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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2009-8235 - MR FINAL

FINAL REPORT OF A MISSION

CARRIED OUT IN

BULGARIA

FROM 14 TO 25 SEPTEMBER 2009

IN ORDER TO EVALUATE THE FOLLOW-UP ACTION TAKEN BY THE COMPETENT AUTHORITIES WITH REGARD TO OFFICIAL CONTROLS RELATED TO THE SAFETY OF FOOD OF ANIMAL ORIGIN, IN PARTICULAR MEAT, MILK AND THEIR PRODUCTS

Executive Summary

The objective of the mission was the evaluation of the follow-up action taken by the Competent Authority (CA) the National Veterinary Service (NVS) in response to the recommendations made in the report of a previous Food and Veterinary Office (FVO) mission to Bulgaria (DG SANCO)/2008-7950) in January and February 2008, in particular, the organisation and operation of the CA; official controls over food business operators' (FBO) compliance with general and specific rules on the hygiene of food of animal origin; the implementation of these rules by FBOs and the correct implementation of the chain of certification. In response to the recommendations made in report DG(SANCO)/2008-7950 the CA submitted an action plan which provided satisfactory guarantees to 7 out of 9 of the recommendations.

The CA is vertically integrated with the regional veterinary services (RVS) answering directly to the Director General of the NVS.

Commission Decision 2007/716/EC allows certain establishments in the meat and milk sectors in Bulgaria to not apply some structural requirements provided for in Regulations (EC) No 852/2004 and No 853/2004 until 31 December 2009, subject to certain conditions, and with products from those establishments to be placed exclusively on the domestic market. The Act of Accession of Bulgaria and Romania also provides for an additional period (recently favourably voted at a SCFCAH meeting for an extension until 31/12/2011) for Bulgaria to upgrade its dairy holdings and milk collection system to full compliance with EU requirements.

The Central Competent Authority (CCA) has generally satisfactorily addressed the recommendations made in the report DG(SANCO)/2008-7950. A well documented supervisory and audit system, adequate resources, high frequency of inspections and adequate means of sanction are in place.

Training programmes are in place and adequately documented. However, training has not been fully effective since some major deficiencies in 3 establishments, noted by the mission team (MT) during this mission, had not been detected by any level of the official supervision.

In a fourth establishment inadequate official supervision, from both local and regional level, meant that serious deficiencies noted by the MT in relation to animal welfare of horses and animal identification went unreported, and in addition, ante-mortem registers did not reflect reality.

The CA reacted quickly to those situations and initiated corrective measures. Guarantees concerning the actions taken or to be implemented concerning the 4 establishments were provided to the MT and sent to the FVO soon after the mission.

The transitional period for the upgrading of establishments has generally led to satisfactory results with the upgrading.

The CA has achieved significant increases in the percentage of EU compliant raw milk and holdings but very high numbers of small non-compliant holdings are still present.

A number of recommendations have been made to the CA with a view to addressing the deficiencies identified during this mission.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ABP	Animal By-Products
AH	Animal Health
CA(s)	Competent authority (ies)
CCA	Central Competent Authority
CP	National Contingency Plan
CRL	Community Reference Laboratory
DG SANCO	Directorate General for Health and Consumer Protection
EC	European Commission
EU	European Union
FBO	Food Business Operator(s)
FCI	Food Chain Information
FVO	Food and Veterinary Office
GDCVA	General Directorate for Control of Veterinary Activity
HACCP	Hazard Analysis and Critical Control Points
MT	Mission Team
NRL	National Reference Laboratory
NVS	National Veterinary Service
OV	Official Veterinarian
PH	Public Health

RVS	Regional Veterinary Service
SCC	Somatic Cell Count
SCFCAH	Standing Committee on the Food Chain and Animal Health
SH	Slaughterhouse
TPC	Total Plate Count

1 Introduction

The mission took place in Bulgaria from 14 to 25 September 2009 as part of the planned mission programme of the FVO. The mission team comprised 4 FVO inspectors and was accompanied during the mission by representatives from the central competent authority (CCA), the NVS.

An opening meeting was held on 14 September with the CCA in Sofia. At this meeting, the objectives, itinerary, and reporting procedures were confirmed, and information complementary to that received in the course of the preparation of the mission was requested by the MT.

2 Objectives Of The Mission

The objective of the mission was the evaluation of the follow-up action taken by the CA in response to the recommendations made in report DG(SANCO)/2008-7950 with regard to:

- CA organisation and operation,
- official controls over FBOs' compliance with general and specific rules on the hygiene of food of animal origin,
- the implementation of these rules by FBOs,
- the correct implementation of the chain of certification.

In particular, controls over meat of domestic ungulates, farmed game, wild game, minced meat, meat preparations, mechanically separated meat, meat products, raw milk and dairy products in the framework of Regulations (EC) No 178/2002, No 852/2004, No 853/2004, No 854/2004 and No 882/2004 were subject to the evaluation.

In pursuit of these objectives, the mission itinerary included the following:

Competent authorities			**Comments**
Competent authorities	Central	**1**	Opening and closing meeting
	Regional	**9**	Stara Zagora, Sliven, Haskovo, and Razgrad in regional offices and establishments. Veliko Tarnovo, Silistra, Yambol, Varna and Pazardzhik during establishment visits
Laboratories			
Official	Regional	3	Sliven, Razgrad and Silistra
Food production/processing / distribution - Activities			
Slaughterhouses		**4**	
Cutting plant/ Meat products / Minced meat		**6**	4 independent (3 of which are in transition) and 2 integrated in a SH

Milk processing plants	**6**	3 in transition
Milk collection centres	**2**	Receiving non-compliant milk

3 Legal Basis for the Mission

The mission was carried out under the general provisions of Community legislation and, in particular Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Full legal references are provided in Annex 1. Legal acts quoted in the report refer, where applicable, to the last amended version.

4 Background

The previous mission to Bulgaria with the same objectives was carried out from 28 January to 8 February 2008, the results of which are described in report DG(SANCO)/2008-7950 – MR Final (hereafter referred to as report 2008-7950).

In response to the recommendations made in report 2008-7950 the CA provided an action plan which provided satisfactory guarantees to 7 out of 9 recommendations. Additional clarifications were requested concerning 2 recommendations for which there was no response. The 2 recommendations where the CA response was considered as insufficient concerned the lack of information on actions to be taken concerning sheep and goat milk and sheep and goat dairy farms. The relevant recommendations for this mission and a summary of the CA response can be found under the relevant heading of this report.

Report 2008-7950 is accessible at: http://ec.europa.eu/food/fvo/ir_search_en.cfm

5 Findings And Conclusions

5.1 Competent Authorities

The NVS is organised at central level into 4 departments covering public health, animal health and animal welfare, diagnostics and research, administrative and financial matters. This organisation is mirrored at RVS level. It is a vertically integrated CA with the RVS Directors answering directly to the Director General of the NVS.

A more detailed description of the CA can be found in the country profile for Bulgaria which is accessible at: http://ec.europa.eu/food/fvo/country_profiles_en.cfm.

5.1.1 Designation of competent authorities

Legal requirement:

Article 4.1 of Regulation (EC) No 882/2004 requires Member States to designate the CAs

responsible for official controls.

Findings:

- There have been no changes to what was described in the report 2008-7950. The NVS is designated as a CA for all veterinary matters according to the provisions of the Veterinary Activity Law (SG No. 87/2005) and the Food Law (SG No. 102/2003).
- The Department of Public Health of the NVS is responsible for the organisation of official controls over all types of establishments approved according to Regulation (EC) No 853/2004.

5.1.2 Co-operation between and within Competent Authorities

Legal requirements:

Article 4.3 of Regulation (EC) No 882/2004 provides for efficient and effective co-ordination and co-operation between the CAs. Furthermore, Article 4.5 requires that, when, within a CA, more than one Unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

Findings:

Recommendation 5 of report 2008-7950 was "To ensure efficient and effective co-ordination and co-operation and proper flow of information between the animal health (AH) and public health (PH) units at all levels as required by paragraph 5 of Article 4 of Commission Regulation (EC) No 882/2004". In their response the CA indicated that a specific working meeting, chaired by the NVS Director General, had been held to identify all the necessary measures for improving the cooperation and coordination between the veterinary PH and AH officers when performing official controls.

- The MT was informed that no specific instruction had been issued as a result of the above-mentioned working meeting to address recommendation 5 of report 2008-7950 but that the matter had been discussed.
- No evidence was detected during this mission of inadequate cooperation or coordination between PH and AH officers at regional level concerning the holding registrations that had been the subject of Recommendation No 5 in report 2008-7950.
- The RVS send summary monthly reports to central level concerning the region's activities for all different areas of activity. However, the animal welfare checks at slaughter, performed by PH officials, are not sent to the central level AH department responsible for animal welfare.
- Despite the coordination foreseen between all central level authorities the Ordinance number 4 (SG 23 of 29.02.2008) issued by the Minister of Agriculture and Forestry contains provisions on the disposal of milk positive for residues (Animal By-products (ABP) category 2) that are not in line with the provisions in the Environment and Water Act of 2004 (issued by the Ministry of Environment) and with the provisions of Regulation (EC) No 1774/2002 (see also section 5.9.7).

5.1.3 Delegation of specific tasks related to official controls

Legal requirement:

Article 5 of Regulation (EC) No 882/2004 sets out the scope of possible delegation to control bodies, the criteria for delegation, and the minimum criteria which must be met by control bodies.

Where such a delegation takes place, the delegating CA must organise audits or inspections of the control bodies as necessary. The Commission must be notified about any intended delegation.

Finding:

There was no delegation of official control tasks within the areas covered by this mission.

5.1.4 Contingency Planning

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires that CAs have contingency plans in place, and are prepared to operate such plans in the event of an emergency.

Article 13 requires Member States to draw up operational contingency plans setting out measures to be implemented without delay when feed or food is found to present a serious risk.

Findings:

Recommendation 4 of report 2008-7950 was "To ensure that the necessary contingency plan required by Regulation (EC) No 2075/2005 is in place, and the CA is prepared to operate it in the event of an emergency as is required by the paragraph 2(f) of Article 4 of Commission Regulation (EC) No 882/2004". In their response the CA indicated that the national contingency plan (CP) would be adopted and come into effect by the end of July 2008. Each of the regional services would then be responsible for developing their regional CP.

- The NVS has issued a national level operational CP for food in general. The MT was informed about the provisions in it and, as an example of its use, about the measures taken concerning the recall of pork meat imported from Ireland at the time of a dioxin problem with that meat.
- The regions are responsible for preparing their respective CP for Trichinella. The RVS' CP for Trichinella could be seen in the 2 regions where it was requested. It was evaluated in one region and was in line with the requirements of Article 7 of Regulation (EC) No 2075/2005.

Conclusions:

The NVS has been clearly designated as the CCA for the areas covered by this mission.

Satisfactory co-operation and co-ordination were generally seen. However, the information flow system in place to routinely inform the central level about the results of animal welfare checks does not cover checks at slaughter. Ordinance number 4 (SG 23 of 29.02.2008) is not in line with national law nor with Regulation (EC) No 1774/2002 with regard to disposal of milk positive for residues (ABP category 2).

The NVS has issued a national operational CP for measures to be taken when food is found to present a serious risk and the RVS' *Trichinella* CPs evaluated were in line with Community requirements.

5.2 RESOURCES FOR PERFORMANCE OF CONTROLS

5.2.1 Legal basis for controls

Legal requirements:

Article 4 of Regulation (EC) No 882/2004 requires that the necessary legal powers to carry out controls are in place and that there is an obligation on FBOs to undergo inspection by the CAs.

Article 8 requires that the CA have the necessary powers of access to food business premises and documentation.

Finding

- The legal powers of the CA are laid down in the Veterinary Activity Law and in the Food Law. The MT was informed that these contain all the necessary powers to enter food business premises and carry out official controls.

5.2.2 Staffing provisions and facilities

Legal requirement:

Article 4 of Regulation (EC) No 882/2004 requires the CA to ensure that they have access to a sufficient number of suitably qualified and experienced staff; that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are free of any conflict of interest.

Findings:

- All inspectors employed by the NVS and the RVS carrying out PH control activities are veterinarians.
- The MT was informed that staffing levels have been reduced by 10 to 12% due to budgetary cuts. Nevertheless in the sectors evaluated the planned inspection frequencies were still being respected.
- A comprehensive system for the prevention of conflicts of interest is in place. It includes a requirement for all civil servants to annually sign 2 declarations. One identifying all their property and a second where the signatories declare that they have no direct or indirect links to private, commercial or political entities that could cause conflicts of interest. The MT saw examples of such signed declarations.

5.2.3 Staffing qualifications and training

Legal requirement:

Article 6 of Regulation (EC) No 882/2004 requires CAs to ensure that staff receive appropriate training, and are kept up-to-date in their competencies.

Findings:

- The MT could verify that training programmes were in place and followed.
- Training is organised at both central and regional levels.
- Training subjects seen included Hazard Analysis Critical Control Points (HACCP), hygiene and controls of milk and milk products, audit procedures, requirements of the hygiene package and animal welfare at slaughter and transport.
- Some significant deficiencies noted by the MT in establishments in relation to their structure and operation (see section 5.8.1) and in relation to animal welfare at slaughter and transport (see section 5.9.5) had not been previously reported by the official supervision at establishment or RVS levels and in some cases not even by the central level

Conclusions:

Adequate resources are in place to carry out the official controls and a national system for the prevention of conflicts of interest has been implemented.

A training system for officials is in place at both central and regional levels and evidence of staff participation was provided. However, training has not been fully effective since some major deficiencies in establishments, noted by the MT during this mission, had not been detected by any level of official supervision.

5.3 Organisation and implementation of official controls

5.3.1 Registration / approval of food business establishments

Legal requirements:

Article 31 of Regulation (EC) No 882/2004 requires Member States to establish procedures for the registration and approval of food and feed business establishments, for reviewing compliance with conditions of registration and for the withdrawal of approvals.

Furthermore, Commission Decision 2007/716/EC allows certain establishments in the meat and milk sectors in Bulgaria to not apply some structural requirements provided for in Regulations (EC) No 852/2004 and No 853/2004 until 31 December 2009, subject to certain conditions. Products from those establishments shall only be placed on the domestic market.

Findings:

The NVS has established a system for evaluating the completion of upgrading, and full compliance with EU requirements, of the transitional establishments listed in Commission Decision 2007/716/EC.

When upgrading is completed the FBO must submit an application stating that it has completed all works listed in its upgrading plan, requesting official confirmation of this and approval for the EU market. After the official veterinarian (OV) responsible for that establishment's supervision issues a report confirming full compliance a regional commission is nominated by the RVS Director and a deadline given for it to carry out an on-site inspection. If everything is satisfactory then a national level commission is nominated and has to carry out it's own on site verification of full compliance.

At the end of these steps it is proposed at a SCFCAH meeting to remove the establishment(s) from the list in Commission Decision 2007/716/EC allowing full access to the EU market for their products.

- Lists of approved milk collection centres were available in the regions visited. The lists identified the number and capacity of their milk storage tanks as well as the species for which they are approved.
- The NVS informed the MT that the large majority of transitional establishments would be able to comply with the deadlines in the respective upgrading plans and that the poor economic situation was the reason why some were falling behind schedule.
- Of the 6 transitional establishments visited (3 dairy, 3 meat), 1 dairy establishment was not expected to be able to carry out the upgrading plan within its deadline of September 2009. The FBO informed the MT that this was due to the economic situation. Additionally the CA informed the MT that if the upgrading of the processing area in question was not done within the deadline set the establishment would not receive approval for that product.

During the visit the MT could confirm that the area which was still not upgraded was adequately segregated.

- In another dairy establishment that had already finalised all the upgrading foreseen and was going to be proposed for full EU approval in October 2009 the MT detected structural deficiencies (see section 5.8.1) that had not been noted by the official supervision at any level. Those deficiencies should have prevented this establishment from being proposed for full approval. The CA initiated corrective measures immediately after the MT's visit.
- The following table shows the evolution of the situation concerning the numbers of transitional establishments from December 2008 to September 2009:

Establishments in transition in:		Meat establishments	Milk establishments	Total
31/12/2008		378	207	585
10/09/2009	Still in transition	144	76	219
	Considered by the CA to be in full compliance with EU requirements	213	121	334
	Closed down	22	10	32
Voted during SCFCAH meeting of 10/09/2009	Accepted as fully compliant with EU requirements	114	74	188
	Closed down	13	3	16
Deadlines for the establishments still in transition	Upgrading finished and awaiting submission to SCFCAH	55	21	76
	September 2009	36	28	64
	October 2009	21	16	37
	November 2009	32	11	43
	Total	144	76	219

Note: The discrepancy between the original total number of transitional meat establishments (378) and the sum of meat establishments (379) obtained from those in full compliance (213), closed down (22), and still in transition (144) is due to one establishment having its slaughter operations considered compliant but its meat processing operations still in transition.

- Of the 8 EU approved establishments visited (5 meat, 3 dairy) one dairy establishment with

approval for placing some products on the EU market and other products exclusively on the national market had a production area (for product for the national market) in very poor structural and maintenance conditions (see section 5.8.2) that should have prevented it from being EU approved. This had not been noted by any level of official supervision. The CA initiated corrective measures immediately after the FVO's visit.

Conclusions:

The CA has implemented an elaborate system for the approval of transitional establishments which is producing generally satisfactory results with the upgrading.

The system for approval of EU establishments provided adequate results overall, with 7 of the 8 establishments visited generally compliant with approval requirements. However, post approval 2 establishments had a number and type of deficiencies such that they no longer met the approval requirements. The CA initiated corrective measures in all cases.

5.3.2 Prioritisation of official controls

Legal requirement:

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. Controls shall be carried out at any of the stages of the production and processing chain and, in general, are to be carried out without prior warning. Controls shall be applied with the same care to exports from the Community, imports into the Community and to products placed on the Community market.

Findings:

- An instruction is in place to carry out a risk assessment of the establishments and determine their corresponding frequency of inspections. Establishments are placed in one of 4 possible risk categories High, Medium, Low and Very low with the corresponding minimal inspection frequencies of once per week, once every 10 days, once per month and once every 2 months.
- The MT could verify that this risk assessment instruction had been followed in the regions visited. The completed standardised form that had been used for performing the risk assessment was seen in the establishments. The corresponding inspection frequencies per establishment were included in the RVS annual working plan for supervisory inspections and were being respected.
- The risk assessment instruction includes 13 parameters. Amongst these parameters some of the situations foreseen for establishments to be considered high risk are situations that in practice should not have allowed the establishment to be approved, such as, for example, system of own checks not implemented, no internal monitoring system in place to take samples for bacteriological testing, FBO management does not realise the responsibility that they should bear for the safety of the food product. The MT was informed of some changes to this instruction which were already planned and that it was expected to be fully revised and re-issued around January 2010.
- The MT was informed that inspection visits are unannounced while audits are done with advance notice.

Conclusions:

The CA has implemented the requirement of risk-based official controls. The MT could see that the

foreseen inspection frequencies were being respected and that the controls also include primary production. Foreseen inspection frequencies to establishments are quite high and the actual number of inspections is even higher.

5.3.3 Sampling and Laboratory analysis

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires CAs to have, or to have access to, adequate laboratory capacity.

Article 11 establishes requirements for sampling and analysis.

Article 12 requires the CA to designate laboratories that may carry out analysis of samples taken during official controls and lay down accreditation criteria for laboratories so designated.

Commission Regulation (EC) No 2075/2005 lays down specific rules on official controls for *Trichinella* in meat.

Findings:

In response to Recommendation No 1 of report 2008-7950 "To ensure the full and complete implementation of Article 11 of Regulation (EC) No 882/2004 and to increase the level of the reliability of the laboratory results in all the areas of the official sampling and testing methods" the CA indicated that national standards for sample collection are in place and provided data concerning positive laboratory test results for *Brucella*.

In response to Recommendation No 2 of report 2008-7950 "To ensure that all the laboratories involved in the official controls comply with the requirements of Article 12 of Regulation (EC) No 882/2004 taking into consideration the derogations provided for in Article 18 of Commission Regulation (EC) No 2076/2005" the CA indicated that 22 of the official testing laboratories are accredited and 4 more are undergoing accreditation. Additionally it informed the MT that samples for official controls are sent for testing exclusively at laboratories that are accredited or in the process of accreditation.

In response to Recommendation No 3 of report 2008-7950 "To ensure that the requirements of Article 18 of Commission Regulation (EC) No 2076/2005 in the national reference laboratory (NRL) for *Trichinella* examination are complied with, in particular with regard to accreditation, allocation of resources and implementation of a quality control scheme" the CA indicated that a quality manual had been developed and that the NRL laboratory for *Trichinella* has both participated in an international ring test organised by the CRL and that it intended to organise a national ring test in September 2008 for all regional laboratories performing official *Trichinella* testing.

In response to Recommendation No 8 of report 2008-7950 "To ensure the full implementation of all provisions of Commission Regulation (EC) No 2075/2005 especially as regards the methods used for testing, systematic sampling of wild boars and testing regime in wild boar population" the CA indicated that the NRL and all regional laboratories involved had implemented the enzyme method provided for in Regulation (EC) No 2075/2005.

- A laboratory network for official laboratories was in place, comprising NRLs for example for salmonella, residues, *Trichinella*, raw milk and regional and local laboratories (in total 30). Of these 30 laboratories, 29 have been accredited (ISO/EN 17025) by the Bulgarian Accreditation body. The accreditation includes also the accredited methods.
- The NRLs have organised ring tests for pathogens (listeria, salmonella) in food of animal

origin, including milk as matrix.

- The National Diagnostic and Research Institute incorporates the NRLs for trichinae, salmonella, and campylobacter.
- The NRL for milk and milk products is part of the Directorate of Public Health in Sofia. However, the NRL for residues (the Central Laboratory for Veterinary Control and Ecology) is responsible for inhibitory substances.
- The MT visited 3 regional laboratories. The staffing, facilities and equipment seen were in general adequate and the laboratories had good documentation of their activities and testing. Standard operational procedures (SOPs) were available.
- Evidence of adequate communication was available between the NRL and the regional laboratories (seminars organised at least twice annually).
- The CCA or the NRL have not audited the regional laboratories. Instead, a system of audits has been established between the regional laboratories. The auditors carrying out these audits have been especially trained for this purpose.
- Evidence of training organised by the NRLs was available (for example, training in 2007 on *Trichinella* equipment and methodology).
- A ring test for trichinae had been organised in November 2008
- The NRL for trichinae is not yet accredited (deadline is by end of 2009).
- The test method for trichinae was the reference method as described in Chapter I of Annex I to Regulation (EC) No 2075/2005. However, the SOP for the reference method was not fully harmonised between the regional laboratories. In 1 of the laboratories visited the sample sizes in case of retesting was 5 g instead of 20 g as required in point 3.III of Chapter I of Annex I to the above Regulation.
- The trichinoscopes checked by the MT in 2 regional laboratories had 2 options for magnification, which were 24.5 and 50 times, although according to point 3.I.(o) of Chapter I of Annex I to the above Regulation in all cases of suspect areas or parasite-like shapes, higher magnifications of 60 to 100 times must be used. However, the CA stated that in case of suspicion, the samples would be sent to the NRL for verification with suitable equipment.
- The pepsin available in one regional laboratory visited was stored at room temperature although it should be kept refrigerated.
- Adequate documentation of testing of domestic and feral pig and horse carcasses was available in the regional laboratories visited and also in the establishments visited for the above domestic species.
- The NRL for milk and milk products had participated in the annual ring tests organised by the Community reference laboratory with good results.
- The NRL had organised ring test for SCC, TPC and inhibitory substances in raw milk in 2008. Most of the 17 laboratories participating in this proficiency test had adequate results, except for inhibitory substances (4 out of 17 laboratories failed in the detection of positive samples).
- Evidence of ring tests organised by the NRL for salmonella was seen. Most laboratories, but not all, had participated with success.

No evidence was available on follow-up or additional training provided to the laboratories which had not been successful in the proficiency test.

Sampling

- Annual sampling plans were available for official sampling of final products, water and checking of the effectiveness of cleaning and disinfection in all establishments visited. Samples were usually taken on a monthly basis. The official sampling had been carried out according to the plan and the results seen were within the Community requirements.

Conclusions:

The 4 recommendations from the report 2008-7950 have been generally satisfactorily addressed. However, some deficiencies remain in relation to follow-up actions for laboratories that have not been performing adequately in proficiency testing.

In addition, in one regional laboratory visited some deficiencies were noted with regard to the procedure for retesting of trichina samples and storage conditions of some reagents.

5.3.4 Procedures for performance and reporting of control activities

Legal requirements:

Article 8 of Regulation (EC) No 882/2004 requires that CAs carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

Article 9 of Regulation (EC) No 882/2004 requires CAs to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned.

Findings:

- A system for official controls as established by the NVS is in place. It is well documented and contains standardised checklists and several instructions available on the web site of the NVS.
- Reports of the official controls carried out by the different levels of supervision were available in all establishments visited. Areas targeted by the official control, the results of those controls and actions to be taken by the FBO were adequately identified in the majority of establishments visited.

Conclusion:

The official controls carried out were documented in accordance with the requirements of Community legislation.

5.3.5 Transparency and confidentiality

Legal requirement:

Article 7 of Regulation (EC) No 882/2004 requires that CAs carry out their activities with a high degree of transparency, in particular by giving relevant information to the public as soon as possible. However, information covered by professional secrecy and personal data protection is not to be disclosed.

Findings:

- The NVS has established a contract with an agency that acts as its "Press Centre". Divulging of information to the public is achieved through various means (publication, press releases, etc.) including the NVS website.
- In order to guarantee adequate confidentiality and harmonised delivery of information press releases must be approved by the Director and any live interviews can only be given at the NVS level.

Conclusion:

The system in place regarding transparency and confidentiality is in line with EU requirements.

5.4 Enforcement measures

5.4.1 Measures in the case of non-compliance

Legal requirement:

Article 54 of Regulation (EC) No 882/2004 requires a CA which identifies non-compliance to take appropriate action to ensure that the operator remedies the situation.

Findings:

- Several examples were seen indicating that when a non compliance is reported, appropriate action is taken in order to ensure that the FBO remedies the situation. These requests for action normally included the writing of reports, with recommendations and deadlines, and appropriate follow-up was carried out when needed.

Conclusion:

In general appropriate corrective action was initiated if non compliances were reported.

5.4.2 Sanctions

Legal requirement:

Article 55 of Regulation (EC) No 882/2004 states that Member States shall lay down the rules on sanctions applicable to infringements of feed and food law and other Community provisions relating to the protection of animal health and welfare and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

Findings:

- The legal powers of enforcement for the CA are laid down in the Food Act and the Veterinary Activity Law. These laws also provide the legal basis for applying administrative fines and the MT was informed that this system has been in place for at least 10 years.
- In one meat processing plant the OV who was responsible for official controls in several establishments informed the MT that she had personally proposed 10 to 12 administrative fines in 2009.
- According to the information received from the CAs the possible amount for administrative fines ranges from around 50 to up to 5 000 E URO.
- The regions must send a monthly report to the NVS about administrative fines given. In a region visited examples were seen of such reporting which stated the number of fines issued and the corresponding total amount fined. According to information from the NVS an annual report is made on administrative fines and other control related issues.

Conclusion:

There is a system in place for applying administrative fines, including a reporting system, and other sanctions, and examples were seen of administrative fines.

5.5 Verification and review of official controls and procedures

5.5.1 Verification procedures

Legal requirement:

Article 4 of Regulation (EC) No 882/2004 requires the CAs to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls.

Article 8 states that they must have procedures in place to verify the effectiveness of official controls, to ensure effectiveness of corrective action and to update documentation where needed.

Findings:

- Since January 2007 an instruction from the Ministry of Agriculture and Food has set out standards for inspections, supervision and audits in regions. According to the information received this instruction forms together with the Multi Annual National Control Plan (MANCP) the basis for frequency of inspections as well as frequency and standards for supervision. The instruction is also available on the homepage of the Ministry as well as in recent months also on the new homepage of the NVS. In addition, a specific instruction from the Ministry on application of the MANCP for raw materials and food of animal origin sets out minimum frequencies for verification procedures at establishment level and that these should be documented.
- The system of verification of official controls is direct supervision on the spot over the FBOs and OVs from regional level. This verification should be carried out at least once a year by the RVS Head of the PH Department and also at least once a year by the RVS Head of the PH Sector. The on the spot verification is performed in all approved establishments covered by this mission.
- Each time such a verification visit is carried out by the RVS 2 reports are made, one concerning the inspection of the establishment and another on the activities of the responsible OV. If there are irregularities with regard to the FBO or with the performance of the OV, the report contains recommendations addressing the irregularities and corresponding deadlines. The OV is then responsible for the follow-up of the recommendations to the FBO and must document that these have been corrected. The MT could see these reports and how the OV had followed up on the corrective actions from the FBO. The MT was also informed of what corrective actions the OV had taken to address the RVS remarks concerning irregularities with the official supervision.
- The supervision and verification system did not detect significant structural deficiencies in 1 transitional establishment and 2 EU approved ones (structural and maintenance in one, structure and operational hygiene in the other, see section 5.8.1).
- In another EU approved slaughterhouse visited significant deficiencies in relation to animal welfare of horses (see section 5.9.5.) and animal identification (see section 5.9.2) were detected which had not been reported by the supervision system in place.

Conclusion:

A well documented system of verification procedures including instructions and documented follow-up is in place. However, out of 14 establishments visited the system did not detect significant deficiencies in 3 establishments and did not report on significant deficiencies in another one. The verification procedures failed to ensure the effectiveness of official controls in the

evaluated sector.

5.5.2 Audit

Legal requirement:

Under Article 4 of Regulation (EC) No 882/2004 CAs are required to carry out internal audits, or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner.

Findings:

- The General Directorate for Control of Veterinary Activity (GDCVA) within the NVS is responsible for internal audits from central level over the activities of the regions.
- The audit teams consist of representatives from GDCVA as well as representatives from regions other than the audited region e.g. Heads of Public Health, Animal Health and Financial Departments.
- The NVS informed the MT that the audit programmes are prepared annually and that they must be approved by the CVO. According to the information received 7 of the 28 regions were audited in 2008. Audits are planned in 9 more regions in 2009.
- In a region visited a 4 day audit had been carried out in June 2008. The corresponding report was quite comprehensive. The aspects covered included accounting, property management, and remarks also on veterinary activities with most related to animal health and public health. The remarks seen on veterinary activities concerned respect of procedures, their documentation, and scheduled control frequencies but no remark was seen (positive or negative) concerning effectiveness and appropriateness of the official controls. The audit report did not contain specific recommendations to address each shortcoming. However it included a request for the RVS Director to inform, within 10 days of reception of the report, of action taken to address the reported shortcomings. The MT could see the reply from the region and that it covered the public health remarks made in the audit report.
- According to the information received from the CA training on auditing principles had been provided to representatives from all regions, to at least the Head of the Public Health Department in each RVS.

Conclusions:

A documented system of audits of the central level over the regions is in place. The audits should have covered all 28 regions within a 4 year period.

The audit report seen covered all areas of operations of the RVS but made no comments on whether the official controls had been effective and appropriate.

5.6 National measures and derogations

Legal requirements:

According to Article 10 of Regulation (EC) No 853/2004 Member States may, without compromising the achievement of the objectives of Regulation (EC) No 853/2004 adopt national measures adapting the requirements laid down in Annex III. The national measures refer to continued use of traditional methods and regions subject to geographical constraints and are subject to notification to the Commission and other Member States. National rules may be maintained or established for placing on the market of raw milk or raw cream for direct human consumption and

to permit the use of raw milk not meeting the criteria for plate count and somatic cell count.

Article 7 of Regulation (EC) No 2074/2005 allows Member States to grant establishments manufacturing foods with traditional characteristics derogations from certain requirements set out in Regulation (EC) No 852/2004.

Findings:

- No national measures or derogations are in place for foods with traditional characteristics or for regions subject to geographical constraints.
- Ordinance number 4 (SG 23 of 29.02.2008) includes a derogation for the use of non-compliant milk with regard to plate count and somatic cell count (SCC) amongst other requirements that raw milk must be pasteurised for at least 15 seconds at 71.7º C and placed on the national market only. It can also be used for the production of cheese with an ageing period of at least 60 days.

Conclusion:

National measures in place are in line with EU requirements.

5.7 Official certification

Legal requirements:

Article 30 of Regulation (EC) No 882/2004 requires that a link exists between the certificate and the consignment and that the information in the certificate is accurate and authentic.

Council Directive 96/93/EC lays down the rules to be observed in issuing the certificates required by veterinary legislation.

Findings:

- An RVS procedure concerning certification which was prepared based on the requirements of the Veterinary Activity Law, was explained to the MT. It included requirements for the OV to confirm that the batches for export have been tested in official laboratories and for the OV, or an official auxiliary, to be present during the loading of the products.
- The MT could see adequate documentation concerning exports of ovine meat to Croatia.

Conclusion:

Certification procedures for export are in line with EU requirements.

5.8 Food business operators' obligations and official controls

5.8.1 General hygiene requirements

Legal requirements:

The FBO shall comply with general hygiene requirements as set out in Annex II of Regulation (EC) No 852/2004. These provisions relate to cleaning and maintenance, layout, design, construction, siting and size of food premises.

Article 4(2) of Regulation (EC) No 854/2004 sets out that the CA shall carry out official controls to verify FBO's compliance with these requirements.

Findings:

- The MT visited 14 food producing establishments of which 6 were benefiting from transitional measures, with regard to the structural requirements, until the end of 2009.
- Ten of the establishments were found to be in compliance with the general hygiene requirements, with only a limited number of minor deficiencies.
- However, in other establishments, a number of more substantial deficiencies were noted by the MT and in a number of cases these deficiencies were not detected by the CA despite very frequent and well documented checks. In particular :
  - In a large EU approved slaughterhouse (SH) serious deficiencies were found in relation to operational hygiene (in one cold store frozen raw meat with damaged wrapping and rodent faeces was seen; maintenance of this cold store was inadequate as evidence of water from the cold units leaking onto wrapped products was also found) and structure (social rooms, including changing rooms, toilets and dormitory in an unacceptable state). Significant deficiencies were also found in relation to equipment, mostly the outdated ventilation system. Use of livestock truck cleaning facility could not be satisfactorily demonstrated, as it took a long time to find, and then to connect the equipment, and neither the length of the hose nor the water pressure was adequate to clean the trucks. Moreover, the procedure demonstrated did not match the written procedure. When the MT returned some days later evidence was seen of corrective action, with some issues already corrected, in particular meat from the cold store confiscated, and deadlines established for other deficiencies. However, the issue of dilapidated equipment was not dealt with.
  - In another large EU approved SH serious deficiencies were found in relation to animal welfare (see section 5.9.5) and animal identification (pigs and horses, see section 5.9.2). ABP was stored, prior to out loading to the rendering plant, in unidentified containers on a public road. Deficiencies were also found in relation to structure (pig line, see section 5.8.2), post mortem (see section 5.9.5) and operational hygiene (pigs, see section 5.8.2). Cleaning of trucks could not be demonstrated as the washing area was situated outside the establishment, contrary to the description in the previous year's audit in 2008 and the establishment’s own procedure. When the MT returned some days later corrective action had been initiated as well, but some issues, such as animal identification, were not corrected.
  - In a mid-sized transitional dairy establishment the MT detected structural deficiencies that had not been noted by the official supervision at any level such as lack of sufficient and adequate storage rooms resulting in incorrect layout and incorrect storage conditions; very old chilling equipment spreading condensation water with a risk of product contamination; and evidence of rodents inside the building.
  - In an EU approved dairy establishment with dual production lines (placing also some product on the national market) a processing room where exposed product was produced for the national market had shown deficiencies: exposed wooden beams, inadequate sealing of an exhaust ventilation pipe allowing easy entrance to pests, rusty pipes going into product vats, several surfaces inadequately maintained and not smooth and easy to clean and disinfect. Moreover, there was no specific equipment or dedicated facilities for cleaning the plastic crates used internally for the movement and storage of products. Several "cleaned" crates seen were dirty and some had year old labels still glued to them.

Conclusion:

Ten out of 14 establishments visited were found to be generally in compliance with the general hygiene requirements but in 4 establishments deficiencies in relation to structure, maintenance and general hygiene were detected, some of them serious. Corrective action was requested following the FVO visit.

5.8.2 Specific requirements

Legal requirements:

Article 3 of Regulation (EC) No 853/2004 sets out that the FBO shall comply with the specific requirements of Annexes II and III of this Regulation.

Article 4(3) of Regulation (EC) No 852/2004 states that FBOs shall adopt specific hygiene measures regarding compliance with microbiological criteria for foodstuffs, compliance with temperature control requirements, and sampling and analyses.

Details on microbiological criteria foodstuffs shall comply with are set out in Regulation (EC) No 2073/2005 and Article 4(2) of Regulation (EC) No 854/2004 sets out that the CA shall carry out official controls to verify FBO's compliance with the requirements of Regulation (EC) No 852/2004 and No 853/2004. These cover a range of items with regard to requirements for SHs, cutting plants, emergency slaughter, game handling, raw milk and dairy products and other products of animal origin.

Findings:

In response to Recommendation No 6 of report 2008-7950 "To strengthen official controls over the FBOs' own check programmes as required by paragraph 3 of Article 4 of Regulation (EC) No 854/2004 in order to ensure higher reliability of the results, especially in the area of the raw milk collection system" the CA indicated that a specific Ordinance (No 4 of 19.02.2008) had been developed to address the requirements concerning production, storage and transportation of raw cow milk and milk products and that together with an instruction on sampling of raw milk to be signed on 16.06.2008 the utmost guarantees could be provided on reliability of the results of analysis of those samples.

- The FBOs visited had their own microbiological sampling programme for final products and process hygiene. The results seen were satisfactory. The final products were tested, depending on the products, for pathogens (Escherichia coli, Salmonella, and listeria). The analyses were carried out in official laboratories.
- The temperature control charts on pasteurisers and chillers/freezers were in general adequate with one exception.
- Microbiological sampling and testing of carcasses and of minced meat and meat preparations complied with Regulation (EC) No 2073/2005 in all the establishments visited but one. In this establishment the frequency for bacteriological carcass sampling was not respected and one sampling parameter, namely Enterobacteriaceae, was excluded. This had not been detected by the official supervision at establishment or at RVS level.
- The MT evaluated the slaughter of lambs in 2 slaughterhouses. In both of them, the slaughter results were acceptable. However, in both cases, between 50 and 100% of carcasses seen had minor visible contamination, (mostly wool but in some cases faecal). In one slaughterhouse contamination was limited to the back legs, and in the second often covering the belly. Moreover, in one SH, cleaning of lamb carcasses with paper towels was seen, despite the fact, that already in 2007 the FVO indicated that this method was inadequate.
- Hygiene of slaughter of pigs was acceptable. However, a number of hygiene deficiencies were noted in one establishment e.g.: splashing due to washing of floors and equipment when carcasses were present, insufficient numbers of sterilisers and wash basins in relation to the staff working on the platform.

Conclusions:

Most of the establishments visited were found to be generally in compliance with the specific hygiene requirements but deficiencies in relation to slaughter hygiene in the slaughter of lambs were detected.

In one establishment carcass sampling frequency and parameters tested were not in line with Regulation (EC) No 2073/2005.

5.8.3 HACCP-based systems

Legal requirements:

On the basis of Article 5 of Regulation (EC) No 852/2004 the FBO shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.

Specific requirements for HACCP-based procedures in SHs are detailed in Section II of Annex II to Regulation (EC) No 853/2004.

Article 4 of Regulation (EC) No 854/2004 requires that official controls in respect of all products of animal origin in the scope of Regulation (EC) No 854/2004 shall include audits of HACCP-based procedures.

Findings:

- HACCP procedures are checked by both OVs carrying out routine supervision and by the RVS Audit Commissions which visit each establishment at least once a year.
- HACCP based procedures were in place in the establishments visited.
- However, in a number of cases, the procedures were not adequate, not complete or not updated. In other cases they were correctly drafted but not respected. In particular, in one SH, the procedure for out-loading of animals for slaughter was not adequate (important items such as dealing with animals unable to stand/walk were missing), and in two others, procedures for cleaning of trucks were not respected.
- In one dairy establishment a power supply cut had caused the FBO to lose all its pasteurisation records that had been kept exclusively electronically. Therefore no documented evidence could be provided identifying the batches with their respective heat treatment parameters and amount of milk pasteurised. The only documented evidence of an adequate heat treatment was a register of daily alkaline phosphatase testing.

Conclusions:

HACCP based systems were in place in the establishments visited. However, in a number of cases, the procedures were not complete or not respected and in one establishment no adequate documentation could be provided concerning the official control of one of the identified critical control points.

The official supervision performed the required audits over the FBOs' HACCP based procedures but did not detect the deficiencies reported by the MT.

5.8.4 Identification marking and labelling

Legal requirements:

Provisions for the identification marking of a product of animal origin are made in Article 5 and Annex II, Section I to Regulation (EC) No 853/2004.

Products from establishments listed in the Annex to Commission Decision 2007/716/EC must bear

a different health mark from that provided for in Article 5 of Regulation (EC) No 853/2004 and shall only be placed on the domestic market.

Article 3 of Directive 2000/13/EC sets out the particulars on the labelling of foodstuffs to be delivered as such to the ultimate consumer.

Regulations (EC) No 1760/2000 and No 1825/2000 set out specific labelling requirements for beef meat.

Findings:

- In most meat establishments visited, frozen meat wrapped on pallets – was labelled in such a way, that the identification mark would not be destroyed at removal of wrapping, contrary to the required in Annex II Section I to Regulation (EC) No 853/2004. The same was noted in several establishments in relation to carton packed meat.
- With one exception all establishments had correctly applied the diamond shaped mark when labelling products that could only be placed on the national market.
- In one establishment butter in storage was sometimes identified simultaneously as produced from compliant and non-compliant milk. Therefore the final identification with the mark for EU trade could not be guaranteed.

Conclusion:

Identification marking and labelling were in general in accordance with EU requirements in all establishments visited, however in a number of meat establishments, the identification mark on wrapped or packed cut meat was not properly applied. In one dairy establishment the correct identification of butter could not be guaranteed. The official supervision had not detected these shortcomings.

5.8.5 Traceability

Legal requirements:

According to Article 18 of Regulation (EC) No 178/2002 the traceability of food and food-producing animals and any other substance intended to be incorporated into a food shall be established at all stages of production, processing and distribution. The FBO shall have in place systems and procedures to identify from whom they have been supplied and the other businesses to which their products have been supplied.

Article 4(6) of Regulation (EC) No 854/2004 requires that verification of compliance with traceability requirements takes place in all approved establishments.

Findings:

- Traceability systems were in place in the establishments visited and subject to official controls. In particular, in a number of milk establishments, traceability exercises were carried out by the CA at each visit to the establishment, practically every month.
- With the exception of the establishment with incorrect identification marking of butter, and which also had unclear lot numbering for sheep cheese, traceability could be successfully demonstrated during exercises carried out by the MT.

Conclusion:

Traceability systems were in place in the establishments visited and subject to official controls in general compliance with traceability requirements could be verified.

5.9 Official inspection tasks in establishments for verification of the food business operators' compliance

5.9.1 Food chain information

Legal requirements:

According to Article 3 of Regulation (EC) No 853/2004, the FBO shall comply with the relevant provisions of Annex II and III to this Regulation. In particular the FBOs operating SHs must as appropriate, request, receive, check and act upon food chain information in respect of all animals, other than wild game, sent or intended to be sent to the SH.

According to Article 5(1) of Regulation (EC) No 854/2004 the OV shall carry out inspection tasks in SHs also as regards food chain information

Findings:

- According to national legislation animals for slaughter must be controlled on-farm by a licensed veterinarian (employed by the State) and be found clinically healthy the day before being sent for slaughter. According to information received from the NVS the system is the same for all species of slaughter animals and has been in place for over 10 years. All movement documents are controlled by the OV on arrival of the animals to the SH.
- The legal basis for the system in place for pigs is Order N RD 09-460/25.7.2008, which requires a licensed veterinarian to carry out the ante-mortem inspection at the holding of provenance and sign a movement document (which is a nationally prescribed template) that is sent to the SH accompanying the pigs. In addition, specifically for pigs a declaration of ownership must state that no vaccination for Classical Swine Fever has been made and that no forbidden drugs have been used. The template form used as a movement document includes all the information required in Annex I, Section 4, Chapter X to Regulation (EC) No 854/2004.
- As regards other species of slaughter animals (e.g. bovines, sheep and goats) the CA stated that the movement documents accompanying animals for slaughter contain all the food chain information as required by Article 3 of Regulation (EC) No 853/2004. However, the template forms used for movement documents do not provide headings, with corresponding fields, to include all the required food chain information on diseases on the farm with food safety aspects, results of samples taken and the name and address of the private veterinarian attending the holding of provenance.
- Food chain information was not available for slaughter horses from Romania as either relevant information was missing from the certificate, passports were not duly completed or the horses could not be linked to the documentation (see 5.9.2).
- In the SHs visited the food chain information was not systematically requested by the FBOs and consequently not checked by them. Instead the FBOs relied on the controls by the OV.

Conclusions:

A system is in place in order to check the required food chain information. In general the OV took over the responsibilities of the FBO and carried out the checks as regards food chain information.

The system in place for pigs is in line with the requirements of Art 5 and Annex I, Section 4, Chapter IV and X to Regulation (EC) No 854/2004 on ante-mortem inspection at the holding of provenance of pigs and certification.

However, since Regulation (EC) No 854/2004 does not include the possibility of carrying out ante-

mortem inspections at the holding of provenance for species other than pigs and poultry this same system is not in line with EU requirements for other slaughter species. Food chain information was not available for slaughter horses from Romania.

5.9.2 Ante-mortem inspection

Legal requirements:

Article 5(1) of Regulation (EC) No 854/2004 requires that the OV carries out inspection tasks, including ante-mortem inspection of all animals before slaughter in accordance with the general requirements of Section I, Chapter II of Annex I of Regulation (EC) No 854/2004.

Findings:

- Records of ante-mortem inspections were available in all SHs visited and the clinical inspections were carried out in line with the EU legislation.
- The MT did not see any records of animals which were rejected for slaughter because of disease or transport damage or missing food chain information in the SHs visited.
- In one SH (slaughtering exclusively small ruminants) the ante-mortem records did not register any animals injured or dead during transport even if long travelling distances were frequent. In a subsequent revisit, in the course of this mission, the MT could see that this had been corrected.
- In another SH a horse had died during transport and several horses were sick (see also section 5.9.5.). However, there were no remarks in the ante-mortem register on the dead animal and its cause of death and the diseases of the sick horses.
- In addition, in the same SH the MT found discrepancies between the number of horses arriving and registered in the Reception and ante-mortem protocol (28 horses) and in the AM inspection journal (26 horses). In addition the total slaughter statistics for 2009 showed 38 horses less than the total number of animals indicated in the intra-Community certificates (ICC). Moreover, the ante-mortem register seen did not indicate any problems in the past with horses injured, sick or found dead at arrival although this same means of transport had previously brought horses several times from exactly the same origin.
- In this same establishment pigs for slaughter did not bear any identification and the FBO stated that this was not a problem since the animals came from a holding also owned by him and therefore did not need identification. This is neither in line with Council Directive 2008/71/EC nor with specific national legislation (Ordinance 61). The official supervision although aware of the situation, had not made any remarks about this lack of identification and contested that identification of these pigs was required.

The MT noted serious deficiencies in relation to the identification of 2 consignments of slaughter equidae seen in this same SH and the 2 ICC for these consignments of horses from Romania:

- Passports for 25 horses had all been issued on 16 September, a day after the ICC had been issued.
- In none of the passports, was the animal description completed nor was the statement “fit for human consumption, “bun pentru consum uman” signed by the OV.
- Of the 28 animals in the consignment 7 had no microchips or any other means of identification, and 3 others had microchip numbers which did not match the list attached to the ICC.
- Three horses lacked passports.
- The number of horses indicated in the ICC was 25 although 28 horses were present in the truck.

- The identification of animals as given in the ICC (age, sex) did not match with the data in the passports in 19 out of 25 cases.
- Considering that the animals had been identified with microchips on the same day that the passports were issued (16 September 2009) the validity of the certification in the ICC is questionable.
- The estimated time of journey indicated in the ICC was 4 hours. Due to the poor road conditions and the lack of a bridge over the Donau in the region, this is unrealistic.
- In several certificates the destination of slaughter horses was not the SH but a holding located in the same town as the SH. This holding is not registered as an assembly centre and therefore the dispatch of slaughter animals to it is not in line with Council Directive 90/426/EEC. However, the Bulgarian CAs had allowed slaughter horses to be unloaded there.

Follow-up on-the-spot

- The MT returned to the establishment during the mission and examined the actions taken. Evidence of sending the 2 dead horses to the rendering plant was available. The FBO had written a complaint to the Horse Collection Centre in Romania. The OV in the establishment had written a report to the RVS and the RVS had written a report to the CCA. A copy of the RVS report was received. The RVS stated that the Romanian CA had arrived on the following day to investigate the matter.
- The MT found an internal register of the FBO which contained data used for calculation of the staff salaries. The data comprised records of carcasses worked upon and monthly summaries. The MT compared this data with the slaughter data for horses and pigs received from the CA, and with the data of horse and pork carcasses analysed for trichinae. The data matched for pork carcasses but for horses there were nearly always 2-5 more horses in the internal documentation of the FBO. This observation and the witnessed irregularities with the observed unloading and its incorrect official documentation leads to the strong suspicion that the consignments of slaughter horses from Romania often comprise more horses than given in the certificates.
- The MT requested to receive further information in relation to the CA action taken with regard to this situation at the latest during the closing meeting. These guarantees were received. The actions taken included applying sanctions to one of the local OVs. No sanctions were imposed over the supervisory local OV or the regional supervision. The OV from the regional veterinary service defended the FBO strongly in the final meeting.

Conclusions:

Ante-mortem inspections when carried out at the SH were generally in line with the EU legislation.

However, in one SH a dead horse and some sick and injured horses, seen on arrival by the MT, were not registered in the ante-mortem register, and pigs arrived for slaughter without the legally required identification with the knowledge of the official supervision. In addition serious deficiencies with the ICC accompanying equidae for slaughter had also never before been reported by the official in spite of all the indications seen that this was not an isolated incident

The local and regional official supervision over this establishment were inadequate.

5.9.3 Post-mortem inspection

Legal requirements:

Article 5(1) of Regulation (EC) No 854/2004 requires that the OV carries out inspection tasks, including post-mortem inspection in accordance with the general requirements of Section I, Chapter II of Annex I and the specific requirements of Section IV of Regulation (EC) No 854/2004.

Findings:

- Systems were in place in the SHs visited to ensure that all carcasses of pigs and horses were sampled and that samples were sent to the regional laboratories for examination. Carcasses were only released after a negative result for *Trichinella* .
- The post-mortem records including records of results of *Trichinella* examination were found to be sufficient.
- Post-mortem inspections were carried out by the OVs in line with EU legislation. However, in 2 SHs some necessary examinations were not always performed on pigs, eg: hearts were not always incised and sometimes not correctly incised, the submaxilliary lymph nodes were not always visually inspected and incised and the mesenteric lymph nodes were not always sufficiently inspected and palpated.
- In one SH the OV did not have an adequate post-mortem inspection post in the pig slaughter line. The OV had to either work in an area with inadequate space (his work was disturbed by the activities of the workers dressing the pig carcasses) or at another point of the platform at which the pig carcasses arrived with the pleura removed.

Conclusion:

Post-mortem registers were generally in line with the EU legislation. Some deficiencies were seen in the post-mortem examination.

5.9.4 Health marking

Legal requirement:

Article 5(2) of Regulation (EC) No 854/2004 requires that health marking of carcasses of domestic ungulates, farmed game mammals other than lagomorphs and large wild game as well as half-carcasses, quarters and wholesale cuts shall be carried out in SHs and game-handling establishments by, or under the responsibility of, the OV when official controls have not identified any deficiencies that would make the meat unfit for human consumption.

Finding:

- No deficiencies in relation to health marking were found by the mission team in the establishments visited.

Conclusion:

Health marks seen were applied as foreseen in the legislation.

5.9.5 Animal welfare at the time of slaughter or killing and transport

Legal requirements:

Article 5(1) of Regulation (EC) No 854/2004 requires that the OV carries out inspection tasks, including animal welfare. Council Directive 93/119/EC sets out Community rules with regard to the protection of animals at the time of slaughter or killing.

Council Regulation (EC) No 1/2005 comprises the Community rules on the protection of animals during transport and related operations.

Findings:

- Spare stunning equipment was available in all SHs visited and, with the exception of some pigs in one SH, animals were effectively stunned
- The MT detected severe deficiencies in relation to animal welfare in a large multi-species SH receiving slaughter equidae from Romania on the day of the MT visit. The number of slaughter equidae received (all from Romania in 2008-2009) has increased significantly (according to Traces data, 14 consignments with 239 horses were received in 2008 and 83 consignments with 2 189 horses in 2009, until 30 August 2009) coming from 3 collection centres, none of which appears on the official list of approved collection centres in Romania .
  - At unloading of a horse consignment coming from a Romanian collection centre, 4 out of 28 horses were found lying on the floor. Of those, one had died during transport, and another lying close to the unloading bay was unable to get up was not killed instantly on the spot but only one hour later after the other 26 live ones had been unloaded.
  - Many of the arriving animals were cachectic, lame, or otherwise in poor condition.
  - The truck did not fulfil the requirements for a long distance transport as given in Chapter VI of Annex I to the Regulation (EC) No 1/2005, although according to the ICC the transport had lasted more than 24h.
  - Although the FBO and the CAs realised that there was an animal welfare problem with the consignment, they did not initiate any emergency measures as required in I.6 of Annex A, to Council Directive 93/119/EC
  - According to data received from TRACES, the SH had regularly received consignments from the same collection centre, using the same, inadequate truck as the transport means for horses. However, the CA had not taken any action in relation to those transports.
  - According to the TRACES certificates the random physical checks of the consignments had in several cases been carried out 2-3 times, in one case even 7 days after the departure time given in the certificate. The estimated travel time had been indicated as between 1-4 hours.
- In the same SH several hundred sheep were kept overnight in a lairage with poor ventilation and such a high concentration of ammonia that it was irritating to the eyes and difficult to breathe. The high ammonia concentration was caused by a leak in the cooling system of the cold store attached which belonged to the establishment. Despite remarks of the MT the animals were not moved to another lairage, available on-the-spot and with a proper ventilation.
- In this SH, the construction of the pig stunning pen was such that the pigs were not properly restrained and the person putting on the tongs had to approach the pigs from the front, resulting in the movement of the pigs backwards. The stunning of the pigs was also not always effective.
- Animal welfare checklists were available in the SHs visited and the MT was informed that they were filled in daily. The checklists covered controls of the animals both on arrival and during slaughter. In the 4 SHs visited no deficiencies had ever been noted in relation to animals arriving, transport conditions or stunning.
- The monthly reports seen on animal welfare in relation to transport of slaughter animals did not record deficiencies. For example, in one SH visited the maximum loading density for sheep had in some cases been clearly exceeded but the CA had still ticked this point in the checklist as being adequately complied with. On the same SH premises, a Bulgarian livestock truck seen was not maintained in such a way that the animals were protected from injuries that the damaged wooden ceiling of the lower floor with protruding boards, could cause to the animal. The reports seen did not indicate any deficiencies.

Conclusions:

The control on animal welfare of slaughter equidae during transport in Bulgaria is inadequate and does not guarantee that the animals are spared from undue suffering.

The deficiencies noted by the MT in relation to animal welfare at transport and at the time of slaughter and lack of reporting on them from the official supervision indicate that animal welfare controls are not ensuring compliance with EU welfare requirements.

5.9.6 Criteria for raw milk

Legal requirements:

Article 8 of Regulation (EC) No 854/2004 requires that Member States shall ensure that official controls with respect to raw milk and dairy products take place in accordance with Annex IV to Regulation (EC) No 854/2004 and the CA carries out official controls to verify that health requirements and hygiene requirements for raw milk and colostrum are complied with and monitors the checks carried out for plate count, SCC and residues of antibiotic substances.

Furthermore, Chapter 4 of Section B of Annex VI of the Act of Accession of Bulgaria and Romania provides for certain transitional measures, until 31 December 2009, as regards deliveries and processing of raw milk in Bulgaria. These allow for milk processing establishments listed in Chapters I and II of the Appendix to Annex VI to receive deliveries of raw milk that do not comply or have not been handled in accordance with the requirements in Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, subchapters II and III provided that the farms supplying that milk must be mentioned on a list maintained by the Bulgarian authorities.

Milk and/or milk based products originating from these farms can only be placed on the national market and Bulgaria shall ensure gradual compliance in the upgrading of dairy farms and the milk collection system to ensure that the requirements in Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, subchapters II and III are fully complied with by 31 December 2009.

During the mission the SCFCAH meeting of 16/09/2009 voted to extend the deadline for upgrading of dairy farms and milk collection systems by 24 months.

Findings:

Recommendation No 7 of report 2008-7950 was "To fully implement the national strategic plan with regard to category III farms and sheep and goat dairy holdings to ensure gradual compliance in upgrading dairy farms and the milk collection system as is required in paragraph (e) of Chapter 4 of Section B of Annex VI of the Act of Accession of Bulgaria and Romania". The CA indicated in their response that all the requirements applicable to raw cow's milk derived from group III farms are laid down in Ordinance No 4 of 19.02.2008.

The categorisation of dairy holdings according to their facilities, equipment and milking hygiene and raw milk quality is given in Ordinance 4. The dairy holdings are classified into 3 groups. Group I holding are fully compliant with Community requirements for raw milk, milking facilities and equipment. Group II holdings are EU compliant in relation to the facilities and equipment, but not in relation to the raw milk. Group III holdings are non-compliant in relation to both aspects.

- According to the data received, most dairy holdings belong to group III. For example, in the region Razgrad the division was 94 holdings in group I, 2 holdings in group II, and 5 132 in group III. Group III holdings are usually holdings with only a few cattle.
- The National Strategic Plan for dairy animal breeding development and optimisation of raw milk quality covered the period 2006-2009. The number of holdings in group I has increased

by 50% approximately from January 2008 to July 2009, with the number of holdings in Group II reduced by 10% in the same period. Currently 2 327 holdings are in group I and 920 in group II. No overall national data on the number of holdings in group III was provided to the MT.

- During the same time period the amount of milk produced by group I holdings increased from 246 242 T to 409 146 T and in group II holdings it dropped from 69 482 to 46 082 T. No overall national data on the amount of milk from group III holdings was provided.
- A system for controls on raw milk quality was in place in the regions visited.
    - The FBOs sent the raw milk for analysis in the framework of their own controls to the regional laboratories, where the milk was analysed for SCC, TPC and inhibitory substances. The testing frequency was one sample per month for SCC and inhibitory substances and 2 samples per month for TPC. A system was in place for the calculation of geometrical averages and reminder letters were sent to holdings or milk collection centres when the Community limits were exceeded.
    - In addition to the own control sampling programme the raw milk was also subject to official sampling. These samples were taken once a month. The results for both own control and official testing were available at the FBOs visited.
- The results seen which originated directly from holdings were in general in compliance with the Community requirements whereas the results seen of raw milk which originated from milk collection centres exceeded the Community limits for TPC.
- The raw milk sampling was carried out mostly at holding level (sampling from each trucks' different compartments) when the milk was collected by the FBO directly from the individual (mostly larger) dairy holdings. However, when the milk was collected from milk collection points, the samples were taken from the raw milk tank at the collection point, not from the milk derived from individual holdings. The CA stated that the samples taken from the holdings would be taken by the truck driver in case these would need to be re-tested for inhibitory substances.
- The CA stated that in addition, all holdings listed as group I and all milk collection centres were sampled and tested once annually for raw milk criteria. The MT could see documentation of these annual visits in a milk collection centre visited.
- All results seen in relation to inhibitory substances were negative.
- The official test method used for inhibitory substances in 2 regional public health laboratories visited did not include a positive control. The bacterial strains used in this test (cultures of *Lactobacillus bulgaricus* and *Streptococcus thermophilus*) were not standardised (received from a local dairy).
- The routine method used for own control (a commercial kit detecting beta/lactams and tetracyclins) did not include instructions for using positive controls. In one own control laboratory the person carrying out the test stated that the positive controls must be in the kit but other than that she did not know how to use them.
- One milk collection centre visited, unannounced and chosen by the MT, had no hot water and the temperature indicator of the collection tank was positioned in such a way that it was not possible to see it. The refrigerator used for storing samples was filthy and mouldy. Records of the origin of the raw milk and of the amounts delivered were available. Each delivery received was also tested for acidity, protein and fat content and sediment. Evidence was available on the annual testing of the dairy herds for bovine tuberculosis and brucellosis.
- The other milk collection centre visited had adequate facilities, equipment and documentation. The required listing of holdings supplying that milk collection centre, with

ear tag numbers of each registered bovine, was present on site.

Conclusions:

The CA has achieved significant increases in the percentage of EU compliant raw milk and holdings but very high numbers of small non-compliant holdings are still present.

The system in place for raw milk quality control is operating as described. Sampling of raw milk for testing on SCC and TPC is not carried out at the level of individual holdings when milk is collected at milk collection points.

The quality of the raw milk in relation to SCC was satisfactory both for individual holdings and collection centres but the TPC levels regularly exceeded the Community limits when originating from milk collection centres.

The quality controls of methods used for testing of raw milk for inhibitory substances are incomplete.

5.9.7 Animal by-products

Legal requirements:

Article 5(1) of Regulation (EC) No 854/2004 requires that the OV carries out inspection tasks, including on animal by-products (ABP).

Annex II to Regulation (EC) No 1774/2002 sets out the requirements for the collection and transport of ABP, including requirements for identification, records and the use of commercial documents.

Findings:

- The collection, transport and disposal of ABP as well as identification were in line with Regulation (EC) No 1774/2002 in most meat establishments visited.
- In a SH visited ABP was stored in a non-satisfactory way in an open container on an easily accessible public road outside of the SH premises. However, corrective measures had been taken by the FBO after the visit.
- In one dairy plant visited there were no arrangements in place for the correct disposal of milk with residues (Category 2 material). Moreover, in Art. 23 of Ordinance no. 4 dated 19 February 2009 it is stated that in the presence of inhibitors in raw milk exceeding the limit values, the milk shall be destroyed by disposal into the urban sewage system or otherwise into trenches designated by the Mayor of the municipality. This disposal is not in line with the requirements of Article 5.2 of Regulation (EC) No 1774/2004. Moreover, according to the information received from the CCA in June 2008 during a FVO mission on ABP (DG (SANCO)/2008-7736) a legal ban on disposal of liquid waste into trenches and municipal sewage systems had then recently been introduced in environmental legislation (Environmental and Water Act).
- According to information received from the CCA the dairy plants which are not disposing of whey or other liquid waste for feeding purposes (Category 3 material) in line with Commission Regulation (EC) No 79/2005, do not have the possibility to dispose of whey or other liquid waste in line with the Regulation (EC) No 1774/2004. Instead it is disposed of into trenches and municipal sewage systems, which is not in line with Regulation (EC) No 1774/2002 and the Environmental and Water Act.

Conclusions:

The requirements concerning ABP were generally met in the meat establishments visited.

Deficiencies were seen on the disposal of liquid waste (both Category 2 and 3) from dairy plants, which was not in line with Article 5.2 and 6.2 to Regulation (EC) No 1774/2004 respectively.

6 Overall Conclusions

The CCA has generally satisfactorily addressed the recommendations made in the report DG(SANCO)/2008-7950. A well documented supervisory and audit system, adequate resources, high frequency of inspections and adequate means of sanction are in place.

Training programmes are in place and adequately documented. However, training has not been fully effective since some major deficiencies in establishments, noted by the MT during this mission, had not been detected by any level of official supervision.

The transitional period for the upgrading of establishments has led to generally satisfactory results with the upgrading.

The system for approval of EU establishments provided adequate results overall, with 7 of the 8 establishments visited generally compliant with approval requirements. However, post approval 2 establishments had a significant number and type of deficiencies to question their approval status. The CA initiated corrective measures in all cases.

In one establishment inadequate official supervision, from both local and regional levels, meant that significant deficiencies in relation to ante-mortem inspection, animal welfare and animal identification went unreported. Ante-mortem registers in this establishment did not reflect reality also.

The system of verification procedures in place was unable to detect the severe supervisory shortcomings noted by the MT concerning establishments' supervision.

The CA has achieved significant increases in the percentage of EU compliant raw milk and holdings but very high numbers of small non-compliant holdings are still present

7 Closing Meeting

A closing meeting was held on 25 September 2009 with the representatives of the CCA. At this meeting the MT presented the findings and preliminary conclusions of the mission and advised the CCA of the relevant time limits for production of the report and their response. The representatives of the CCA acknowledged the findings and conclusions presented by the MT and discussed some points concerning the situation found in one particular establishment.

Additional information and documentation concerning some other points, and the requested guarantees on action already taken and planned in order to address the findings in the establishments visited was also provided.

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.

N°.	Recommendation
1.	To take further measures to improve verification procedures in order to ensure that the lack of effectiveness of the official controls, noted by the MT in 4 establishments, are also detected by those verification procedures, as required by Article 8 of Regulation (EC) No 882/2004.
2.	To take further measures to ensure that the FBOs comply with their obligations as laid down in Chapter II of Regulation (EC) No 853/2004 and with the general and specific hygiene requirements set out in Article 4 of Regulation (EC) No 852/2004.
3.	Urgently to take further measures to ensure that staff responsible for official controls are able to identify non-compliances when verifying the FBO's compliance with the relevant requirements, to guarantee that official controls are effective as required in Article 4.2(a) of Regulation (EC) No 882/2004.
4.	To ensure that the FBOs sampling and microbiological analysis of carcasses are in line with the requirements set out in Regulation (EC) No 2073/2005, and to improve the official controls regarding this aspect in line with Article 1 of Regulation (EC) No 2073/2005.
5.	To ensure that the FBOs' HACCP based systems are in line with Art. 5 of Regulation (EC) No 852/2004.
6.	To review the current food chain system in place so as to fully implement the requirements for food chain information for large and small ruminants and horses as foreseen in Annex II, Section III of Regulation (EC) No 853/2004.
7.	Urgently to address the inadequate official supervision, at both local and regional levels, which failed to report on the serious deficiencies of animal welfare of horses, animal identification and ante-mortem inspection, as required by Article 4 of Regulation (EC) No 882/2004.
8.	To ensure that the post-mortem examination in pigs is carried out in compliance with Art. 5, (1)(d) and Annex I, Section IV of Regulation (EC) No 854/2004.
9.	Urgently to improve the official controls on animal welfare during transport and at slaughter to ensure that the animal welfare conditions during transport and at the time of slaughter or killing are in accordance, with Regulation (EC) No 1/2005 and with Council Directive 93/119/EC respectively.
10.	To continue efforts to improve the quality of the milk collection system, dairy holdings and raw milk quality in order to bring them to full compliance with the requirements of Chapter I (II and III), Section IX of Annex III to Regulation (EC) No 853/2004, within the deadlines prescribed in Chapter 4 of Section B of Annex VI of the Act of Accession

N°.	Recommendation
	of Bulgaria and Romania respectively.
11.	To ensure that adequate arrangements for collection and disposal of liquid waste (Category 2 and 3) from dairy plants are in place as required by Art. 3.3 of Regulation (EC) No 1774/2004.

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

http://ec.europa.eu/food/fvo/ap/ap_bg_2009-8235.pdf

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Dir. 90/426/EEC	OJ L 224, 18.8.1990, p. 42-54	Council Directive 90/426/EEC of 26 June 1990 on animal health conditions governing the movement and import from third countries of equidae
Dir. 93/119/EC	OJ L 340, 31.12.1993, p. 21-34	Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing
Dir. 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
Dir. 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
Dir. 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
Dir. 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
Dir. 2000/13/EC	OJ L 109, 6.5.2000, p. 29-42	Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs
Reg. 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
Reg. 2075/2005	OJ L 338, 22.12.2005, p. 60-82	Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for Trichinella in meat

Legal Reference	Official Journal	Title
Reg. 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
Reg. 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
Reg. 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
Reg. 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
Reg. 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
Reg. 1774/2002	OJ L 273, 10.10.2002, p. 1-95	Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption
Dec. 2007/716/EC	OJ L 289, 7.11.2007, p. 14-37	2007/716/EC: Commission Decision of 30 October 2007 laying down transitional measures for structural requirements of certain establishments in the meat and milk sectors in Bulgaria provided for in Regulations (EC) No 852/2004 and (EC) No 853/2004 of the European Parliament and of the Council
Reg. 1760/2000	OJ L 204, 11.8.2000,	Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000

Legal Reference	Official Journal	Title
	p. 1-10	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
Reg. 1825/2000	OJ L 216, 26.8.2000, p. 8-12	Commission Regulation (EC) No 1825/2000 of 25 August 2000 laying down detailed rules for the application of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the labelling of beef and beef products
Reg. 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
Reg. 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
Accession Treaty		
Reg. 1/2005	OJ L 3, 5.1.2005, p. 1-44	Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97