU approval inspections, the officials did not take into account the specific requirements for export of dairy products to the EU, for example separate EU/non-EU production, specific EU requirements for raw milk quality and other ingredients of milk origin, and EU requirements in relation to the testing of water.

5.2.7 Laboratory Service

Laboratory networks have been established under both the MHSD and MA. These laboratories operate at federal, regional (regions or territories) and local level (districts, cities).

The SVS has 50 state veterinary laboratories under its supervision and also laboratories at district level.

Rospotrebnazor has a laboratory network comprising 90 territorial laboratories (Centres of Hygiene and Epidemiology). The laboratories under the MHSD also approve and control the activities of the own control laboratories in the establishments.

During the mission 4 official laboratories were visited. The laboratories visited were all accredited by the State Committee on Standardisation and Meteorology (GOST standard). One of the laboratories visited was preparing for ISO 17025 accreditation. The laboratories were well equipped or were in the process for getting new equipment (for example, new laminar flows, new automated equipment for bacteriological diagnostics, PCR equipment, new ELISA readers). The laboratories were using national test methods as described in GOST. Both private and official samples were analysed in the official laboratories visited.

Some deficiencies were, however, identified in relation to internal quality controls and documentation and no instructions had been issued to the staff carrying out on inactivation of the active chlorine in water samples.

5.3 ANIMAL HEALTH CONTROLS

5.3.1 Holding registration, animal identification and movement controls

RU has not established a federal centralised system for the registration of holdings. The identification system for cattle remains as described in the previous report and is based on the identification system chosen by the owners/keepers.

The dairy holdings visited were registered at district level and were subject to regular veterinary controls. The animals on the holdings visited were identified based on a system established by the owner or keeper, namely ear tags and/or transponders.

Movement controls are in place for herds which are suspected or diagnosed to have bovine brucellosis or Tuberculosis (TB).

The following shortcomings were identified:

- Holding registers were available but did not contain equivalent information as required by EU legislation (for example, the animal leaving the holdings were not always indicated in the register).
- The SVS does not have up-to-date information on the number of animals present at the holdings. Information on the total number of animals is only obtained when the SVS visits the holdings.

5.3.2 Notification procedures of disease outbreaks

According to the Veterinary Law, notification of infectious animal disease outbreaks (including suspicions) to the district OV is compulsory. If the outbreak is confirmed, an urgent report is addressed to the CCA (SVS and *Rosselkhodnazor* and it's territorial department).

5.3.3 Controls on bovine tuberculosis and brucellosis

The SVS establishes programmes to regularly test cattle for bovine tuberculosis (TB), brucellosis and enzootic bovine leucosis (EBL). Dairy cows are tested for TB and brucellosis bi-annually as well as the calves from 6 months of age. Abortions must be submitted to microbiological analysis, including *brucella subspecies*. Results of these analyses were available on the holdings visited. Vaccination of cattle against *Brucella abortus* are carried out in problematic regions.

The following deficiencies were identified and some provisions of the national legislation were not followed, for example:

- In one holding visited the re-tests for 2 TB reactor cattle were not done within the legal time period of 45-60 days after initial results. The time span before re-testing exceeded more than 100 days in one case. On the same holding no documented evidence was available that these animals have been isolated from the rest of the herd and that the milk was excluded for human consumption;
- Results of tests were not reported in some cases; and
- Some of the test results seen did not include the results of the measurements of the thickness of the skin-fold.

5.3.4 Foot and mouth disease and rinderpest

The last foot and mouth disease (FMD) occurred in 2006 in the border area close to China.

The last outbreak of rinderpest occured in 1998, in the region of Amur.

The CCA stated that bi-annual vaccinations against FMD (with a trivalent vaccine A/O/ASIA 1) are carried out in the greater Moscow area (around the Research Institutes dealing with live FMD virus) and along the border with Kazakhstan, China and Mongolia. In 2007, 10 282 serum samples were tested for FMD antibodies (for serotypes A/O/ASIA 1).

Dairy holdings are subject to regular controls (at least once every 2 years) by the CA (*Rosselkhodnazor*). A CA checklist is used for the inspections and reports of these inspections were available on holdings visited.

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

5.4.1 Dairy holdings and milk collection centres

The health status of the dairy holdings visited was satisfactory. The premises where the dairy cattle was kept complied with general hygiene requirements for their operation.

The milking practice on the dairy holdings visited was generally done in a satisfactory way. The practices included foremilk stripping and the milking was carried out in a hygienic way by the FBO staff.

However, the following shortcomings were identified:

- In 2 holdings and one collection centre visited, not all requirements in relation to hygienic conditions for the storage of milk were respected, for example lack of thermometers, flaking paint, rusty equipment, partly open roof, floor, ceiling and walls not easy to clean and disinfect, lack of pest control.
- On one holding visited, the correct milking procedure was not followed by some staff members.

5.4.2 Criteria for raw milk and its transport

A system for raw milk quality control is in place and evidence of its operation was seen in the dairy establishments visited. Raw milk is analysed for TPC, SCC and inhibitory substances both in the own control laboratories of the establishments and also in the official laboratories. Results of the analyses were available.

TPC and SCC

The testing frequency for TPC and SCC was once every 10 days (as described in the GOST standard).

The deficiencies identified in relation to TPC and SCC were basically the same as identified during the earlier FVO mission in 2004:

- The system in place for SCC and TPC differs from the system described in Section IX, Chapter I, point III, 3 of Annex III to Regulation (EC) No 853/2004. The criteria for best, premium class milk, exceed the EU limits in relation to TPC/ml (<300 000 instead of 100 000) and SCC/ml (<500 000 instead of < 400 000).
- The methods described for SCC in GOST Standard differ from the methods described in Annex VIa to Regulation (EC) No 2074/2005. The GOST Standard 23453 describes 2 methods in use for SCC. The first method (Mastoprim) is principally a cow-side test similar to California mastitis test (qualitative), the second is based on viscositymetry (quantitative). The methods described for TPC are either

based on plate count method or testing for reductase activity (qualitative).

- No evidence was provided that these methods had been validated against the reference methods of Annex VIa to Regulation (EC) No 2074/2005.
- Although the dairy establishments visited received a certain amount of raw milk meeting EU standards, none of them had established separation procedures for EU eligible raw milk to allow the production of potential EU export products.

Inhibitory substances

Milk samples at the holdings visited were tested regularly by the FBO for the presence of inhibitors before dispatch to the dairy establishments. At the dairy establishments visited, milk samples from the individual holdings were tested regularly for the presence of inhibitors as were pooled milk samples from the tankers. The samples were also tested in an accredited laboratory of the Veterinary Service, as regulated by Federal law, every 10 days. Most of the results seen were negative.

Transport of raw milk

The Russian legislation has set standards for the transport of raw milk from the holding of origin to a maximum limit of 6°C and for the arrival of milk at dairy establishments at 8°C. It is prohibited to process raw milk above these set limits.

However, some shortcomings were identified:

- Milk has been received at arrival and used for further processing exceeding the temperature limit in 3 establishments visited. Evidence was present that milk arrived on several occasions exceeding the EU temperature standard of 10°C on arrival e.g. 11,5°C; and
- The transport documents for milk transported from several holdings to a collection centre did not mention the temperature during transport.

5.4.3 Controls on use of veterinary medicines

Doctors of veterinary medicines (University veterinary degree) and also Veterinarians with a lower degree have according to Article 18 of the Veterinary Law the right to prescribe veterinary treatment.

The CCA stated that since 2006 veterinary practices do not need any licence. However, private veterinary practitioners have to be registered. Since 2006 no licence is required for the purchase of veterinary medicines. However, big industrial farms must have contracts with companies producing veterinary medicines. On all the larger dairy cattle holdings visited, private practitioners were employed by the animal keeper.

The Veterinary Law prohibits the use of milk derived from treated or sick animals for human consumption.

SanPin 2.3.2.1078-01 "Hygienic requirements of safety and nutrition value of foodstuff" comprises requirements in relation to limits of acceptable levels of antibiotic residues for milk and milk products and methods of detection including detection limits.

Records of veterinary treatments were available in all 5 holdings visited. Animals under treatment were identified either electronically or physically (for example, colour band

around the leg). In none of the holdings visited was evidence available on the use of chloramphenicol, furazolidone and nitrofurans.

However, the following deficiencies were identified:

- The use of chloramphenicol, furazolidone and nitrofurans is not prohibited by federal law (see Endnote). The CCA and the CA met stated that these products are, however, not used on livestock. Nevertheless, according to the 2007 residue monitoring plan 50 out of 1 611 milk samples were tested positive for chloramphenicol.
- No evidence was available that the use of veterinary medicines was under the control of the private veterinarian (employed by the holding) in 2 of the 5 holdings visited.
- The withdrawal periods were recorded in only one holding visited.
- Only one holding visited provided evidence on the amount of milk from treated animals or animals with sub-clinical mastitis or unhealthy animals, which was declared unfit for human consumption.
- Control reports of the SVS did not include controls on the use of veterinary medicines and on the respect of withdrawal periods.

5.5 APPLICATION OF HYGIENE RULES AND OFFICIAL CONTROLS AT ESTABLISHMENT LEVEL

5.5.1 General and specific hygiene requirements

Requirements concerning general and specific hygiene were met, in general, in the production areas and lines of products which were destined for EU export, at all the establishments visited. In 3 establishments visited some areas were in need of refurbishment. The FBOs, however, had a maintenance programme in place to demonstrate up-grading of the areas concerned.

The heat-treatment of products which were destined for EU export was in compliance with the requirements of Article 2, point 3 of Decision 2004/438/EC.

The following shortcomings were identified:

- Preventive measures against pests were insufficient in three establishments visited (e.g. several doors and other openings to the exterior did not close tightly, the presence of excreta of rodents).
- Deficiencies were identified relating to operational hygiene in one establishment visited.

5.5.2 HACCP-based systems

According to article 11 of the Federal Law from 30.03.1999 № 52-FZ

"Sanitary-and-epidemiologic well-being of the population" the FBOs and legal entities are in charge of own controls, including laboratory studies and tests of incoming raw materials and end products, ensuring that they comply with the requirements of sanitary rules, and carrying out of sanitary preventive activities during manufacture, transportation, storage and placing on the market of products.

The national legislation requires that all dairy establishments have established a Production Control Programme (PCP). The PCP covers areas like water testing, pest control, medical examination of staff, cleaning and disinfection procedures, laboratory analyses, registers of ingredients and products of animal origin. The PCP can be based on HACCP principles.

The FBOs had procedures in place in all establishments visited based on the HACCP principles.

The own control laboratories at the milk plants visited had generally good documentation. The facilities and equipment were adequate taking into account the testing range (no testing of pathogens).

However, the following deficiencies were noted:

- The procedures described were not always up-to-date or were incomplete in the establishments visited. In one establishment, the plan did not contain all hazards nor all reporting procedures and action to be carried out in case of non-compliance; in another establishment visited, the reworking of milk products was not included in the HACCP and in a third establishment visited, raw milk was not included in the plan.
- The national requirements do not take into account some EU requirements for potable water testing, for example *Escherichia Coli*, *Enterococcae* and no evidence of chlorine inactivation of water samples was seen.
- The procedure for milk tanker drivers to sample and test the milk collected at the holdings of origin was incomplete in 2 establishments visited and no in internal control procedures had been established to check the performance of the drivers.
- The procedures for control on receipt of raw milk were incomplete in one establishment visited (the documented volumes of milk received did not always match on different documents).
- The internal control reports did not reflect all observations made by the mission team, in particular regarding general and specific hygiene requirements in several establishments visited.

5.5.3 Traceability systems and EU separation programmes

The establishments visited had traceability systems in place. Evidence was available that the FBO's established traceability systems had been checked during the CA audits in the establishments visited. Traceability in four establishments visited was checked and did allow tracing back to the raw milk delivery.

However, the following deficiencies were noted:

- The establishments did not have procedures in place for the separation of EU and non EU production i.e. for the production of milk-based products with ingredients of animal origin from EU and non-EU approved establishments, for the use of raw milk which does or does not meet the raw milk quality control as defined in Annex III to Regulation (EC) No 853/2004 and for the storage of final products produced according to EU standards and other standards (see also Chapter 4).
- Raw materials for example, gelatine and whey powder, are sourced from and stored in intermediate establishments. Three establishments visited could not provide evidence that these intermediate establishments are approved for storage of EU eligible products and listed on the list of establishments for these types of products for export to the EU.
- The CAs did not identify significant deficiencies identified by the mission team, for example the absence of EU separation programmes, the presence of non-EU conforming products of animal origin, the use of dry milk components for production of EU export products derived from non-approved Russian dairy establishments or from dairy plants in neighbouring countries (e.g. Belarus), for which no guarantees were given of EU-eligibility, and the use of raw milk not meeting EU requirements.

5.5.4 Identification marking and labelling

None of the establishments visited stored EU eligible products at the time of the FVO visit so it was not possible to check the identification marking and labelling of such products.

5.5.5 Action in case of non-compliance

Non-compliances identified during inspection visits by the CAs are reported and well documented. Follow-up of actions are carried out during unscheduled visits.

In the case of inhibitors being detected at holding level, milk is not delivered to the dairy establishments. The CAs and FBOs stated that no inhibitors had been detected at holding level. However, inhibitors had been detected at dairy establishments and in these cases the CAs and FBOs stated that milk has been returned to the holding of origin.

The following shortcoming was identified:

- In 2 establishments visited, the FBO stated that they had not informed the CA when inhibitory substances had been detected. Evidence was available that the FBO had returned the milk to the holding of origin but no evidence could be provided that the holding of origin received the returned milk.

5.6 OFFICIAL CERTIFICATION

(see Endnote)

5.6.1 Certification from holding to milk establishments

A system is in place to certify each batch of milk sent from the holding of origin to the dairy establishments or an amount of milk sent on a monthly basis. This certificate provide guarantees on the animal health status of the herd at the holding of origin with regard testing of subclinical mastitis and testing of certain diseases, for example, TB, brucellosis and EBL and preventive measures such as vaccination against FMD, anthrax and other animal diseases.

The following deficiencies were identified:

- The certificates do not provide guarantees that milk comes from healthy animals. Instead it is stated that the area is free of infectious animal diseases, and the test dates for subclinical mastitis, for TB, brucellosis and EBL and information on preventive vaccination is provided.
- The date of testing for TB, brucellosis and EBL as certified did not match the actual date of testing in the holding for the herd in 2 farms visited.
- One certificate seen at a dairy establishment was incomplete as the amount of milk sent to the dairy establishment was not mentioned.
- Evidence was present that the certificates did not cover the total amount of milk transported from the holding of origin in one dairy establishment visited.

5.6.2 Certification of milk products for export to the EU

The certification chain for milk and milk product destined for EU export is the following:

- The OV at the dairy establishment issues a certificate (Form 2) for the consignments prepared for export to the EU. This certificate contains general product information, information on the origin and destination, and animal and public health statements. It forms the basis for further certification of products for export to the EU.
- The OV of *Rosselhoznadzor* at the dairy establishment or at the customs control point issues the certificate (Form 5) on the basis of the previous certificate (Form 2) to accompany the consignment to the Russian Border and issues and signs the certificate for export to the EU.

The following deficiencies were identified:

- The statements in the certificate (Form 2) regarding the origin of the raw milk from healthy animals were not supported by the certificates accompanying raw milk from the holding of origin.
- The certificates (Form 2) seen did not contain sufficient information to support the statements in Form 5 and the export certificates e.g. statement that milk came from healthy animals, the area was free from contagious OIE list A diseases during the last 12 months and establishments were approved for export.
- Several certificates (Form 2) were seen, which referred to laboratory results for products not covered in these certificates, such as results for products with another production date.
- Certificate Form 5 contains the statement on the radioactivity of the product before shipment, at the request of the importing country. This is not required by the EU in

Decision 2004/438/EC. The OV responsible for this certification step could not provide evidence that this was requested by the countries of destination concerned (Estonia, Greece, and Germany).

- Certificates (Form 2) were seen in one dairy establishment visited and at the custom control point, not containing statements to support the guarantees that the milk-based products meet the requirements for export to the EU in Form C as laid down in Decision 2004/438/EC. The statements in the export certificate to the EU for dairy products were therefore not supported by statements in the certificate Form 2. Instead at the custom control point visited, the OV provided evidence that the statements of these export certificates were supported by a general statement of the FBOs that the establishments concerned produced dairy products according to EU standards for a one year period (one of the establishments concerned has in the meantime been withdrawn from the list of approved establishments for export of dairy products to the EU but the OV was not aware of the updated list of EU approved establishments).
- None of the establishments visited could demonstrate that they could produce dairy products in line with EU standards regarding the raw milk quality controls and the use of raw ingredients, which undermine the statements of the veterinary certificates issued for export.
- Some certificates issued for export to the EU were not issued in the language of the country of destination and the language of the border inspection post where the dairy products enter EU territory.
- Moreover, blank model certificates for export of dairy products to the EU as laid down in Decision 2004/438/EC were not available at the veterinary control point visited.
- Certificates were seen at the veterinary control point visited containing wrong reference numbers.
- In one establishment visited the date of loading as mentioned on the certificate for export of milk products to the EU did not match the actual date of loading which was 2 days earlier.

5.6.3 Certification of milk products for transit through the EU

The following deficiencies were identified:

- Certificates seen, issued for transit through the EU, were not issued in the language of the country of transit and the language of the border inspection post where the dairy products entered EU territory.
- The certificates issued for transit through EU territory to Kalingrad at one establishment visited did not meet the requirements of the model for transit as laid down in part 3 of the Annex to Decision 2004/438/EC.

6 CONCLUSIONS

6.1 COMPETENT AUTHORITIES

The CAs have sufficient legal and enforcement powers and staff numbers. However, the co-ordination between different CAs responsible for control of dairy establishments is not always effective and the partly overlapping competencies could lead to gaps in the control system, as demonstrated with the lack of responsibility for specific EU requirements on water testing.

The staff numbers for carrying out official controls were adequate in the regions visited and the staff was well aware of the national requirements. However, the knowledge of the staff in relation to Community legislation on milk and milk-based products was insufficient.

The training provided in relation to the specific EU requirements for CAs has been insufficient.

The resources (i.e. staff, financial and equipment) in the regions and district visited were sufficient.

The control system in place for dairy establishments producing for the EU export market does not verify that specific EU requirements are taken into account.

No evidence of independent audits on EU-export requirements was provided to the mission team.

Although the CCA had distributed instructions in relation to the EU approval procedure many CAs met were not aware of these guidelines. Inspections carried out before the EU approval had often failed to take into account the specific Community requirements. No official approval for EU export is provided for the establishments.

The laboratory services operating under the MHSD and MA functioned, in general, adequately and efforts have been put into upgrading the equipment. Some deficiencies were noted in relation to internal quality controls.

6.2 ANIMAL HEALTH CONTROLS

Legislation in relation to holding registration and animal identification is under development, otherwise the situation remains the same as in 2004.

The requirements for bovine TB and brucellosis are similar to the requirements applied in the EU. However, the Russian legislation is less strict in relation to the start of the testing age for TB (6 months).

Some deficiencies were noted in relation to the implementation of the national legislation on TB and brucellosis.

Vaccination against FMD and bovine brucellosis is carried out in some regions.

6.3 APPLICATION AND OFFICIAL CONTROLS OF HYGIENE RULES AT DAIRY HOLDINGS AND MILK COLLECTION CENTRES

The application and control of hygiene rules at the dairy holdings was found to be

satisfactory in relation to most aspects. The milking hygiene was in general adequate but the conditions of raw milk storage were unsatisfactory in the collection centre and 2 holdings visited.

Some deficiencies were noted in relation to the transport temperatures of raw milk.

Contrary to the situation in the EU, the use of chloramfenicol, nitrofurans and furazolidone is not prohibited. However, no indication of the usage of these medicines was available on the holdings visited.

Although records of veterinary treatment of bovines were available on the holdings visited, some deficiencies were identified.

6.4 APPLICATION AND OFFICIAL CONTROLS OF HYGIENE RULES AT ESTABLISHMENT LEVEL

In the establishments visited, the general and specific hygiene requirements were, in general, met in relation to the facilities and production lines destined for manufacturing of possible EU export. However, some deficiencies were identified in relation to maintenance, HACCP, pest control and testing programme for potable water. The situation in relation to the implementation of HACCP-based systems had improved since the earlier FVO mission, as PCPs based on HACCP were available in all establishments visited. Traceability systems have been established. However, some deficiencies were identified as the official control systems in place follow the national requirements and the CA had failed to identify significant deficiencies in the establishments in relation to EU exports. There is no system in place which could ensure that dairy products have been produced according to EU standards (lack of procedures for separation of EU and non EU production, use of raw materials and raw milk which are non EU-eligible).

Furthermore, no separate criteria have been established for raw milk destined for possible EU export production. However, the raw milk results seen in relation to some holdings fulfilled the EU criteria thus separate production would be possible.

The testing for inhibitory substances was carried out adequately.

Adequate documentation was available on actions taken in relation to non-compliance.

6.5 OFFICIAL CERTIFICATION

The procedure in place for certification does not take into account relevant Community requirements as specified in Directive 96/93/EC and Decision 2004/438/EC.

The certificates used for the milk sent from the holding to the establishment do not provide sufficient guarantees to ensure that the milk fulfils all animal health requirements of the EU export certificate.

The internal certificates used do not provide sufficient information to support several of the statements in the export certificates laid down in Decision 2004/438/EC.

Some other deficiencies in relation to certification were also identified, including certification of milk products for transit through the EU.

6.6 FOLLOW-UP ON MEASURES TAKEN IN RELATION TO RECOMMENDATIONS OF REPORT DG(SANCO)/7188/2004

Progress has been achieved in relation to own control systems in relation to the HACCP plans and testing of raw milk for inhibitory substances. The situation of the official laboratories visited had also been improved, especially in relation to the equipment. However, the Russian CAs have taken insufficient action to address the other findings and deficiencies of the above report, including the core deficiency, lack of guarantees of separate production of EU export products from EU eligible material only.

6.7 OVERALL CONCLUSION

Then competent authorities of the Russian Federation have not established additional controls and procedures to guarantee that specific Community requirements for production of heat-treated milk products, destined for export to the European Union, are followed. The Community requirements for these products are not fully met. Several deficiencies were noted in relation to certification.

7 CLOSING MEETING

A closing meeting was held on 4 July 2008 with representatives of the CCA. At this meeting, the main findings and conclusions of the inspection were presented by the mission team. The CCA took note of these findings and conclusions.

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 provide appropriate training on the relevant EU requirements as given in Regulations (EC) No 852/2004, No 853/2004, No 854/2004 and Council Directive 96/93/EC for the Competent Authorities involved in official controls of dairy establishments from which imports to the Community are permitted to ensure that they are aware of the legal provisions, as required in points 9.2 and 11.2 of the model health certificate MILK-HTC of annex II, part 2 of Commission Decision 2004/438/EC.
2	To ensure that dairy establishments, which are on the list of establishments from which imports of milk and dairy products to the Community are permitted, comply with relevant Community requirements, in particular with those of Articles 3-6 of Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004 and that these establishments are supervised by an official service, as required by

No.	Recommendation
	Article 12, points 2(a) and (b) of Regulation (EC) No 854/2004.
3	To ensure that dairy establishments, which are on the list of establishments from which imports of milk and dairy products to the Community are permitted, source and use for the manufacturing of milk and milk products, destined for EU exports, only raw materials of animal origin from third countries and establishments which are on the list of third countries and establishments approved in accordance with Articles 11 and 12 of Regulation (EC) No 854/2004, respectively, from which imports of these products are permitted.
4	To ensure only raw milk fulfilling the requirements of Section IX, Chapter I.III.3 (a) of Annex III to Regulation (EC) No 853/2004 and of point 11.1.(a) of the model health certificate MILK-HTC of Annex II, part 2 of Commission Decision 2004/438/EC is used for manufacturing dairy products destined for export to the EU market.
5	To adapt the testing procedure for potable water in the EU export establishments to ensure all parameters as required in Annex I to Council Directive 98/83/EC are examined.
6	To take urgent action to ensure that certification of dairy products destined for EU exports is carried out according to the requirements of Council Directive 96/93/EC and Commission Decision 2004/438/EC.
7	To take urgent action to ensure that veterinary medicinal products, containing substances that are prohibited for use under EU legislation, are not used in food producing animals from which milk and milk products are obtained for export to the EU, as required in point 1 (d) part I of Chapter I of section IX of Annex III to Regulation (EC) No 853/2004.
8	To ensure that a register on veterinary treatments on food producing animals, from which milk and milk products are obtained for export to the EU, is kept on the holding, as required by Art 10 of Council Directive 96/23/EC and by Annex I, part A (III), point 8 (b) to Regulation (EC) No 852/2004, and that this register includes the withdrawal period .
9	To correct deficiencies to guarantee that exporting establishments are in line with EU standards, as required by Article 12 of Regulation (EC) No 854/2004 in the establishments visited.

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

http://ec.europa.eu/food/fvo/ap/ap_the_russian_federation_7884_2008.pdf

9 ENDNOTES

Concerning	Detail
Section 5.6	In their comments to the draft report the CCA of Rospotrebnazor stated that their intention is to issue Health Certificates for milk and dairy

Concerning	Detail
	products destined for export to the European Union and that they are ready to take part in the working out of the standard legal certificate necessary for export of domestic products.
Section 5.4.3	In their reply to the draft report, the CA of RU stated that chloramphenicol, nitrofuran and furazolidon are not included in the list of the antimicrobial preparations resolved for application in veterinary science and animal industries for treatment or prevention of infectious and noncontagious illnesses in animals in 2007-2012.

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 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 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 ß-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
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 re-published in OJ L 226, 25.6.2004, p. 83	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 intended for human consumption

Reference	OJ Ref.	Detail
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 2074/2005	OJ L 338, 22.12.2005, p. 27–59	Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
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
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 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
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.	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

Reference	OJ Ref.	Detail
	12	and Council Decision 95/408/EC
Decision 98/140/EC	OJ L 38, 12.2.1998, p. 14–16	98/140/EC: Commission Decision of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in third countries
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
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
Regulation (EC) No 1760/2000	OJ L 204, 11.8.2000, p. 1–10	Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97
Regulation (EC) No 882/2004 - Article 46 (TC)	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