

EXHIBIT 60



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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

CANADA

FROM 23 NOVEMBER TO 06 DECEMBER 2010

IN ORDER TO EVALUATE THE OPERATION OF CONTROLS OVER THE PRODUCTION OF FRESH MEAT, MEAT PRODUCTS, MINCED MEAT, MEAT PREPARATIONS AND CASINGS FOR HUMAN CONSUMPTION DESTINED FOR EXPORT TO THE EUROPEAN UNION UNDER THE AUSPICES OF THE AGREEMENT BETWEEN THE EUROPEAN COMMUNITY AND CANADA ON SANITARY MEASURES TO PROTECT PUBLIC HEALTH AND ANIMAL HEALTH IN RESPECT OF TRADE IN LIVE ANIMALS AND ANIMAL PRODUCTS

Executive Summary

The report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Canada from 23 November to 6 December 2010.

The objective of the audit was to evaluate the capacity of the Canadian authorities to implement and to enforce the sanitary measures and the control systems put in place to fulfil the requirements for fresh meat, meat products, minced meat and meat preparations of bovines, pigs, horses and large game (farmed and wild), and casings for human consumption intended for export to the European Union (EU). The audit was carried out under the auspices of the "Agreement between the European Community (EC) and Canada on sanitary measures to protect public health and animal health in respect of trade in live animals and animal products."

Official controls are carried out regularly and as stipulated by applicable Canadian standards. A new control system, the Compliance Verification System (CVS) was implemented in 2008. The system includes verification tasks, follow-up and enforcement measures. The system was applied as described. With the exception of one plant the establishments visited were of an acceptable standard and follow-up controls by the Competent Authority (CA) were largely effective. Inadequate application of equivalent standards in this establishment and a lack of enforcement of Canadian rules was noted. The activities of the establishment were suspended voluntarily and a written guarantee was received by the Canadian authorities. Procedures for export approval of establishments are in place and were followed for recent approvals of establishments. Nevertheless, establishments were approved for certain activities without having the required facilities. A yearly review of the licence to operate is carried out including verifications of the guarantees for export attestations. Nevertheless, a verification of the structure of the establishments and hygiene of operations are currently not carried out.

For the production of beef and pig meat the Canadian authorities require split systems with regard to the use of growth promoters or feed additives. The system of Ractopamine Free Pork meat was adequately implemented. Split systems for the production of beef in the establishments visited were noted. No requirement for split systems is in place for the production of bison and horse meat. Since August 2010 horses destined for slaughter should be accompanied by an Affidavit signed by the last owner, documenting the identity of the horse, medical treatments for the previous six months and confirming that growth promoters have not been used. The majority of horses slaughtered for EU export are imported directly from the US and this requirement also applies. The imported horses were accompanied by the signed Affidavit of the last owner. Nevertheless, no official guarantee was requested from the United States (US) authorities that Affidavits were verified and could be considered as reliable. Trichina controls in pig and horse meat were implemented and adequately supervised. Animal welfare controls at slaughter of horses provided an equivalent guarantee whereas such a guarantee for the slaughter of pigs could not be provided. Some shortcomings with regard to certification of export consignments were noted.

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

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
BSE	Bovine Spongiform Encephalopathy
CA	Competent Authority
CAR	Corrective Action Request
CCA	Central Competent Authority
CCIA	Canadian Cattle Identification Agency
CCP	Critical Control Point
CFAP	Centre for Food-borne and Animal Parasitology
CFIA	Canadian Food Inspection Agency
CVS	Compliance Verification System
EC	European Community
EID	Equine Identification Document
EU	European Union
FBO	Food Business Operator
FSEP	Food Safety Enhancement Programme
FVO	Food and Veterinary Office
HACCP	Hazard Analyses and Critical Control Points
ID	Animal Identification
IIC	Inspector In Charge
MHMOP	Meat Hygiene Manual of Procedures
MOP	Manual of Procedures
OIE	World Organisation for Animal Health
OV	Official Veterinarian
QMS	Quality Management System
RVO	Regional Veterinary Officer
US	United States
VIC	Veterinarian in Charge

1 INTRODUCTION

The audit took place in Canada from 23 November to 6 December 2010. The audit was undertaken as part of the FVO's planned mission programme. The audit team comprised three FVO inspectors. The FVO audit team was accompanied during the audit by representatives from the central competent authority (CCA), the Canadian Food Inspection Agency (CFIA).

An opening meeting was held on 23 November 2010 with the CFIA. At this meeting the FVO audit team confirmed the scope of and itinerary for the audit, and additional information required for the satisfactory completion of the audit was requested.

2 OBJECTIVES AND SCOPE OF THE AUDIT

The **objective** of the audit was to evaluate the implementation, controls on and the enforcement of the sanitary measures in place aimed at ensuring fulfilment of the requirements applicable to exports from Canada to the EU of the commodities included in the scope of the audit and the follow up of the previous mission (ref. DG(SANCO/2007-7387). The requirements are set out in the Agreement between the EC and the Government of Canada on sanitary measures applicable to trade in live animals and animal products.

The **scope** of the audit covered the structure and operation of public health control systems in Canada's meat sector over the production of fresh meat, meat products, minced meat and meat preparations of bovines, pigs, horses and large game (farmed and wild), and casings for human consumption destined for export to the EU.

In pursuit of this objective the following sites were visited:

			Comments
Competent Authorities	Central		Opening and closing meeting.
	Regional	3	Alberta, Ontario and Quebec provinces.
	Offices	2	1 Area Office, 1 District Office
Laboratories		3	Trichinella examination of horse meat.
Slaughterhouses		4	Slaughter of horses, cattle and bison (3). Slaughter of pigs (1)
Farmed game handling establishments		3	
Wild game handling establishments		1	
Cutting plants		4	Attached to the slaughterhouses visited
Cold stores		1	
Livestock holdings		3	1 horse feedlot and 1 bison farm, 1 pig farm (Quebec province)

		Comments
<i>feedmills</i>	1	
<i>Border Posts</i>	1	<i>At the Border to US (Quebec province)</i>

3 LEGAL BASIS FOR THE AUDIT

- The Agreement between the EC and the Government of Canada.
- The general provisions of EU legislation and, in particular, Article 46 of Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Other relevant EU legislation, which was taken into consideration during the audit and legal acts quoted in this report are provided in the Annex to this report.

4 BACKGROUND

The Agreement between the EC and the Government of Canada on sanitary measures applicable to trade in live animals and animal products (hereafter referred to as: the Agreement) approved on behalf of the Community by Council Decision 1999/21/EC contains inter alia the list of live animals and animal products for which equivalence of sanitary measures has been established for trade purposes, and where equivalence of these measures has not yet been concluded upon. It also establishes which standards apply in trade.

In the context of exports from Canada to the EU, for animal health measures as regards fresh meat, meat products, farmed game meat, wild game meat, minced meat and casings for human consumption, the Agreement provides that existing certification is to be used. As regards meat preparations, Canadian exports should meet EU requirements.

Details concerning the animal health situation can be found at the World Organisation for Animal Health (OIE) website: <http://oie.int.eng.en/>

According to the OIE a number of diseases affecting bovines, pigs and horses have never occurred or have not occurred for almost 50 years, including: foot and mouth disease, rinderpest, African horse sickness, Glanders, African swine fever, classical swine fever and swine vesicular disease. For public health measures, the Agreement provides that as regards fresh pig meat, agreed model health attestations are to be used, attesting to the products meeting the relevant Canadian standards. For fresh meat of bovines and horses, meat products, farmed game meat and casings, minced meat, meat preparations, and wild game, existing certification is to be used. Certain special conditions are set out under Footnote A (I) of the Agreement.

Canada is included in Annex II to Commission Regulation (EU) No 206/2010 authorising Member States imports of fresh meat and in Annex II, Part 2 of Commission Decision 2007/777/EC authorising Member States imports of meat products.

A previous audit to Canada to review the structure and operation of control systems in Canada's meat sector for export to the EU took place in 2007. The report is published on the Commission website: http://ec.europa.eu/food/fvo/index_en.cfm

The CCA's response to the majority of the recommendations contained in that report were assessed by the FVO to be acceptable. However, the response to three recommendations relevant for the scope of this audit e.g. identification and movement controls of live horses to be slaughtered for the EU, controls of veterinary drugs used in horses and bison and residue controls and certification for exports were not considered to be satisfactory.

The CFIA provided the following trade statistics to the FVO audit team:

Figures in kgs	2007	2008	2009	2010 ¹
Horse meat	8 686 764	14 958 059	12 646 519	7 125 866
Beef	56 916	0	334	31 718
Bison	1 401 461	904 741	861 314	299 747
Pork	0	0	538 129	379 167
Farmed game	26 631	33 856	60 567	630
Casings	14 985	16 390	0	0
Meat products	18 316	24 675	50 458	13 868

No messages have been reported for the import of meat and casings of Canadian origin in the period from the previous audit March 2007 until this audit via the Rapid Alert System for Food and Feed.

5 FINDINGS AND CONCLUSIONS

5.1 LEGISLATION AND COMPETENT AUTHORITIES

5.1.1 Legislation

Legal requirements

The recognition of animal health sanitary measures is laid down in the Agreement. The legal requirements regarding animal health measures are established in Regulation (EU) No 206/2010.

Certain EU legislation as quoted in points 6, 8, 9, 10, 15, 16 and 17 of Annex V to the Agreement has been repealed.

Legal requirements regarding public health measures applicable to the sector audited are established in the following main EU legislation: Regulations of the European Parliament and of the Council (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004, (EC) No 854/2004, (EC), (EC) No 2073/2005, (EC) No 2075/2005 and (EC) No 999/2001.

Special conditions as quoted in points 8, 9 and 17 (meat products, farmed game meat and casings

¹ Not covering the whole year

for human consumption) are set out under Footnote A(I) and concerning points 6, 9 and 15 (fresh meat, farmed game meat and minced meat) specifically mentioned under the respective points.

Requirements for certification conditions for the introduction into the EU of fresh meat, farmed game meat, wild game meat and minced meat intended for human consumption are laid down in Regulation (EU) No 206/2010. For pig meat the certification conditions are laid down in Commission Decision 2005/290/EC.

Requirements for certification conditions for the introduction into the EU of meat preparations are laid down in Commission Decision 2000/572/EC.

Requirements for certification conditions for the introduction into the EU of meat products for human consumption are laid down in Decision 2007/777/EC.

Requirements for certification conditions for the introduction into the EU of casings for human consumption are laid down in Commission Decision 2003/779/EC.

Findings

The main federal Canadian legislation regarding public health sanitary measures regulating the production of meat intended to be exported to the EU comprises the following:

- Food and Drug Act and Regulations
- Health of Animal Act
- Meat Inspection Act
- Meat Inspections Regulations

Consumer Packaging and Labelling Act (as it relates to food) - Consumer Packaging and Labelling Regulations.

Standards are laid down in the Meat Hygiene Manual of Procedures (MHMOP) and in the Food Safety Enhancement Programme (FSEP).

Observations

- The Meat Inspections Regulations incorporate by reference other applicable legislative and technical documents such as the Food and Drug Act and Regulations, the MHMOP and the FSEP.
- The MHMOP elaborates the provisions of the Meat Inspection Act. Meat Hygiene Directives are issued as needed in order to amend the MHMOP and includes in Chapter 11.7.3. specific provisions for export to the EU. As regards wild game and minced meat and meat preparations reference is made to applicable EU legislation. Similarly, for farmed game, although equivalence is agreed in principle, reference is made to applicable EU legislation as well.
- The FSEP is used by the FBO to develop their control programmes and the Hazard Analysis Critical Control Points (HACCP).

Conclusions

For commodities for which equivalence has not been agreed relevant EU requirements are

applicable. In addition, for one commodity, farmed game, for which equivalence is agreed in principle, relevant EU legislation is applicable.

5.1.2 Competent Authorities

Legal requirements

Article 46 of Regulation (EC) No 882/2004 stipulates that EU controls in third countries shall verify compliance or equivalence of third country legislation and systems with EU feed and food law and animal health legislation. These controls shall have particular regard to points (a) to (e) of the aforementioned article, point (g) is covered in section 5.4 of this report as regards horses.

Findings

5.1.2.1 Organisation of Competent Authorities

The CFIA is responsible for ensuring official supervision in federally registered establishments. Approval for export, import controls, export controls and certification are also under the CFIA remit.

5.1.2.2 Competent Authorities' powers, independence and authority for enforcement

The CFIA has the necessary power, independence and authority for enforcement under the applicable legislation, and can initiate proceedings for serious non-compliances resulting in imposing fines or imprisonment.

5.1.2.3 Supervision

Details regarding official supervision of establishments in the evaluated sectors are laid down in the MHMOP.

Regular official controls in EU approved premises are usually carried out by CFIA inspectors. In slaughterhouses, in addition to inspectors (official auxiliaries), veterinarians are also assigned to carry out ante-mortem and post-mortem inspection and other official tasks as the Official Veterinarians (OV)/Veterinarian In Charge (VIC).

In cutting plants, meat processing establishments and cold stores regular supervision is required by CFIA inspectors – Inspector in Charge (IIC).

The implementation of the FBOs obligations are verified by the CFIA inspectors or OVs via the CVS. The minimum frequency for the verification tasks is set on a risk basis and can vary from daily up to yearly verifications (for more details see Chapter 5.1.2.6).

Regulatory system audits are carried out by quarterly visits via a Quality Management System (QMS) system by the Regional Veterinary Officers (RVO) or regional CFIA supervisors, corresponding to an internal system audit evaluating the efficiency of the VIC supervision and of the inspectors control in order to identify weaknesses in the control system. The intention is that the outcome can be used for appropriate revisions of the system. The QMS system consists of a CFIA file review and an on-site review with each inspector.

Observations

- In general the system was implemented as described. Nevertheless, in one case it was noted that the supervisory system had not detected some non-compliances, and others were not adequately followed up (more detail under point 5.1.2.6).

5.1.2.4 Training of staff in the performance of official controls

According to the CFIA, new employees in meat hygiene (veterinarians or inspectors) require specific training before their first posting through the National Meat Hygiene Training Programme. The first three assignments should be conducted at a beef, pork and poultry slaughterhouse, the fourth should be at a processing plant and the fifth should be one or several secondary species (e.g. horse) slaughterhouses. On average the first and second training sessions for red meat species should comprise four weeks, the poultry training three weeks, the training at a meat processing establishment four to five weeks and the training regarding secondary animal species inspection one week for each species. Furthermore, basic meat hygiene training has to be completed, consisting of two week modules each.

Observations

- When requested, training files of officials were available and also covered EU relevant topics.

5.1.2.5 Resources

The CCA informed the FVO audit team that across the country the total number of CCIA staff has increased from 4 498 to 7 053 in the last 12 years, mainly reflecting that more staff were based locally.

Observations

- In all establishments and offices visited sufficient resources were available for the official control.

5.1.2.6 Organisation of control systems

The relevant recommendation from the previous audit in 2007 was:

"To ensure that official supervision of EU approved food businesses is carried out in the frequency and manner stipulated in Canadian standards, as detailed in Section 11.7.3 of the Meat Hygiene Manual of Procedures including the appointment of appropriately trained staff."

The CCA undertook to request the OV through a specific monthly CVS export task to ensure that the establishments comply with the EU requirements.

The CVS introduced since 2008 includes verification tasks to be used by CFIA inspection staff to access compliance. Each task includes detailed procedures to follow for the verification. The CVS is integrated with enforcement options.

Each verification task is assigned a minimum frequency based on food safety risk, legislative requirements, export requirements and Food Business Operators (FBO) past record and is established yearly through an establishment task profile. In addition to the ordinary verification tasks, the so-called 9 000 tasks, such as follow-up, supervision and a monthly tour through the establishment has been included since 1 October 2010.

Three documents are used: the verification work sheet, the verification report and the corrective action request (CAR).

Observations

- The verification report is sent to the FBO.

- The verifications also include a rating as acceptable, acceptable with comments (30 days of notice for rectification) or unacceptable.
- In case of unacceptable findings a CAR is issued.
- If the situation is not rectified within an established deadline, the VIC can ask for a management review of the situation by a Management Review Team. This final review can result in an acceptable situation or alternatively the issue of a Final Notice of Non-Compliance and suspension of the approval or licence to operate and ultimately in the refusal to operate.
- In general the system was applied as described but a few shortcomings were noted:
 - In one establishment visited the yearly review of the establishment approval was not documented.
 - Despite several shortcomings lasting for some years (several shortcomings already noted during the last audit in 2007) in one establishment visited, the enforcement tools included in the system were not used efficiently, allowing unacceptable conditions in the establishment to persist since the last audit with regard to structure, maintenance and operational hygiene not complying with the Canadian standards (for more details see points 5.6.3 and 5.6.8).

5.1.2.7 Documented control procedures

The relevant recommendation from the previous audit in 2007 was:

"To ensure that with regard to controls over meat and meat products documented procedures reflect changes in EU legislation and amendments to procedures applied in Canada."

The CCA undertook to update the MHMOP with regard to EU legislation and procedures applied in Canada with regard to beef labelling, microbiological standards, *Trichinella* controls, Ractopamine-free pork certification programme, specific *Salmonella* requirements for Finland and Sweden and phasing out wooden pallets based on the upcoming equivalence determination.

In general, Canadian legislation as specified in the Agreement is the basis for official controls. The MHMOP contains in its Chapter 11.7.3 additional requirements (regarding hygiene and controls) for export of fresh meat and meat products to the EU. It is accessible by all parties on the website of the CFIA.

Observations

- The Canadian requirements for exports of meat and meat products to the EU do not address the following in sufficient detail or in an updated format and is therefore not included in the verification work sheets for official controls (see point 5.1.2.6. for more information):
 - Requirements with regard to EU-eligibility and traceability of bison and elk destined for slaughter concerning medical treatment and movement records based on owner declarations. In addition, the issue of elks for slaughter coming from farms receiving regular veterinary inspections, where, so far, this declaration has been based only on a yearly declaration. The CCA explained that this would require relevant updates to the Agreement in order to create the necessary legal basis.
 - Testing of meat destined for Sweden and Finland (reference to former EU-legislation and not to Regulation (EC) No 1688/2005) in Chapter 11.7.3.2.2.(5) of the MHMOP.

- Sourcing of casings to be from only EU-eligible sources and the associated certification requirements. The issue of species and country of origin of the casings or treated intestines is not addressed, including reference to applicable EU legislation concerning additional Bovine Spongiform Encephalopathy (BSE) animal health attestations depending on the BSE risk status of the sourcing country (Decision 2007/777/EC, Commission Decision 2007/453/EC, Section C and D of Annex IX to Regulation (EC) No 999/2001).

Conclusions

In general, a well organised and well implemented supervisory system of official controls is in place. Nevertheless, the system was not able to detect the inadequately applied official controls and enforcement measures in one of the establishments visited.

The new CVS is in general well implemented. Nevertheless, the enforcement tools were, in particular, in one case not sufficiently implemented, due to inadequate application of Canadian requirements.

The Canadian legislation implementing EU requirements is not fully up to date to reflect Canadian requirements with regard to eligibility controls and traceability of bison and elk, and EU requirements concerning sourcing and certification of casings for export to the EU and *Salmonella* testing of meat for export to Finland and Sweden.

5.2 HOLDING REGISTRATION, ANIMAL IDENTIFICATION

Legal requirements

As regards **fresh meat of bovines, horses, farmed and wild game** intended for human consumption, point II.2 of the relevant model certificates "BOV", "EQU", "RUF" and "RUW" in part 2 of Annex II to Regulation (EU) No 206/2010 sets out conditions regarding the animal health situation for the animals and the situation on their holding or from their hunting area of origin that must be certified.

Similarly, point 10 of the model certificate for **fresh meat of domestic swine** of Annex II of Decision 2005/290/EC sets out conditions regarding the animal health situation for the animals and the situation on their holding of origin.

All the above conditions imply that systems for holding registration and animal registration should be in place.

Findings

"To ensure that applicable provisions (Part XV of the Health of Animals Regulations) for identification and movement controls, in particular for bison to be slaughtered for EU export are fully implemented."

The CCA undertook to carry out an audit by March 2008 of the FBOs reporting within the established deadline (30 days) to the database for slaughtered bovines and bison.

The registration of premises (holdings) is mandatory in the provinces of Quebec, Alberta and Manitoba for cattle and sheep. In other provinces and for other species (pigs, horses, bison) holding registration is voluntary. Regulatory initiatives are currently under way for the development of a mandatory traceability system in the cattle, sheep and pig sectors.

Currently individual identification of cattle, bison and sheep is mandatory. Animals are identified via a double tagging system consisting of Radio Frequency Transmitters.

There are identification and dangle tags (cattle and sheep in Quebec, all dairy cattle in Canada) or a single tag. Animals have to be tagged when moved from the farm of origin.⁶ Animal identification of other species is voluntary.

Two databases are in operation in Canada: 'Agri-Tracabilité Quebec' in the province of Quebec and another operated by the 'Canadian Cattle Identification Agency' (CCIA). The CFIA has access rights to both databases.

Observations

- Since the previous audit the traceability of cervidae in Quebec province is now mandatory and reporting of cattle birth and movements has also become mandatory in Alberta province.
- There is no possibility of data sharing from the existing databases.
- Pigs for slaughter under the Ractopamine Free Programme in the slaughterhouse visited were accompanied by an affidavit confirming the origin of the animals but the animals were not identified in a way that could confirm the origin of the animals.
- Horses for slaughter were branded or carried a back-tag which they had received at auction markets (for more details see point 5.4).
- Bison sent for slaughter were identified with a unique identifier.

Movements

Movements of the identified species cattle and bison are recorded at slaughter (tags of slaughtered animals are retired), at movement to a rendering plant and at export. The premises where tags retire have to notify the database within 30 days of the tag retirement. Slaughter of unidentified cattle and bison is authorised provided the origin of the animal can be established.

Movements of cervidae are accompanied by health certificates.

Bovines and pigs reared under the two programmes under which beef and pork meat are EU eligible (Hormone Free Beef and Ractopamine Free Pork) require specific identification and have to comply with traceability requirements.

Observations

- About 300 CFIA officials have access to the CCIA database. Only provincial officers in Quebec have access to 'Agri-Tracabilité'.
- An audit has shown that about 95 % of bovine animals arriving for slaughter are bearing approved ear tags. When cross-checking with the database of reported slaughter a compliance rate of only 75 % was noted. However, in one selected case it was verified that slaughter of bison was notified within 30 days of slaughter and that the tags were retired.
- Overviews over tags delivered to certain premises can only be obtained via a specific request to the CCIA from the CFIA officials.
- Since 31 July 2010 it has been required that horses destined for slaughter should be accompanied by a signed (by the last owner) Affidavit documenting the identity and the non-use of growth promoters and medical treatments for the previous six months in order to document the eligibility of the animals to be slaughtered for export to the EU.
- Currently about 100 pig farms are registered under the 'Ractopamine-free Pork Certification

Programme' (for more details see Chapter 5.3) and about 37 bovine feedlots are registered with CFIA under the 'Hormone Free Beef Programme'.

- Regarding slaughter of bison and elk a similar type of affidavits have been proposed by the CFIA, however, they are not adopted yet (for more details see Chapter 5.4).

Conclusions

Progress was noted with regard to the registration of cattle farms, which is now compulsory in the major part of Canada.

No legally binding requirements have been set up yet for eligibility controls and traceability of bison and elk to be slaughtered and exported to the EU.

5.3 RACTOPAMINE-FREE PRODUCTION OF PIG MEAT DESTINED TO BE EXPORTED TO THE EU AND ITS CONTROLS

Legal requirements

Point 9.1 of the health certificate for pig meat (Annex II to Commission Decision 2005/290/EC) requires the OV to certify that the fresh meat complies with the relevant Canadian public health standards and requirements (which have been recognised as equivalent to the EU standards and requirements, and specifically, is in accordance with the Meat Inspection Act and subsections (2) and (3) of section 11.7.3 on the European Union of Chapter 11 of the Meat Hygiene Manual and is fit for human consumption.) Subsection (2) stipulates that only pork meat from pigs raised without hormonal growth promotants certified by the CA are eligible for export to the EU.

According to Article 29.1 of Council Directive 96/23/EC, third countries from which Member States are allowed to import animals and products of animal origin covered by this Directive, have to provide guarantees for residue monitoring of groups of residues and substances referred to in Annex I of the Directive. Beta-agonists are included in Group A, point 5, of this Annex. In particular, the third paragraph of this point requires that guarantees must have an effect at least equivalent to those provided for in this Directive and must, in particular, meet the requirements of Article 4 and specify the particulars laid down in Article 7 of this Directive and meet the requirements of Article 11.2 of Council Directive 96/22/EC.

Findings

Ractopamine has been approved since July 2005 by the Health Canada as a pig feed ingredient. The compound can be sold over the counter directly to feedmills and producers for incorporation into pig feed. From this background a CFIA Ractopamine Free Pork Programme has been established. The programme is an integrated system including requirements for the feedmill and the producer at the farm with regard to issuing of affidavits for the production, sampling, documented procedures at the feedmill, farm and slaughterhouse and verification procedures.

The CFIA Ractopamine Free Pork Programme has been implemented since January 2009. It includes three dedicated feedmills, around 100 dedicated farms and one dedicated slaughterhouse.

Animal feeds/feedmills

In relation to animal feedstuff the main national legislation is the following:

- The Feed Regulations and the Health of Animals Regulations.

Three feedmills, which must not use Ractopamine, have been nominated by the FBO which is in charge of the programme, to produce the Ractopamine free feed.

Observations

- Three yearly visits are carried out by the CFIA regional feed division, including verification of all ingredients used for all feeds produced.
- No sampling for Ractopamine takes place. According to the standard this would only take place in the case of a mixed production e.g. the feedmill also produces feed with Ractopamine. According to the CA no shortcomings with regard to the use of Ractopamine has been found.
- The feedmill is also audited yearly by the VIC to verify the guarantees with regard to application of the CFIA Ractopamine Free Pork Programme. The audits carried out did not show any shortcomings.
- According to the manufacturer of the Ractopamine free pig feed, the concentration of Ractopamine should be 5 ppm in pig feed rations from feedmills producing feed containing Ractopamine. Nevertheless, the detection limit for the laboratory method for Ractopamine is 1 ppm which means that only carry-over of more than 20 % would be detected in feedmills also producing feed containing Ractopamine.

Holdings

Holdings intending to produce under the CFIA Ractopamine Free Pork Programme have to apply to the FBO slaughterhouse that is in charge of the programme and has to provide a protocol for the production of Ractopamine free pigs. When the programme has been accepted by the FBO, the feedmill is informed, who in turn notifies a database managed by the pig producers of Canada about listing the farmers included in the programme.

Observations

- The Programme allows for a mixed production system e.g.: raising both pigs with and without feed containing Ractopamine.
- Records were kept of feed used, including statements of the feed to be free of Ractopamine.
- A procedure was in place authorising pigs for transport to the slaughterhouse only when the plans for feeding the animals had been verified and for the issuing of an Affidavit.
- Medical records were in place. However, the cause of treatment and number of animals treated was not recorded.
- Piglets supplied were accompanied by an affidavit but their traceability back through the system was not adequate due to missing lot numbers on supply documents that could be linked to the treatment records.

Slaughterhouse/Cutting Plant

The slaughterhouse was dedicated only to slaughter Ractopamine free pigs from the integrated system and a protocol was in place describing the eligibility controls of the animals received for slaughter and for segregation of meat if non-eligible meat was received for cutting.

Observations

- The Programme allows for a mixed system of slaughter e.g.: slaughtering both pigs raised with and without Ractopamine.
- Pigs were accompanied by an Affidavit assigned to the lot of pigs received. However, the lot was not identified, due to the concept of dedicated production of only Ractopamine free pigs.
- Verification of the eligibility was made by the FBO. Pen cards to be used for ante-mortem inspection could only be issued if the actual farm identity on the affidavit was verified by accessing the database of the Canadian pig producers.
- Five samples were taken per year according to the National Residue Monitoring Programme for examination for Ractopamine. No urine samples are taken at farm level. According to the CA it is of no relevance in a single string production system (dedicated feedmills, farms and slaughterhouses).

Conclusions

Despite a few shortcomings detected the Ractopamine Free Pork Programme as implemented can be considered largely as adequate to guarantee that pork meat exported to the EU will be free of Ractopamine.

The detection limit for Ractopamine is not adequate to detect even relatively high levels of carry-over of Ractopamine in the feedmills, which raises some concern about proper verification tools in the case of the application of a mixed production system.

5.4 CONTROL MEASURES REGARDING HORSE MEAT DESTINED FOR EXPORT TO THE EU

Legal requirements

Requirements for certification conditions for the introduction into the EU of fresh meat of horses intended for human consumption as laid down in point II.1 of the relevant model certificate "EQU" in part 2 of Annex II to Regulation (EU) No 206/2010 sets out conditions regarding the public health attestations. Subsection II.1.7 of the certificate stipulates that only horse meat from horses covered by residue monitoring plans submitted in accordance with Council Directive 96/23/EC in particular Article 29 are eligible for export to the EU can be certified by the CA.

According to point II.1.4., an ante-mortem inspection in accordance with Chapter II, Section I of Annex 1 to Regulation (EC) No 854/2004 has to be carried out before meat can be declared fit for human consumption

Findings

The relevant recommendations from the previous audit in 2007 concerned:

"To ensure that the provisions for identification and movement controls of animals, in particular

live horses to be slaughtered for export to the EU allows the verification of the EU eligibility of these animals as specified in Council Directive 96/23/EC."

The CCA undertook to discuss the options of either limiting the slaughter of horses for export to the EU having an individual treatment record or hold all horses for an extended period of time prior to slaughter.

"To review the import controls over live horses for immediate slaughter and to ensure that the Canadian import requirements as set out in the Health of Animals Regulations and the Import Reference Document are consistently met."

The CCA undertook to amend the Automated Import Reference System to ensure that it reflects the CFIA Import Reference Document (Animal health Regulations).

"To ensure that the controls over the use of veterinary drugs in particular in live horses and bison and residue controls are in line with the provisions of relevant Community legislation, in particular Council Directives 96/22/EC and 96/23/EC."

The CCA undertook, in the absence of legal requirements for having medical treatment records, to discuss with the industry, either a compulsory participation in a quality assurance scheme or require a Livestock Information Sheet with the compulsory information included as a prerequisite for EU-eligibility of the horses.

An action plan for exports of horse meat produced by the CFIA in response to the request of 17 April 2009 (by letter from the Commission Services) to Third Countries exporting horse meat to the EU to implement systems on equine ID, traceability and keeping of medical records in order to provide equivalent guarantees to those provided for in EU legislation was forwarded to the Commission Services on 23 October 2009. The action plan was evaluated and was acceptable. Nevertheless, the CFIA was requested to update the Commission Services concerning guarantees that could be delivered by the US authorities regarding the treatment history of US horses exported to Canada for direct slaughter or rearing.

A letter was sent to the Commission Services on 26 March 2010 in which the CFIA advises of the continuing discussions with the US authorities on the implementation of the action plan requirement concerning US authorities' official controls on the treatment history of horses to be exported to Canada for slaughter/rearing. No further action taken by the CFIA in this regard was noted.

Live horses for immediate slaughter are imported from the US. According to the CFIA, approximately 66 000 live horses were imported annually from the US for immediate slaughter out of a total annual slaughter of horses of approximately 93 000. All of these horses were slaughtered in EU approved premises. In light of the restrictions of horse slaughter in the US an increase has taken place since the previous audit.

There are less animals imported to Canada for other purposes (breeding, feeding), only about 5 000.

From 31 July 2010 slaughterhouses exporting horse meat must have a system of records of all animals for slaughter including individual description, records of illness and treatment (for the last six months) and a so-called Equine Identification Document (the EID), signed by the owner as an affidavit. The EID is applicable for all horses including Canadian and US horses. Both US and Canadian horses for slaughter have to be accompanied by an EID and moreover the US horses are accompanied by a health certificate and an owner-shipper certificate.

In addition a group of horses assembled with the intention of being utilised for human consumption can be eligible for slaughter with a group declaration of the identification and of the medical treatment and the illness, covering a minimum six month period. This system has to be officially approved and controlled appropriately but only covers one feedlot in Canada so far and covers only

a minor part of the horses slaughtered for export to the EU.

5.4.1 Controls of imported horses

An inspection Protocol has been issued on the controls of the US horses to be carried out at the border.

The FVO audit team was informed that live horses imported for immediate slaughter are, from their entry into Canada until their slaughter, under veterinary control (sealed truck, documentary control and report to custom point of entry after slaughter).

A zoosanitary certificate with the following conditions is required for imports of live horses for immediate slaughter:

- The animal was inspected by a veterinarian within 30 days preceding the date of importation.
- The animal was found by a veterinarian to be free of any communicable disease.
- The animal was, to the best of the knowledge and belief of a veterinarian, not exposed to any communicable disease within 60 days preceding the date of the inspection.

Observations

- The import certificates issued by the US authorities make the following statements as to the residency, fitness for travel and health status:
 - Residency: 'These horses have resided in the USA at least 60 days immediately prior to exportation or since birth'.
 - Fitness for travel: 'These animals were found health and fit for transport'. Fit for transport means that on the day of inspection no animal has an illness or an injury or any other condition that could be aggravated during transport causing the animal to suffer. The exporter has been advised that any deterioration in health and physical condition that may render the animals unfit for travel may result in rejection of entry of the shipment into Canada.
 - Vesicular Stomatitis: 'During the previous 21 days these animals have not been in any US specific states (Arizona, Texas, New Mexico)'.
 - Health Status: 'The animals were found to be free of any communicable diseases and to the best knowledge not exposed to any communicable diseases within 60 days preceding the date of inspection'.
- The US certificates for live horses require individual description of the horses. In addition, the US back-tag was indicated on all certificates seen.
- In addition the animals are accompanied by an owner-shipper certificate basically listing the animals US-back tag.
- At the border the animals are inspected in the truck by a CFIA official to assess the animals fitness for travel and to detect any signs of diseases. An identification check is carried out on 25 % of the animals. In case of suspicion a facility was available for individual examination. No animals had been detained for a closer examination since the introduction of the control procedure.
- After the inspection, the truck is sealed, a permit for entry and a certificate of import inspection (pre-notification to the slaughterhouse) is issued.

- The controls were carried out as described and no shortcomings were noted.
- The FVO audit team was informed that if animals unfit for travel are found the consignment would not be allowed enter Canada.
- Eligibility controls of the accompanying documentation in the case of US horses were carried out at the slaughterhouse by the FBO (the EID and the Health Certificate).
- The slaughter of the animals was reported back to the border veterinarian.

Rules for anabolic steroids

- No statement in the US Health Certificate is required or provided as to the former use of the horses, their treatment with veterinary drugs, in particular with regard to certain substances having a hormonal or thyreostatic action or to beta-agonists.

Treatment records

- The imported horses from the US were accompanied by the signed Affidavit (EID) of the last owner, covering the medical treatment during the last six months, which in many cases was a horse dealer. Nevertheless, no official guarantee was received by the CFIA from the US authorities that this guarantee was verified and could be considered as reliable.

Risk-based official control programme

- Apart from the control of the Canadian horse-feedlot mentioned below, no other risk based official controls of Canadian or US premises where horses are kept and designated for slaughter are carried out in order to verify identification and medical treatments.

5.4.2 Controls of domestic horses

- It could be verified that since August 2010 horses destined for slaughter were accompanied by a signed (by the last owner) Affidavit (EID) documenting the identity and the non-use of growth promoters and medical treatments for the previous six months. Nevertheless, the majority of slaughtered horses are imported directly from the US to which this requirement also applies.
- The eligibility controls were verified by the VIC as a documentary control. In addition, the identification of some of the animals (non-specified frequency) was verified with the accompanying documentation.

Rules for anabolic steroids

- Horses of Canadian origin have to be accompanied with the Affidavits (EID), covering at least the last six months stating that according to their knowledge the animal has not been treated with any of the substances listed in the document as not being permitted for use in food processing equine meat.

Treatment records

- In the Canadian horse feedlot visited the animals were identified by group, medical records were available that could be referred to lot treatment and Identification (ID) of the animals and a system of internal traceability was established that could be verified, although it was very complicated. Off-label use of drugs was applied in the feedlot visited by doubling up the established withdrawal periods.
- Residue sampling on horse meat is carried out at the slaughterhouse level in accordance with the National Residue Plan. In addition, a weekly random screening for antibiotic inhibitors is carried out and suspect samples were taken when appropriate. The results seen were

satisfactory.

Risk-based official control programme

- In the Canadian horse feedlot visited, the system of identification was approved by the CA and treatment and traceability was verified by a licensed veterinarian. Animals, both US and Canadian horses, were not brought to slaughter until they had resided for at least six months in the feedlot.
- Risk based official controls of Canadian horse farms, auctions and other premises where horses are kept for sending for slaughter are not carried out.

Conclusions

The control system in place in Canada for verification of the current use of substances in horses to be slaughtered as specified in Council Directive 96/23/EC is inadequate, as it only allows for official verification of identification, movement and treatment records of a limited fraction of the horses to be slaughtered.

Live horses from the US for immediate slaughter, are, from their entry into Canada until their slaughter, under veterinary control (sealed truck, documentary control and report to custom point of entry after slaughter). Nevertheless, no equivalent guarantees are given and no documentation provided regarding the current use of substances as specified in Council Directive 96/23/EC.

5.5 LISTING OF ESTABLISHMENTS

Legal requirements

Article 12 of Regulation (EC) No 854/2004 requires that products of animal origin may be imported into the EU only if they have been dispatched from, and obtained or prepared in, establishments that appear on lists drawn up, kept up-to-date and communicated to the Commission.

Findings

The relevant recommendation from the previous audit in 2007 was:

"To review the approval procedure for food businesses intending to export to the EU to ensure that listed establishments fulfil the required conditions and auditable documentation on the approval process is available and to ensure that amendments to the lists of EU approved establishments are communicated to the Commission Services in a timely manner as foreseen by Article 12 of Regulation (EC) No 854/2004."

The CCA undertook to update the approval protocol in the MHMOP (11.7.3.6.1. (i)) to include an EU-specific check list and a yearly review (CVS task) by the inspector/OV and a quality verification by the supervisor.

Approvals of establishments for export to the EU follow a procedure specified in Chapter 11.7.3 of the MHMOP.

Upon application by the establishment, an inspection is performed by a regional veterinary officer (RVO). Once the RVO is satisfied that the facilities, operations and inspections comply with the requirements, the Director of programme network will forward a recommendation to the Director of the Food and Animal Origin Division at CFIA headquarters, who will (after potentially another inspection) make a formal recommendation of approval to the European Commission.

Observations

- Approval documents for establishments (slaughterhouses, cutting plants and casings establishments) already approved for some years were not available for review.
- The yearly review of approval (slaughterhouses, cutting plants and casings establishments) only covers how the verifications of the guarantees for export attestations and of activities carried out. The procedure does not specifically require an inspection.
- Verification of EU control tasks are carried out monthly. Nevertheless, a verification that the structure and hygiene of operations are still eligible for approval is not carried out. Moreover, it could not be documented that all EU relevant control tasks included in the CVS had been addressed in a given time period.
- For one of the slaughterhouses with an approved *Trichinella* laboratory, it was not included under its entry on the EU list of establishments approved for export to the EU.
- The licence of one horse slaughterhouse included the activity “*Trichinella* Treatment Facility” even though it did not have this facility. The CA explained that this was either a typing error or a misunderstanding (*Trichinella* laboratory on site).
- No formalised review of existing approvals by the CFIA is in place.

Conclusions

Approval procedures for establishments with the intention of exporting to the EU are in place and adhered to.

The yearly procedure does not foresee a review of facilities and operations. Moreover, the system could not provide controls demonstrating that over a given period of time, the approval conditions for export to the EU were met and in two cases the establishments visited did not have the required facility or the activity was not listed.

5.6 OFFICIAL CONTROLS AT ESTABLISHMENT LEVEL

Legal requirements

Article 12 of Regulation (EC) No 854/2004 lays down that the CA of the third country of origin has to guarantee that establishments placed on the list of establishments from which imports of specified products of animal origin to the EU are permitted, together with any establishments handling raw material of animal origin used in the manufacture of the products of animal origin concerned, complies with the relevant EU requirements, in particular those of Regulation (EC) No 853/2004, or with requirements that were determined to be equivalent and that an official inspection service supervises the establishments and has real powers to stop the establishments from exporting to the EU in the event that the establishments fail to meet the relevant requirements.

In addition,

- the requirements for certification conditions for the introduction into the EU of fresh meat of:
 - Domestic bovines and horses, farmed and wild game intended for human consumption regarding public health requirements are laid down in point II.1 of the relevant model certificates "BOV", "EQU", "RUF" and "RUW" in part 2 of Annex II to Regulation (EU) 206/2010 and as regards animal welfare requirements (wild game excluded) in point II.3 of the relevant model certificates "BOV", and "EQU", and in point II.2.4 of the relevant model "RUF" in part 2 of Annex II to Regulation (EU) No

206/2010.

- Pig meat intended for human consumption regarding public health, and animal welfare requirements at the time of slaughter or killing as laid down in points 9 and 11 of Annex II of Commission Decision 2005/290/EC. According to point 9.1 the Canadian public health standards for pig meat are recognised as equivalent to EU standards.
- the requirements for certification conditions for the introduction into the EU of meat products, meat preparations and casings for human consumption:
 - Meat products: public health requirements as laid down in point II.2 of the model Animal and public health certificate of Annex III to Commission Decision 2007/777/EC. Meat preparations: public health and animal welfare requirements as laid down in points II.1 and II.3 of the model animal and public health certificate (MP-PREP) of Annex II to Commission Decision 2000/572/EC.
 - Casings: animal health requirements as laid down in Annex IA of Commission Decision 2003/779/EC.

Findings

5.6.1 Ante-mortem inspection

For animals slaughtered for meat intended for EU export, ante-mortem inspection is carried out by the OV/VIC at the slaughterhouse, with the exception of pigs of less than 100 kg carcass weight for which ante-mortem inspection can be done by a CFIA slaughter inspector.

According to Canadian requirements (MHMOP, Chapter 17, Annex F, Point F.4.2) “*all red meat species shall be inspected by an inspector while they are at rest and 5 to 10% of such animals, from several lots, shall be examined on both sides while in motion. Records shall be kept indicating those lots examined in motion*”.

Canadian legislation does not allow the slaughter of animals outside the slaughterhouse.

Observations

- Sufficiently detailed records of ante-mortem inspection were present in all the slaughter establishments visited.
- The main responsibility for ID checks for horses in slaughterhouses lays with the FBO who fills in the “Ante-mortem Examination (Screening)” form. This was verified by a random checks verification carried out by the OV/VIC. In some cases this form was signed by the VIC before the ID checks were verified.
- In one horse slaughterhouse, the lairage layout and procedures in place did not allow proper ID checks to be carried out by the FBO, in particular for animals covered by a lot identification document. The animals did not pass the inspection in a single file and it could therefore not be ensured that each individual animal had been checked. In the pig slaughterhouse visited, the layout of the lairage did not allow appropriate ante-mortem inspection for all animals (large pens which could only be inspected from the end and

therefore did not allow proper inspection of animals in the middle of the pens).

5.6.2 Post-mortem inspection

Post-mortem inspection is carried out by CFIA inspectors under veterinary supervision. The final decision on the carcasses detained by the inspectors is taken by the VIC or an OV.

Observations

- Post-mortem inspection was in most cases carried out in accordance with the Canadian requirements. However, some exceptions were identified in individual establishments:
 - In one horse slaughterhouse, the procedure in place and the facilities did not allow appropriate post-mortem inspection of the carcass resulting in several un-inspected carcasses.
 - No decapsulation of the horse kidneys and limited or absent inspection.
 - Obvious pathological changes were missed at the post-mortem inspection in one slaughterhouse.
- In one horse slaughterhouse the carcasses were health marked by the operator before passing final post-mortem inspection. The CFIA inspector was marking contamination on the carcasses for the operator to remove it as unfit for human consumption, the operator would stamp the carcasses without an additional check by a CFIA inspector. According to the CFIA the effectiveness of this trimming would be checked and documented once per year in accordance with a specific task under the CVS.
- No deboning of bovine meat was observed during the FVO visits, but some bison carcasses in the chillers in one establishment were marked for removal of the vertebral column.

5.6.3 General and specific hygiene requirements

The relevant recommendation from the previous audit in 2007 was:

"To ensure that the deficiencies observed in the visited establishments are rectified and to review the follow-up action taken in the establishment where previously identified deficiencies had neither been rectified nor addressed in recent reports."

The CCA confirmed that action plans were received and undertook to monitor the implementation of the action plans in EU approved establishments.

In three out of the four slaughterhouses and in the casings establishment visited the application of the general hygiene requirements were found to be acceptable while the situation was found to be unacceptable in the fourth slaughterhouse. In the coldstore visited the FVO audit team only focussed on the approved *Trichinella* treatment facility and the supporting documentation and not on the general and specific hygiene requirements.

Observations

- Some of the problems identified were of a more general character and found in most of the establishments visited, e.g.:
 - No proper facilities for cleaning the operators' aprons and tools in most establishments. High pressure hose pipes were used instead of cleaning equipment

(and platforms) between carcasses with the risk of contaminating carcasses both by splashing and by operators touching the hose pipes and the carcasses without washing their hands.

- Condensation was observed both in the production areas and in the chillers in several establishments.
 - Insufficient maintenance of floors and walls.
 - Numerous touching points between carcasses and equipment on kill floors.
 - Wooden pallets were still being used with no clear evidence that they are being phased out.
 - No clear identification or separation between the edible/inedible product bins.
 - Frequent use of dark coloured concrete walls which do not allow the effectiveness of the cleaning to be properly assessed.
 - Poor housekeeping in chillers for packed products.
- Some shortcomings identified were of a more sporadic character and only found in some of the establishments visited, e.g.:
 - In the one horse slaughterhouse where the condition was considered to be unsatisfactory the slaughter hall was very small, congested and found to be in a poor state of maintenance. Due to the congestion, resulting in insufficient separation between clean and unclean areas, a potential risk of cross contamination was evident. The activities of this establishment were suspended after the visit and a written guarantee for rectification of the situation was received by the FVO audit team.
 - No sick pen available in the lairage, lack of sterilisation of some equipment between each carcass as required, insufficient ventilation in the chillers leading to mould formation on overhead structures, poor general layout and design not allowing the operations to be carried out in a hygienic way and insufficient protection against pests.

5.6.4 HACCP-based systems

It has been compulsory since 2005 for all federally approved meat establishments in Canada to have HACCP systems in place. This requirement is covered by the Canadian Food Safety Enhancement programme (FSEP).

The CFIA CVS include several tasks for HACCP verification.

The HACCP systems were evaluated in two of the establishments visited by the FVO audit team and found generally to be satisfactorily implemented and documented.

However, one example was seen where the Critical Control Point (CCP) controlling the risk of *E. coli* O157 was based on a letter of guarantee from a supplier (basically stating that the supplier was in compliance with the legal requirements regarding testing). No additional testing or controls were in place to support this CCP.

5.6.5 Microbiological testing

In all the slaughterhouses visited the microbiological sampling and testing of carcasses of both pigs, bovines and horses and of minced meat followed the US requirements. Nevertheless, export certificates for bovine and horse meat and minced meat to the EU state that the provisions of

Regulation (EC) No 2073/2005 have been complied with, but on the spot checks revealed that in one case the VIC signing the documents for bovine and horse meat and minced meat was not fully aware of the requirements. Furthermore, in this establishment no *Salmonella* testing had been performed on products exported to Sweden and Finland and the special certification requirements for these countries had not been complied with.

5.6.6 Traceability and identification marking

The CFIA controls in place are to ensure that only eligible animals are slaughtered for the production of meat intended for export to the EU.

A verification system is in place where traceability checks are carried out before the VIC signs export certificates for the EU. Furthermore, during official controls in EU approved meat establishments the RVO perform supervisory checks on the export certification procedure, including traceability verification.

Health marks and numbered EU export labels to be applied to cardboard boxes with eligible meat is kept under official supervision by the CFIA staff.

Meat transfer certificates are to accompany meat intended for export to the EU between the EU approved establishments to ensure continued eligibility.

Observations

- Certificates for elk and bison meat checked by the FVO audit team did not always allow proper traceability. The only way of tracing the meat back was via the quantity and/or in some cases the dates.
- Meat intended for export to the EU was produced, labelled, packed and stored separately in the slaughterhouses visited. However, in one of the horse slaughterhouses there was insufficient separation between EU eligible and non-EU eligible carcasses on the slaughter line.

5.6.7 Animal welfare at the time of slaughter

The relevant recommendation of the previous audit from 2007 was:

"To strengthen animal welfare controls in order to ensure equivalence with EU requirements as set out in Council Directive 93/119/EC."

The CCA undertook to update Chapter 12 of the Manual of Procedures (MOP) concerning stunning and back-up instruments and to closely monitor the stunning of horses.

The FBO has the main responsibility for animal welfare in slaughterhouses. The CFIA "Guidelines for plant employees involved in handling live animals" (Chapter 17, Annex A of the MHMOP) gives a brief description of the animal welfare requirements that should be reported to the VIC. For one establishment where training of plant employees was checked, these guidelines were found to be included in a summarised form in the training programme of the operators.

Chapter 12 of the MOP covering "Guidance on animal welfare topics in the current Meat Programmes MOP: Enforcement and authority of inspectors" is not currently in force. According to the CFIA, this chapter will be introduced in horse plants under a pilot project in January 2011.

During the FVO visits, animal welfare could only be evaluated for pigs and horses. No slaughter of bison or elk took place during the FVO visits.

Electrical stunning equipment was used for pigs and captive bolts or rifles with free bullets were used for horses. Stunning and bleeding were found to be carried out correctly during the on the spot

visits. Spare equipment for emergency stunning was available in all the slaughterhouse visited.

Observations

- Plant operators involved in handling live animals and the CFIA personnel questioned seemed to be aware of the welfare requirements.
- However, during the visit to a pig slaughterhouse where a pig with a prolapsed rectum was identified by the FVO audit team during the visit; neither the VIC nor the FBO took any immediate action to segregate this animal from other animals continuously biting the prolapsed rectum. Action was taken only after repeated requests from the FVO audit team. The priority expressed by the operator was the unloading of another lot of pigs.
- In one of the slaughterhouses visited, the design of the lairage was not suitable for semi-wild animals such as bison and the structure did not allow proper cleaning and disinfection.

5.6.8 Documentation of official controls

Records in the form of tables are filled in with the results of CVS inspection tasks and the supervisory visits under the Quality Management System (QMS). In the case of any non-compliances identified during the compliance verification a CAR is to be issued. This document includes sections on the follow up to the corrective action taken and its acceptability (for more details see Chapter 5.1.2.6).

Observations

- The CVS and QMS checks were generally found to be well documented and transparent.
- The follow-up actions in relation to CARs issued were not always found to be satisfactory. In one case the CAR had been closed without the FBO taking appropriate corrective action (for more details see Chapters 5.1.2.6 and 5.6.3, first bullet).
- No records were found in order to document that verification of all relevant EU requirements in the establishments visited had been carried out. (For more details see Chapter 5.5).
- The eligibility of casings for export to the EU has to be verified once a year by a CFIA inspector in the casings establishment visited according to the CVS. Nevertheless, such a verification was not documented.

Conclusions

The ante-mortem and post-mortem controls for pigs and horses were adequately applied. Nevertheless, shortcomings were noted with regard to ante-mortem inspection due to inadequate lay-out and with regard to post-mortem inspection procedures of horses and pigs.

Controls over health marking were carried out regularly and were in most cases seen as adequate. Nevertheless, the official supervision of the health marking in one establishment was inadequate to ensure in all cases that the health mark was applied only to carcasses where all parts were fit for human consumption after post-mortem inspection due to a lack of additional post-mortem-inspections of the carcass when needed.

With the exception of one plant that did not comply with numerous provisions of Chapters 2.5 and 2.6 of the Canadian MHMOP, in particular with regard to general construction requirements and detailed requirements, the establishments visited were of an acceptable standard and follow-up controls by the CA were largely effective. In this establishment, Canadian rules were inadequately

applied and in addition a lack of enforcement of the Canadian rules was noted.

HACCP based systems were implemented in all establishments visited. Shortcomings related to the proper application of the Hazard Analysis and the definition of CCPs were seen in one establishment.

The controls on traceability and identification marking were adequate.

The microbiological testing of exports of meat to Sweden and Finland and of minced meat did not comply with EU requirements as set out in Chapter 11.7.3 .6.3 of the MHMOP.

Animal welfare controls at slaughter of horses had improved since the last audit and could provide conditions which could offer guarantees of humane treatment as regards slaughter equivalent to those provided for in EU legislation.

Concerning the slaughter of pigs, the animal welfare controls were not adequately applied and a guarantee of humane treatment could not be provided.

5.7 LABORATORY SERVICES

Legal requirements

Certificate "EQU" in point II.1.3 in part 2 of Annex II to Regulation (EU) No 206/2010 sets out conditions regarding *Trichinella* examination of meat to fulfil the requirements of Regulation (EC) No 2075/2005.

The certificate in point 9.1 of Annex II to Commission Decision 2005/290/EC stipulates that the Canadian public health standards for pig meat are recognised as equivalent to EU standards.

Chapter 11.7.3.3.2 of the Canadian Meat Hygiene Manual sets out the conditions for *Trichinella* testing of pig and horse meat.

Findings

The relevant recommendation of the previous audit from 2007 was:

"To improve the supervision of Trichinella testing and of the freezing treatment of pork meat to destroy Trichinella in order to ensure that the performance of the testing and the freezing treatment meet standards as laid down in Chapter 4.10.2 and Chapter 11.7.3 of the Meat Hygiene Manual of Procedures."

The CCA informed the FVO audit team that on-site audits of all *Trichinella* laboratories will be completed by the CFIA Centre for Food-borne and Animal Parasitology before 31 December 2007. Through the creation of the monthly EU-specific CVS task it will be verified by the OV that the *Trichinella* protocols, control measures and documentation have been complied with.

All four slaughterhouses visited had approved *Trichinella* laboratories on site. The laboratories are certified by the CFIA's Centre for Food-borne and Animal Parasitology (CFAP) in Saskatoon for testing carcasses for the presence of *Trichinella* using the CFIA's Double Separator Funnel Procedure for the detection of *Trichinella* larvae in horse meat and pork. The Canadian method is accepted by the EU as being equivalent to the reference method in Regulation (EC) No 2075/2005.

The CFAP is an ISO 17025 accredited laboratory and runs the national programme to certify industry laboratories to conduct on-site testing for export purposes. The industry laboratory certification programme consists of technical training, guidance for quality assurance and laboratory set-up, and ongoing auditing and proficiency sample testing requirements to ensure compliance

with CFIA standards. Industry laboratories are not ISO accredited, but they must follow CFIA certification standards which are based on ISO standards.

The proficiency sample testing scheme requires that sets of four samples (three positive at various levels and one negative) have to be tested by each individually approved *Trichinella* tester four times per year and include a follow-up procedure (retesting or retraining) in case of unsatisfactory results.

As an alternative to the *Trichinella* testing, freeze treatment of the meat can be carried out in order to destroy live *Trichinella* larvae (procedure described in previous FVO report). Establishments approved for the freeze treatment of pork have to be approved and listed for this activity (Point 12, *Trichinella* Treatment Facility) and operate in accordance with CFIA's "*Trichinella spiralis* control options for pork" (MHMOP, Chapter 4, Annex B, Section B.3). The methods used are equivalent to the methods described in Annex II to Regulation (EC) No 2075/2005.

The FVO audit team visited one coldstore approved for the freeze treatment of pork destined for export to the EU.

Observations

- All the *Trichinella* laboratories visited had recently undergone audits from the CFAP. All the audit reports seen included a high number of shortcomings, mainly in relation to the working instructions and standard operating procedures, not having a copy of the latest approved method available and the use of microscopes not fulfilling the requirements.
- Proficiency sample testing had been carried out as required in all the laboratories visited and the results were found to be largely satisfactory.
- The *Trichinella* sampling and laboratory testing was generally performed and documented in accordance with the requirements in the establishments visited. However, some shortcomings were identified by the FVO audit team:
 - In two of the four laboratories the FVO audit team identified the continued use of microscopes not capable of the required 10 to 40 power magnification or higher (e.g. maximum 36 power magnification only).
 - In one of the laboratories visited the pepsin in storage had expired. The FBO explaining that pepsin was not stored in the laboratory but in a chiller at a different location. The pepsin seen was identified by a label where the year 2010 had been changed to 2011. It was later explained that documentation had been found which showed that the pepsin had not expired. The problem had been the transfer of newly received pepsin to old containers in the storage area.
 - In one horse slaughterhouse the tongues were not identified and all the heads were condemned immediately after the post-mortem examination, which did not allow for a re-sampling of at least 50g sample from animals with a positive or inconclusive result.
- The freeze treatment of pork in the coldstore visited was performed in full compliance with the requirements and was well documented.

Conclusions

The official supervision of *Trichinella* testing was in general adequate. Nevertheless, some laboratory equipment and the procedures in case of positive and inconclusive results (no appropriate reference material of horses was available for retesting) were not in line with the requirements.

The official supervision of freezing treatment of meat to destroy *Trichinella* was adequate.

5.8 OFFICIAL CERTIFICATION

Legal requirements

Article 9 and Annex VII to the Agreement prescribe the principles of model attestation and guidelines for certification whereas the equivalency determination indicated in Points 6, 8, 9, 10, 15, 16, and 17 of Annex V to the Agreement stipulate the model health attestation.

The models of the health certificates for imports into the EU of the products of animal origin covered by this audit are laid down in the following EU acts:

- Commission Decision 2005/290/EC for imports of fresh pig meat;
- Regulation (EU) No 206/2010 for imports of fresh meat of domestic bovines, including minced meat, (model "BOV"), fresh meat, excluding minced meat, of horses (model "EQU"), fresh meat excluding minced meat, of farmed game (model "RUF") and fresh meat, excluding minced meat, of wild game (model "RUW");
- Commission Decision 2007/777/EC for imports of meat products;
- Commission Decision 2000/572/EC for imports of meat preparations;
- Commission Decision 2003/779/EC for imports of casing for human consumption;
- Article 18 and Annex V to Regulation (EU) 206/2010 for imports of meat. Point (h) of Annex V sets out that CAs of the exporting country shall ensure that rules of certification equivalent to those laid down in Council Directive 96/93/EC are followed.

Findings

The relevant recommendation from the previous audit in 2007 was:

"To ensure that export certificates for the reviewed commodities are completed in line with Directive 96/93/EC and to ensure adequate supervision of export certification to the EU."

The CCA informed the FVO audit team that the fencing requirements were met for domestic swine due to their housing in enclosed buildings. For the other species (bison and elk) for which it is relevant the legislation will be reviewed. As regards traceability records the MHMOP would be amended to outline that verification of the records to ensure that eligibility of the products and accuracy of the certificates would take place.

The procedures for export certification for meat and meat products are laid down in Chapter 11.2 of the MHMOP.

The consignments are regularly visually verified by an inspector or veterinarian and a specific form 'Annex H' is produced. The link between the consignment and the certificate is established by use of

an official export stamp by which the number of the certificate is stamped on the consignment (e.g. on each box).

All official CFIA veterinarians are authorised to sign veterinary export certificates. Certificates (CFIA form 1454) are provided via CFIA regional offices and the relevant annexes to the official export certificate are printed from the MHMOP.

Observations

- With regard to fresh meat, certifying officers sign clauses for which they have no supporting evidence and where they are aware that these standards are not industry practice. Vehicles for the transport of live animals are not disinfected, but the clause 'animals, which have been transported from their holdings in vehicles cleaned and disinfected before loading' is regularly signed. In the case of farmed game, double fencing or equivalent measures is not industry practice but the clause 'has been obtained from animals that have remained separate since birth from wild cloven-hoofed animals' is always signed. The clause in point II.2.3. of the certificate for bovine meat (BOV) concerning origin of the meat from approved farms listed in TRACES was also certified.
- Casings for further processing were not accompanied by Transfer Certificate in the casings establishment visited.
- The link between Transfer Certificate and export certificate for export of bison meat was only ensured by the indicated amounts of meat received and shipped and slaughter dates without using a specific batch number of the received meat.
- *Salmonella* attestation of exports to Sweden and Finland was not based on the EU requirements and testing was not implemented. Microbiological testing of minced meat was based on pre-operational and operational US requirements and not on the provisions for process hygiene and food safety criteria included in Regulation (EC) No 2073/2005.
- Verification by the RVO includes controls over official documentation and stamps and comprises controls over storage and use of certificates and relating registers but does not include verification of any aspect of the contents of the certificates and the correct application of certification procedures.

Conclusions

Controls over storage and use of export certificates for meat were adequate. Nevertheless, the certification was not fully in line with OIE certification principles as reflected in Council Directive 96/93/EC due to the fact that statements were certified that were not correct and could not be ascertained.

Supervision or the certification was not adequate to address the deficiencies noted.

6 OVERALL CONCLUSIONS

In general the control system pertaining to controls over the production of fresh meat, farmed game meat, minced meat, meat preparations meat product and casings is functioning in the manner specified in the Agreement between the European Community and Canada. In certain areas deviations from the agreed equivalent standards were observed; these were mainly related to supervisory controls, export approval of establishments and export certification. In areas such as the export of horse meat, standards did not fully provide adequate guarantees.

7 CLOSING MEETING

A closing meeting was held on 6 December 2010 with the CCA. At this meeting, the preliminary findings of the audit were presented by the FVO audit team and discussed. The representatives of the CCA acknowledged the findings presented by the FVO audit team. They informed the FVO audit team that the Commission Services would be informed about the results of further actions taken in the establishment where production was suspended.

8 RECOMMENDATIONS

An action plan describing the action taken or planned in response to the recommendations of this report and setting out a timetable to correct the deficiencies found should be presented to the Commission within 60 working days of receipt of the report.

Nº.	Recommendation
1.	To put the necessary control measures in place in order to ensure adequate application of official controls and enforcement measures in line with the guarantee required by Article 12 (2) of Regulation (EC) No 854/2004 and the applicable Canadian legislation in Chapters 14 and 18 of the MHMOP.
2.	To ensure that the approval conditions for export to the EU are subject to regular review as required by Chapter 18 of the MHMOP and that approvals are fully reflecting the activities carried out as required by Article 12 (2)(a) of Regulation (EC) No 854/2004.
3.	To ensure that with regard to determine the eligibility and to verify the traceability of bison and elk to be slaughtered and exported to the EU, sourcing of casings and certification of casings and exports of meat to Sweden and Finland, meet the requirements of Council Directive 96/23/EC, Section C and D of Annex IX of Regulation (EC) No 999/2001, Commission Decision 2007/453/EC and Regulation (EC) No 1688/2005.
4.	To ensure that equivalent guarantees regarding the current use of substances as specified in Council Directive 96/23/EC are given for horses imported from the US for immediate slaughter.
5.	To ensure that the deficiencies observed in the establishments visited are rectified and the guarantees required by Article 12 (2) of Regulation (EC) No 854/2004 or by the relevant Canadian standards are met as applicable.
6.	To strengthen animal welfare controls of pigs in order to ensure equivalence with EU requirements as set out in Council Directive 93/119/EC.
7.	To ensure that the certificates of exports to the EU are completed in line with principles of OIE as laid down in Council Directive 96/93/EC and that the certification

N°.	Recommendation
	procedure is adequately controlled.

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

http://ec.europa.eu/food/fvo/ap/ap_ca_2010-8522.pdf

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dec. 1999/201/EC	OJ L 71, 18.3.1999, p. 1-2	1999/201/EC: Council Decision of 14 December 1998 on the conclusion of the Agreement between the European Community and the Government of Canada on sanitary measures to protect public and animal health in respect of trade in live animals and animal products
Reg. 999/2001	OJ L 147, 31.5.2001, p. 1-40	Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
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. 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. 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

Legal Reference	Official Journal	Title
Reg. 1688/2005	OJ L 271, 15.10.2005, p. 17-28	Commission Regulation (EC) No 1688/2005 of 14 October 2005 implementing Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards special guarantees concerning salmonella for consignments to Finland and Sweden of certain meat and eggs
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. 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. 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
Reg. 1162/2009	OJ L 314, 1.12.2009, p. 10-12	Commission Regulation (EC) No 1162/2009 of 30 November 2009 laying down transitional measures 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
Reg. 206/2010	OJ L 73, 20.3.2010, p. 1-121	Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements
Dir. 92/118/EEC	OJ L 62, 15.3.1993, p.	Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health

Legal Reference	Official Journal	Title
	49-68	requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC
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. 96/22/EC	OJ L 125, 23.5.1996, p. 3-9	Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of β -agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
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. 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
Dec. 79/542/EEC	OJ L 146, 14.6.1979, p. 15-17	79/542/EEC: Council Decision of 21 December 1976 drawing up a list of third countries from which the Member States authorize imports of bovine animals, swine and fresh meat
Dec. 2000/572/EC	OJ L 240, 23.9.2000, p. 19-24	2000/572/EC: Commission Decision of 8 September 2000 laying down animal and public health conditions and veterinary certification for imports of minced meat and meat preparations from third countries and repealing Decision 97/29/EC

Legal Reference	Official Journal	Title
Dec. 2003/779/EC	OJ L 285, 1.11.2003, p. 38-41	2003/779/EC: Commission Decision of 31 October 2003 laying down animal health requirements and the veterinary certification for the import of animal casings from third countries
Dec. 2004/432/EC	OJ L 154, 30.4.2004, p. 44-50, corrected and re-published in OJ L 189, 27.5.2004, p. 33	2004/432/EC: Commission Decision of 29 April 2004 on the approval of residue monitoring plans submitted by third countries in accordance with Council Directive 96/23/EC
Dec. 2005/290/EC	OJ L 93, 12.4.2005, p. 34-39	2005/290/EC: Commission Decision of 4 April 2005 on simplified certificates for the importation of bovine semen and fresh pig meat from Canada and amending Decision 2004/639/EC
Dec. 2005/306/EC	OJ L 98, 16.4.2005, p. 32-33	2005/306/EC: Commission Decision of 16 February 2005 approving on behalf of the European Community amendments to the Annexes to the Agreement between the European Community and the Government of Canada on sanitary measures applicable to trade in live animals and animal products
Dec. 2007/453/EC	OJ L 172, 30.6.2007, p. 84-86	2007/453/EC: Commission Decision of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk
Dec. 2007/777/EC	OJ L 312, 30.11.2007, p. 49-67	2007/777/EC: Commission Decision of 29 November 2007 laying down the animal and public health conditions and model certificates for imports of certain meat products and treated stomachs, bladders and intestines for human consumption from third countries and repealing Decision 2005/432/EC