EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

DG(SANTE) 2018-6458

# FINAL REPORT OF AN AUDIT

# CARRIED OUT IN

# CANADA

# FROM 10 SEPTEMBER 2018 TO 24 SEPTEMBER 2018

# IN ORDER TO

# EVALUATE THE CONTROL SYSTEMS IN PLACE GOVERNING THE PRODUCTION OF HORSE AND GAME MEAT INTENDED FOR EXPORT TO THE EUROPEAN UNION

***In response to information provided by the competent authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.***

***Executive Summary***

*The report describes the outcome of an audit carried out by Directorate-General for Health and Food Safety in Canada from 10 to 24 September 2018 to review the structure and operation of control systems in the meat sector (fresh meat from* equidae*, farmed game and wild game) for export to the EU and, in this context, to assess the effectiveness of the actions announced/taken by the competent authorities in response to the recommendations made on foot of a previous audit covering horse meat, in 2014 (report DG(SANTE)/2014-7216).*

*The audit found that the different competent authorities involved in the official controls of the production and certification chain of horse and game meat are clearly designated and well organised. A comprehensive set of operating procedures for controls, underpinned by appropriate and adequate reporting tools, is in place. Certification procedures were found to be adequate.*

*The production of farmed game meat intended for export to the European Union generally complies with the relevant Canadian and Union requirements, including the requirement that all carcases fit for export to the EU undergo laboratory testing for chronic wasting disease and originate from herds in which, according to the federal and provincial surveillance programmes, chronic wasting disease has not been suspected or confirmed. Some shortcomings in respect of the obligation to keep accurate and reliable records of medical treatments at holding level were identified.*

*While all slaughterhouses visited generally met the general and specific hygiene requirements, the competent authority does not ensure that the lists of establishments approved for export to the EU are kept up to date and accurately reflect the activities currently carried out, or that the establishments fulfil all conditions for listing. As such, the competent authority' actions implemented in response to the same point raised during the 2014 audit, have not been sufficiently effective.*

*The audit identified certain issues in relation to the reliability of the controls over both imported and domestic horses destined for export to the EU, with the exception of horses kept in feedlots for a minimum of six months. The system does not provide full guarantees that horses have not been treated with illegal substances within the last 180 days before slaughter, or that the withdrawal periods of veterinary medicinal products had been respected. The official follow-up of non-compliant results is limited; whilst the competent authority puts the responsibility for corrective actions and follow-up of non-compliances largely on the shoulders of the slaughterhouses, it does not carry out inspections of holdings keeping horses to verify and ensure the effective implementation of corrective actions. The competent authority's action is, in this regard, hampered by a lack of direct powers over primary producers and transient agents. The absence of cooperation and coordination with the provincial authorities, which do have such enforcement powers, constitutes a missed opportunity. The same finding was noted during the 2014 audit.*

*Several antimicrobials and antiparasitics are available over-the-counter; the provincial legislation is currently being amended, limiting the number of veterinary medicinal products being sold without veterinary prescription.*

*The report contains recommendations to the Canadian competent authorities aimed at addressing the identified shortcomings.*

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Abbreviations and definitions used in this report

| **Abbreviation** | **Explanation** |
|---|---|
| CA(s) | Competent Authority(ies) |
| CBSA | Canadian Border Service Agency |
| CCA | Central Competent Authority |
| CETA | Comprehensive Economic and Trade Agreement between the EU and Canada |
| CFIA/ACIA | Canadian Food Inspection Agency/*Agence Canadienne d'Inspection des Aliments* (the CCA) |
| CVS | Compliance Verification System |
| CWD | Chronic Wasting Disease |
| CWD-VHCP | CWD-Voluntary Herd Certification Program |
| DG SANTE | General-Directorate for Health and Food Safety |
| EID | Equine Identification Document |
| EU | European Union |
| FBO | Food Business Operator |
| FSEP | Food Safety Enhancement Program |
| HACCP | Hazard Analysis and Critical Control Point |
| IM | Inspection manager |
| MAPAQ | *Ministère de l'Agriculture, des Pêcheries et de l'Alimentation du Québec* |
| MFFP | *Ministère des Forêts, de la Faune et des Parcs du Québec* |
| MHMOP | Meat Hygiene Manual Of Procedures |
| MIA | Meat Inspection Act |
| MIR | Meat Inspection Regulation |
| Model certificate "EQU" | Health certificate for export of horse meat to the EU |
| Model certificate "RUF" | Health certificate for export of farmed game meat to the EU |
| Model certificate "RUW" | Health certificate for export of wild game meat to the EU |
| SI | Slaughter Inspector (auxiliary official staff) |
| TRACE | Livestock Identification and Traceability Program |
| VIC | Veterinarian In Charge |
| VMP | Veterinary Medicinal Product |

## 1 INTRODUCTION

The audit took place in Canada from 10 to 24 September 2018. The audit was undertaken as part of the Directorate General for Health and Food Safety (DG SANTE) planned audit programme. The audit team comprised two auditors and was accompanied during the audit by representatives from the Central Competent Authority (CCA), the Canadian Food Inspection Agency (CFIA), representatives of the regional CFIA offices, and by officials of the provincial authorities.

An opening meeting was held on 10 September 2018 with the CFIA. At this meeting the 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

The objective of the audit was to evaluate the implementation of official controls over and enforcement of the sanitary measures in place intended to ensure the fulfilment of the requirements applicable to exports to the EU of fresh meat from *equidae*, farmed game and wild game. In this context, the audit also assessed the implementation and effectiveness of the action taken by the competent authorities (CAs) in response to certain recommendations contained in the report of the previous audit (ref. DG(SANTE)/2014-7216), hereafter referred to as 2014 audit.

In terms of scope, the audit included the verification of controls over veterinary medicinal products (VMP) and residues thereof in relation to live horses and horsemeat, and of the guarantees provided in respect of chronic wasting disease (CWD) in farmed and wild cervids, the meat of which is exported to the EU, as set out in the model certificates "RUF" and "RUW" laid down in Commission Regulation (EU) No 206/2010.

In pursuit of the objective, the following sites were visited:

| **COMPETENT AUTHORITIES** | | | **COMMENTS** |
|---|---|---|---|
| COMPETENT AUTHORITIES | Central | 2 | Opening and closing meetings |
| | Provincial/Regional | 2 | Present at sites visited |
| | Local | | Present at sites visited |
| **FOOD PRODUCTION / PROCESSING / LIVE ANIMALS / VETERINARY MEDICAL PRODUCTS - ACTIVITIES** | | | |
| Slaughterhouses | | 4 | For horses and game (elk, deer and bison) |
| Cutting plants | | 4 | Co-located |
| Livestock holdings | | 2 | Game farms |
| Feedlots | | 1 | One horse feedlot |
| Veterinary Medical Products | | 3 | Two wholesalers / one retailer |
| Laboratories | | 2 | On-site *Trichinella* laboratories attached to slaughterhouses |

## 3 LEGAL BASIS

The audit was carried out under the general provisions of the EU legislation, and in particular Article 46 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, and Article 5.8 of the *Comprehensive Economic and Trade Agreement* (hereafter referred to as CETA), made applicable on a provisional basis by Council Decision (EU) 2017/38.

A full list of the EU legal instruments relevant to the scope of this audit is provided in Annex I to this report. Legal acts quoted refer, where applicable, to the last amended version.

## 4 BACKGROUND

On 28 October 2016, the Council adopted a package of decisions on the CETA, including:

- a decision on signature of the agreement (Council Decision (EU) 2017/37 of 28 October 2016);
- a decision on the provisional application of the agreement (Council Decision (EU) 2017/38 of 28 October 2016).

Chapters and Annexes of the CETA applicable to this audit are referred to in the relevant chapters/sections of this report (Annex 5-E of the CETA contains, *inter alia*, the list of live animals and animal products for which equivalence of sanitary measures has been established for trade purposes (e.g. public health requirements on fresh meat from *equidae* and farmed game from deer), including special conditions listed in Appendix A (compliance with EU rules on transmissible spongiform encephalopathies, *ante-mortem* and *post-mortem* inspections, process hygiene criteria as per United States of America (US standards). In the context of exports from Canada to the EU the CETA (Annex 5-I, par. 3) provides that "until certificates on the basis of equivalence have been adopted, existing certification shall continue to be used".

Details concerning the animal health situation in Canada can be found at the World Organisation for Animal Health (OIE) website: http://www.oie.int/. According to the OIE a number of diseases affecting horses have never occurred or have not occurred for almost 50 years, including African horse sickness and glanders. Sporadic cases of trichinellosis in wildlife (eight cases between 2012 and 2018) had been noticed in the past; one case of trichinosis, in a horse imported from the US, was detected in 2010.

The previous audit to review the structure and operation of control systems in Canada's meat sector for export to the EU with particular focus on horsemeat was carried out from 2 to 15 May 2014, the results of which are described in 2014 audit. This report is published on the Commission website at:
http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3442.
The action plan received from the Canadian authorities in response to the report's recommendations provided, overall, satisfactory guarantees.

# 5 FINDINGS AND CONCLUSIONS

## 5.1 LEGISLATION AND IMPLEMENTING MEASURES

### Legal requirements

Article 46 (1) (a) of Regulation (EC) No 882/2004

Annex 5-A,B,D,E,F,I and J of the CETA

### Findings

1. CETA establishes equivalence only in relation to public health requirements for fresh meat from *equidae* and farmed game, with some additional conditions for production of such meat when destined for export to the EU: Appendix A of Annex 5-I include *inter alia* compliance with EU rules on decontamination, routine ante-mortem inspection, testing for *Trichinella* in horses, and EU microbiological food safety criteria.

2. The Canadian Meat Inspection Program (considered as equivalent) consists of the following Acts, Regulations, Policies and Standards:

    a. The Meat Inspection Act (MIA) deals with import, export and inter-provincial trade of meat and products, the registration of establishments, the inspection of animals, meat and products in registered establishments and the standards for those establishments, for animals slaughtered, and for meat products prepared;

    b. The Meat Inspection Regulations (MIR) supplement the MIA with details/ specifications and incorporates/references other applicable legislation and technical documents, e.g. the Food and Drugs Act and Regulations, and CFIA Manuals;

    c. Meat Hygiene Manual of Procedures (MHMOP); the MHMOP is divided into specific chapters which elaborate on MIR requirements. Chapter 11 includes the export requirements for different markets, including for the EU. The MHMOP had been amended to include the amendments in the health certificate for export of horse meat and wild game meat to the EU;

    d. Food Safety Enhancement Program (FSEP) Manual; the FSEP is a multi-commodities CFIA programme to implement the Hazard Analysis Critical Control Point (HACCP) principles of the *Codex Alimentarius* Commission. The FSEP manual is essential for operators of federally registered establishments in developing their control programmes and HACCP plans, as required under the MIR([1]).

3. The Health of Animals Act and Regulations require mandatory individual identification of bovine animals, bison, sheep and porcine animals (mandatory identification of goats is ongoing). Identification of horses is only required by federal export programmes when

[1] In their response to the draft report, the CCA stated that multiple food related acts have been consolidated into one called *Safe Food for Canadians Regulations* (SFCR). The SFCR entered into force on January 15, 2019 and requires some FBOs to have written Preventive Control Plans in place, like FSEP.

having the status of food-producing animals (see Chapter 5.5). Federal and provincial surveillance programmes require all farmed cervids to be identified (see Chapter 5.4).

4. Provincial legislation in Québec (*Loi sur la protection sanitaire des animaux* – 1986) in its Article 55.7 prohibits the supply to a slaughterhouse of animals destined for human consumption to which prohibited substances have been administered, or the meat of which contains residues of VMPs above the MRL. When residues are detected in a slaughtered animal, movement restrictions at the holding of origin may be imposed and contravening operators may be fined.

5. CWD is a disease of immediate federal notification. Surveillance of CWD in farmed cervids is based on the national standards for the CWD Voluntary Herd Certification Program (CWD-VHCP). The CWD-VHCP is complemented by the National Cervid Farm-level Biosecurity Standard.

6. Provinces have their own complementary CWD surveillance programmes (mandatory in certain provinces like Alberta) for testing hunted and farmed cervids, and provincial legislation with regard to public and animal health. The CCA stated that hunted wild cervids are only processed in provincially registered establishments, and their meat is not exported (see Chapter 5.4).

7. Although national legislation provides for zoning/regionalisation of the national territory in case of animal diseases, these are not yet applicable to CWD. (see Chapter 5.4).

**Conclusions on legislation and implementing measures**

8. National legislation is in place and fully covers the area subject of this audit.

9. National and provincial provisions for CWD surveillance provide the legal framework for the guarantees required by the model certificates "RUF" and "RUW" laid down in part 2 of Annex II to Regulation (EU) No 206/2010.

10. The national provisions for zoning/regionalisation of the Canadian territory in the event of cases of CWD are not yet applicable, and the CCA cannot currently certify certain guarantees required for exports of wild game meat and as set out in the model certificate “RUW" laid down in part 2 of Annex II to Regulation (EU) No 206/2010.

### 5.2 COMPETENT AUTHORITIES

**Legal requirements**

Article 46 (1) of Regulation (EC) No 882/2004.

Annex 5-A of the CETA.

## Findings

### *5.2.1 Structure and organisation*

11. Annex 5-A of the CETA establishes the CFIA as the CCA responsible for development, implementation and maintenance of federally mandated programmes for meat inspection and animal health, and for issuing health certificates attesting to agreed Sanitary and Phytosanitary measures. CFIA is included in the portfolio of both the Minister of Agriculture and Agri-Food and the Minister of Health of the Government of Canada. With headquarters in Ottawa, the CFIA is organised into four operational areas (Western, Ontario, Quebec and Atlantic) that are subdivided into 18 regional offices and local offices in meat processing facilities (front-line staff). The CFIA website: www.inspection.gc.ca provides additional detail.

12. Each federally registered slaughter establishment is assigned a CFIA Veterinarian in Charge (VIC), responsible for *ante-mortem* and *post-mortem* inspection and overall operations of the establishment, including enforcement activities; under the functional and line-supervision of the VIC or of an Inspection Manager - IM (in their respective locations), a team of Area Operation Inspectors and other veterinarians may be assigned for *ante-mortem* and *post-mortem* inspection (screening). They are the first point of contact for industry and the fist level of decision makers in registered establishments. VIC/IM report to the Regional Chief Inspector (RCI) who is responsible and accountable for inspection activities/decisions and corporate issues in its respective region.

13. Each establishment federally registered for processing, storage or packaging and labelling of meat products is assigned a responsible CFIA Food Processing Inspector (FPI) under functional and line supervision of a Food Processing Supervisor (FPS).Inspections may be conducted individually or in teams, which may include Subject Matter Experts to perform specific functions or provide additional support.

14. Health Canada is the federal institution which, as part of the Ministry of Health, has responsibility for national public health. The Health Products and Food Branch (HPFB) is responsible for evaluating and monitoring the safety, quality and efficacy of food and VMPs. The Veterinary Drugs Directorate (VDD) of HPFB Human Safety Division establishes mandatory withdrawal periods and MRLs for veterinary drugs in food derived from animals, and develops warning statements for veterinary drug labels. Personnel of the regional branches working in the Health Product Inspection and Licensing Regulatory Operations are responsible for inspections at drugs manufacturers, importers and wholesalers.

15. Provincial ministries of Agriculture and provincial veterinary services are in charge of implementation of Provincial legal acts dealing with the conservation and development of inter alia captive and free ranging cervids, including the implementation of the Provincial CWD surveillance programmes. Supervision of holdings keeping food-producing animals and enforcement of Provincial legislation in the field of agriculture,

zoo-technics and veterinary also fall within their competencies. In Quebec, the *Ministère des Forêts, de la Faune et des Parcs du Québec* (MFFP) is responsible for enforcement of the Acts respecting the conservation and development of wildlife (including CWD surveillance in wildlife), whilst the *Ministère de l'Agriculture, des Pêcheries et de l'Alimentation du Québec* (MAPAQ) monitors CWD at farm and slaughterhouses level.

16. The relevant Provincial CAs (Ministries of Agriculture) carry out official controls at VMP retailers, except in Québec where the vast majority of VMPs require a veterinary prescription and are not distributed by retailers but by distributors, veterinary surgeons, pharmacies and veterinary pharmacies.

17. Controls on the use of VMPs by veterinary practitioners falls under the shared responsibilities of the Provincial Orders of Veterinary Surgeons and of services of Provincial Ministries of Agriculture. In Québec, only the use of VMPs by farmers is under the jurisdiction of MAPAQ, whilst the use of VMPs by practicing veterinarians is under the authority of the Provincial Order.

#### *5.2.2 Legal powers, independence and authority for enforcement*

18. The overall Canadian supervisory system is well organised, and measures to ensure that staff are free of conflicts of interest, are in place.

19. CFIA has no legal basis for inspection of animal holdings, except when carrying out animal health screenings (e.g. for brucellosis and tuberculosis), or when empowered by a specific written authorisation included in the agreement documents signed between horses owners and food business operators (FBOs) operating slaughterhouses. However, CFIA staff have not made use of the latter. As a result, CFIA follow-up of non-compliances at farm level has not occurred to date (as was found during the 2014 audit).

20. In contrast, the provincial authorities (Veterinary Services of provincial Ministries of Agriculture) do have the legal power to enter premises where animals are kept (with the exception of private dwellings) and to enforce their legislation (e.g. in Québec) in case food producing animals are sent to slaughterhouses within the withdrawal periods of medical treatments administered to them. However, in the absence of coordination/cooperation between CFIA and provincial authorities, a potentially effective tool for the enforcement of federal and provincial legislation at holding level, is not used (see also Chapter 5.5).

#### *5.2.3 Resources*

21. The different CAs met in meat processing establishments, laboratories and for CWD surveillance, although recognising some difficulties in recruiting staff due to a general lack of veterinarians nationwide, did not identify shortage of staff as an issue.

### *5.2.4 Organisation of official controls*

22. Verification of compliance of EU-listed establishments with the relevant requirements of EU legislation and the Canadian provisions (recognised as equivalent) is carried out annually by the VIC.

23. Official controls over federally registered establishments listed for export to the EU comprises daily presence of VICs and SIs for carrying routine supervision, *ante-* and *post-mortem* inspections. Routine visits are performed by Regional supervisors, whilst once every two years, the HACCP-based programmes are reviewed in each establishment.

24. Certification tasks are performed at establishment level by the VIC, or other OVs of the team; SIs may assist in verification tasks and documentary checks of the consignments.

25. Health Canada performs official controls over VMPs wholesalers, based on risk evaluation and at a minimum frequency of one inspection every four years. Summarised inspection reports are publicly available on the web-site of the department.

26. The use of VMPs by licensed veterinarians is verified at provincial level by the Orders/Associations of veterinarians. The frequency varies by province and on the basis of the findings of the previous control, and are generally performed at a frequency of once every three to seven years. Provincial CAs carry out inspections on licensed veterinarians mainly following complaints.

27. On-farm controls are performed by the CAs when carrying out health screenings for tuberculosis and brucellosis, ideally every five years in game farms. Feedlots for horses, participating in the specific CFIA programme for lot identification, are inspected once a year by CFIA OVs and twice a year by an accredited veterinarian contracted by the FBO.

28. Some provincial authorities carry out an inspection of VMPs retailers annually; and a standardised report template is available for inspectors. This is not the case in Québec, where there are no retailers for VMPs (see paragraph 16).

29. Horse traders and horse feedlots other than those implementing the CFIA programme for lot identification are not registered with the CFIA or the provincial authorities, and thus they are not subject to official controls.

### *5.2.5 Documented control procedures*

30. The Compliance Verification System (CVS) included in Chapter 18 of the MHMOP is a computerised tool used by CFIA inspectors to verify FBO compliance with regulatory requirements. It comprises a series of tasks generated in accordance with national frequencies, to be performed by inspectors (VICs and area/products managers) in order to cover all legal requirements. Each verification task includes detailed procedures for the inspection staff to follow when conducting verifications. Recently the CVS has been

amended, and some tasks do not have a set frequency, but allows the CFIA inspectors to create a risk profile and adjust inspection oversight based on risk.

31. The specific tools relevant for official controls in the areas covered by this audit were available at all establishments visited. They include:
    a. *verification worksheets* - used by inspectors each time a CVS system task is performed;
    b. *verification reports* - issued generally on a weekly basis and shared with the FBO, in which the main findings of the verification worksheet are reported; it deals with minor non-compliances not requiring the issue of a Corrective Action Request (CAR), and the FBO is requested to indicate the corrective/mitigating measures put in place, and the deadline for their implementation;
    c. *inspection report* - CAR, issued by the inspector to the FBO in case of major non-compliances with a (potential) risk for product safety;
    d. *follow-up module* - used for verification one month after the deadline for the implementation of the corrective measures by the FBO.

32. The CVS document and communicate verification results, including the follow-up to identified non-compliances, and the enforcement action taken when non-compliances have not been corrected by the FBO as required.

33. The CVS verification tasks were generally carried out and documented as required in all the establishments visited. The audit team noted some deficiencies which were not included in the CVS tools, or were again noted although having been included in a previous CAR which had been closed due to action having been taken.
34. Annex M of the MHMOP (hereafter Annex M) is used for the annual assessment of compliance with the EU requirements in EU-listed establishments. Additionally, the check-lists used as a verification of consignments ready for export also contain some references to EU requirements to be checked.

35. Certification of fresh meat intended for export to the EU is not performed through the TRACES system, but it is based on hard copies certificates issued and signed by the VIC following verification completed by the CFIA inspector that the shipment meets the importing country requirements.

36. The controls over VMPs retailers seen in Alberta are documented through standard check-lists.

**Conclusions on competent authorities.**

37. The different CAs involved in the official controls of the production and certification chain of horse and game meat are clearly designated, well organised, and adequately resourced. A comprehensive set of operating procedures for controls, underpinned by appropriate and adequate reporting tools, is in place.

38. The absence of cooperation and coordination between federal and provincial authorities presents a missed opportunity for enforcement of federal and provincial legislation at holding level.

### 5.3 LISTING OF ESTABLISHMENTS

**Legal requirements**

Article 12 of Regulation (EC) No 854/2004.

Article 5.7.(4) and Annex 5-E and F of the CETA

**Findings**

39. Article 5.7(4) and Annex 5-E and F of CETA provide basic requirements for listing of food establishments for export to the EU: guarantees must be provided that the premises and their operations comply with the relevant Canadian legislation which has been recognised as equivalent to EU requirements.

40. In response to recommendation No. 6 of 2014 audit ("*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 the lists of establishments approved for export to the EU are kept up to date, fully reflecting the activities carried out and communicated to the Commission as requested by Article 12 (3) of Regulation (EC) No 854/2004*") the CCA stated that they would develop a CVS task specific for verification, for a yearly delivery at all EU eligible establishments, to be implemented as from April 2015**.** Verification of EU requirements by inspection staff will be documented in the CVS database and this information will be tracked and reported to senior management on a regular basis.

41. The CCA stated that the specific task for verification of compliance of food-processing establishments with the EU requirements is included in **"***Chapter 18.4.3 Section 3: Export"* at the subsection *"2: Export other than USA"***.**

42. Annex M is used for annual verification of export requirements specific to the EU in the establishments visited. In addition, some VICs have documented the verification of the EU requirements before certification of consignments of horse and/or game meat, through specific checklists.

43. Although two out of four slaughterhouses visited had ceased horse slaughter since April 2017 and will not resume this production, these two premises were still on the EU list at the time of the audit. The audit team noted that, although the on-site laboratory for testing of horse meat for *Trichinella spp*. was not operational since April 2017 and that no contract with external laboratories could be documented, this non-compliance was not mentioned in the official controls documented by the VIC in April 2018 (by completing Annex M), the HACCP Area Manager in September 2017 or the Area Supervisor during quarterly visits. Moreover, the Annex M completed by the VIC in January 2018 stated that the establishment was fully compliant with the EU requirements, including for activities never carried out, like the production of casings, minced meat and meat preparations). The FBO operating this establishment applied on 13 August 2018 to be delisted for the production of horse meat.

44. One game establishment is also listed for export of wild game meat: however, CFIA informed the audit team that since 2017 the MHMOP has been amended to include the statement that Canada cannot currently certify wild game meat for export to the EU.

**Conclusion on listing of establishments**

45. The actions implemented by the Canadian CCA in response to recommendation No. 6 of the 2014 audit have not been sufficiently effective in ensuring that the listing details of half of the visited establishments accurately reflect the activities currently carried out, or that the establishments did fulfil all the conditions for listing.

### 5.4 OFFICIAL CONTROLS OVER PRODUCTION OF FARMED/WILD GAME MEAT

#### Legal requirements

Model certificates "RUF" and "RUW" in part 2 of Annex II to Regulation (EU) No 206/2010.

Regulations (EC) No 852/2004, No 853/2004 and No 854/2004.

#### Findings

46. The model certificate "RUW" requires that meat is derived exclusively from wild animals which have been examined for CWD with negative results, and come from a region where CWD has not been confirmed/officially suspected in the last three years.

47. According to the CCA, and although one of the four establishments listed for export of game meat to the EU is also authorised to export meat from wild animals hunted in the field, no wild game meat is produced in Canada in federally approved establishments, or exported to the EU.

48. As mentioned in paragraph 7, and although national legislation provides for zoning/ regionalisation of the national territory in case of animal diseases, this does not yet apply to CWD. The CCA applies the compartmentalisation in accordance with the OIE

provisions, where the compartment is the single game holding participating in the national CWD-VHCP and thus considered at a low risk. The rest of Canada is consequentially considered to have an "unknown status" with regard to CWD. Based on these procedures, Canada cannot currently certify meat derived from wild cervids originating from the EU-listed establishment, and the MHMOP has been amended accordingly.

49. The model certificate "RUF" requires that meat contains or is derived exclusively from animals which have been examined for CWD with negative results, and come from a herd where CWD has not been officially suspected or confirmed.

50. The FBO operating the slaughterhouse must ensure that all farmed cervids slaughtered for the EU market are tested in laboratories of the CFIA network for detection of the prion protein responsible for CWD. In Québec, the CWD testing is carried out in MAPAQ laboratories. Test results are usually available within a few days from sampling, while the carcases are retained until the result is available; in the event of positive results, all carcases belonging to the same batch (holding of origin) will be declared as non-eligible for export to the EU. Animals for national or other markets are tested in a variable percentage, depending on the specific provincial requirements.

51. To be able to guarantee that farmed cervids originate in herds where CWD has not been confirmed or officially suspected, the CAs operate national and provincial CWD surveillance programmes.

52. Identification of animals in game holdings (irrespective of CWD VHCP) is based on the provincial legislative implementing requirements, based on the Livestock Identification and Traceability program (TRACE) jointly administered by CFIA and industry; TRACE is regulated and enforced under Part XV of the *Health of Animals Regulations*, made under the authority of the *Health of Animals Act*. Identification includes an official ear-tag (metal tag in Alberta, plastic tag with radio-frequency identification - RFID - in Québec) and a dangle tag for herd management. National and provincial programmes also require FBOs to keep an annually updated inventory of the animals kept, and to keep records of medical treatments.

53. When in a herd an animal is found positive to the CWD test, confirmation is requested from the National Reference Laboratory (NRL) in Ottawa; details of the holding are located on the CFIA CWD case number tracking sheet, published on the web site of the CFIA. The CFIA veterinarian is responsible for ensuring that the owner registered on the deer movement permit is not under movement restrictions for CWD, before certifying consignments of game meat for the EU.

*54.* Holdings in which positive cases are detected are subject to movement restrictions and to epidemiological investigation, and to tracing back of animal movements that occurred in the past five years. Moreover, holdings in the CWD-VHCP are depopulated and compensated from the federal budget. Since April 2018, holdings not enrolled in the CWD-VHCP are not depopulated. Holdings enrolled in provincial programmes or not

participating in a surveillance scheme (few provinces have no CWD surveillance programmes) are not depopulated; however, provinces like Saskatchewan and Alberta are in the process of amending their legislation to allow stamping out and compensation in infected herds enrolled in their provincial CWD surveillance programmes. Few holdings have been found infected in the past years. However, at the time of the audit, three holdings were found infected in 2018: one in Saskatchewan, one in Alberta and one in Québec. All holdings found positive in the previous years have been depopulated, whilst two of 2018 have been subject to stamping out measures (the one in Québec having been notified only in the course of this audit, thus still awaiting decisions on the measures to be applied – see paragraph 61([2])).

55. Holdings keeping farmed cervids are registered in accordance with provincial legislation and the farmers are licensed, as required by the same provisions.

56. The audit team verified the documents related to medical records, animal inventory and records of official controls, in two game holdings. In one holding the medical records were incomplete, as they did not cover all treatments and all groups of animals. In the same farm, the CCA explained the absence of official control records on-farm by the fact that such records are given to the FBO only when non-compliances are detected.

#### *5.4.1 National surveillance programme*

57. The participation in the CWD-VHCP is optional; however, once owners/cervid farms are enrolled in the CWD-VHCP, compliance with the regional CWD-VHCP is mandatory. The CWD-VHCP includes four main requirements: maintenance of animal inventory records, testing of all dead/slaughtered cervids, introduction of live cervids from herds with the same or higher status, and implementation of biosecurity measures as per the National Cervid Farm-level Biosecurity Standard.

58. The national CWD-VHCP requires all farmed cervids younger than 12 months to be identified with at least two unique identification devices, one of which is an official device, and one of which can be read from distance (usually an ear-tag). Animals must be traceable during their whole life and an inventory must be kept on-farm. In addition, the farm is subject to yearly verification by a veterinarian or by trained and qualified provincial/territorial game farm inspectors, and must implement the biosecurity measures laid down in the national Standard. Movements from/to VHCP holdings and their CWD status are recorded by the FBO and records are kept for a period of five years after the cervids have left the herd. Acquisition of live cervids must be from herds of an equivalent or higher CWD status, otherwise the status of the receiving farm will be downgraded to the same certified level of the herd of origin. When all the CWD-VHCP requirements set out in the National Standards, including surveillance, have been followed for a minimum of five years, the farm receives a status of "low risk" of CWD.

59. The table below shows the number of game farms (CWD-VHCP participants in i*talics*):

[2] In their response to the draft report, the CCA stated that the herd in Québec had been depopulated by the CFIA in late 2018.

| Province | Elk | Red deer | Whitetail | Fallow, Mule deer, Reindeer | TOTALS per Province |
|---|---|---|---|---|---|
| **Yukon** | **4** | **0** | **0** | **0** | **4** |
| **British Columbia** | **0** | **0** | **0** | **12** | **12** |
| **Alberta** | **151** | **0** | **17** | **4** | **172** (*85*) |
| **Saskatchewan** | **137** | **0** | **43** | **16** | **196** (*25*) |
| **Manitoba** | **23** | **0** | **3** | **2** | **28** *(1)* |
| **Ontario** | **29** | **55** | **6** | **7** | **97** (*7*) |
| **Québec** | **29** | **63** | **12** | **17** | **121** (*8*) |
| **New Brunswick** | **3** | **6** | **3** | **1** | **13** |
| **Nova Scotia** | **1** | **5** | **0** | **1** | **7** |
| **TOTALS** | **377** | **129** | **84** | **60** | **650** (*126*) |

### *5.4.2 Provincial surveillance programmes*

60. To complement the national CWD-VHCP, provincial authorities have drafted and implemented own surveillance programmes which may require different testing regimes and actions to be taken in infected holdings.

61. **QUÉBEC:** For farmed/captive cervids, the MAPAQ is in charge of enforcing the *Loi sur les produits alimentaires* (Food Products Act) and the *Loi sur la protection sanitaire des animaux* (Animal Health Protection Act), by analising samples taken from animals over 12 months of age at farm and slaughterhouse level. For wild deer, the MFFP is responsible for enforcing the *Loi sur la conservation et la mise en valeur* under which the *Réglement sur les animaux en captivité* had been passed. At the time of this audit, there was no evidence of presence of CWD in Québec([3]), and the MFFP was conducting analyses on a certain percentage of cervids hunted in the areas considered most at risk, mainly in the south of the province near the Canada-US border (regions of Estrie and Montérégie). For the rest of the province, cervids analysed were mainly those showing clinical signs suggestive of CWD. In the last ten years, more than 9,500 cervids were tested, all negative. In addition, five animals of each batch of slaughtered cervids were tested. During this audit the audit team was informed that a screening test conducted by the provincial laboratory revealed a non-negative result in an asymptomatic farmed animal. Confirmatory tests carried out by the NRL confirmed that this was a positive result. As an immediate response, MAPAQ issued a notice requiring testing for all farmed cervids older than 12 months brought to slaughterhouses, regardless of the destination market. In addition, MAPAQ tested five animals per lot per day if they came from a non CWD-VHCP registered herd, while registered animals were 100% tested. In the case of detection of CWD, a restricted area for the movement of captive deer is

[3] In their response to the draft report, the CCA stated that as of May 9, 2019, there was no data confirming the presence of CWD in wildlife in Québec.

established in accordance with Article 91 of the *Réglement sur les animaux en captivité* under the authority of the MFFP: no living deer can be moved to another guard site if it is kept in a site that is within 100 km of the location where the CWD was detected. This provision was applied regarding the detection of CWD made at the time of the audit.

62. **ALBERTA:** CWD is found in wildlife in the eastern part of Alberta, as well as in the bordering province of Saskatchewan. The *Office of Alberta's Chief Provincial Veterinarian* (OCPV) is responsible for implementation of the CWD surveillance and certification programme, collaborating with "Alberta Environment and Parks" fish and wildlife division on CWD surveillance in wildlife. Since 2002, Alberta's Mandatory CWD Surveillance Program is in place, requiring all elk and deer farmers to submit all animals over one year of age that die on farms or are slaughtered, for CWD testing.

#### *5.4.3 General requirements applicable to all establishments*

63. Four establishments (slaughterhouses with attached cutting facilities) are listed for export of farmed game meat to the EU (one also for wild game meat); all are also listed for export of horse meat. The two establishments slaughtering cervids and bison respectively, were found generally compliant with requirements, bar minor deficiencies.

64. Traceability exercises carried out by the audit team on consignments of farmed game meat dispatched to the EU were satisfactory.

**Conclusions on production of farmed/wild game meat destined for export to the EU and its control.**

65. The production of farmed game meat intended for export to the EU in general complies with the equivalent Canadian requirements and the additional EU ones, although some shortcomings in respect of the obligation to keep accurate and reliable records of medical treatments at holding level, were identified. In compliance with the requirements of the health certificate "RUF" laid down in part 2 of Annex II to Regulation (EU) No 206/2010 all carcases fit for export to the EU undergo laboratory testing for CWD and originates from herds in which, according to the Federal and Provincial surveillance programmes, CWD has not been suspected or confirmed.

### 5.5 OFFICIAL CONTROLS OVER PRODUCTION OF HORSE MEAT

**Legal requirements**

Model certificate "EQU" laid down in part 2 of Annex II to Regulation (EU) No 206/2010.

Regulations (EC) No 852/2004, No 853/2004 and No 854/2004.

**Findings**

### *5.5.1 Controls over imported and domestic live horses*

66. Since the entry into force of the amended EU health certificate for horse meat (March 2017), meat from horses imported into Canada from the US and destined for immediate slaughter in federally registered slaughterhouses cannot be certified for export to the EU. These animals are certified by the United States Department of Agriculture OVs as having resided in the US for 60 days, in accordance with Canadian animal health requirements. This requirement does not support the statement of the EU certificate, indicating that the EU-eligible animal must have been kept for a minimum of 90 days in a third country from which export of horse meat to the EU is authorised, and in which certain VMPs must not have been administered to domestic *equidae*.

67. Since October 2011, all shipments of horses from the US by ground transportation may only be introduced via designated points of entry. At these points, the authorities have appropriate facilities in place to unload the animals and for CFIA staff to perform their checks. Trucks are then sealed until the final destination. CFIA data for the number of horses imported from the US for immediate (within four days) slaughter, consignments imported, and the consignments rejected at the border are the following:

| Year | Horses | Consignments | Consignments rejected |
|---|---|---|---|
| **2015** | **36,314** | **1,327** | **32** |
| **2016** | **28,891** | **1,067** | **19** |
| **2017** | **11,301** | **414** | **2** |
| **2018** | **7,062** | **253** | **1** |

68. Horses destined for feedlots ("feeder horses") are also subject to import controls, which have been delegated by the CFIA to the Canadian Border Service Agency (CBSA). At the entry point, the horses are inspected in the truck to verify fitness for travel and any other irregular signs. If problems are identified, the consignment is referred to the CFIA OV. The CBSA is not required to seal consignments of horses destined for feedlots after they have been found eligible for the import, and as long as they are accompanied by the correct model certificate, which includes the requirement for testing for infectious equine anaemia. The CCA data on horses imported from the US and destined to feedlots are the following:

| Year | Horses | Loads | Rejected loads |
|---|---|---|---|
| **2015** | 1605 | 44 | 3 |
| **2016** | 1281 | 41 | 2 |
| **2017** | 1361 | 48 | 5 |
| **2018** | 1324 | 46 | 0 |

69. The CFIA stated that the regulatory requirements for controls on animal health and animal welfare at the border entry point do not require the unloading of animals. Imported horses are therefore not always unloaded during import controls, but may be unloaded in case a closer examination is needed. No cross-checks are carried out by the veterinarian between the information on the Equine Information Document (EIDs - individual horse documents with description or identification) and individual horses. The CFIA stated that the EIDs are not legally required for the verification of import conditions at the point of entry. The import controls focus on animal health and animal welfare conditions.

70. Consignments containing horses of US origin, but destined to be kept in Canadian feedlots for at least six months as "feeder horses" are also accompanied by an Equine Certification Document (ECD) signed by an authorised veterinarian in the US which refer to the animal health certificate covering the number of animals in the consignment and states that the EIDs have been completed; errors in the EIDs are not a reason to refuse the entry of horses in the feedlot, as these horses will remain at least six months there to become EU-eligible.

71. Currently there is no legal requirement for mandatory identification of domestic horses; some race horses may be identified by microchips or tattoos. According to the CCA, around 39,164 premises host 291,561 domestic horses. A few commercial horse holdings raise animals for meat production for the Japanese market.

72. Horses of Canadian origin must be accompanied by an EID, completed by the previous owner and if applicable by the transient agent (trader) who had the responsibility for the care of the equine, from the time of purchase for slaughter until the arrival of the animal to a meat processing establishment. Transient agents are not subject to any official control and are not required to keep records of animal movements or medical treatments, even when they keep the animals for more than a few days in their own premises/feedlots.

73. In order to reduce administrative burden, animals which form part of a CFIA-approved Equine Lot Programme may be identified with a group identification mark and the EID may be replaced by a Sub Lot Equine Information Document (SLEID). At present, one Equine Lot Programme - covering three feedlots at different locations, supplying horses to one slaughterhouse - has been approved by the CFIA. The horses in the programme are obtained from individual owners, through auctions or imported from the US.

74. Only auction sites (dealing mainly with bovine animals, but occasionally receiving horses) are registered with the Provincial authorities. Feedlots (other than those registered under the Equine Lot Programme) and transient agents are not registered and are not subject to official controls by either CFIA or provincial authorities.

75. The audit team noted in the horse feedlot operating under the Equine Lot Programme visited that the medical records were correctly kept; in line with requirements of Annex E2 or E4 to Chapter 17 of the MHMOP respectively, VMPs used within the last 180

days prior to slaughter were declared for the entire group. This feedlot, at the time of the visit, had more than 6000 horses.

76. There is no legal obligation for farmers to keep records of medical treatments of horses, except for horse feedlots participating in the Equine Lot Programme.

77. One FBO running a visited slaughterhouse had been notified three times in 2017 through the Rapid Alert System for Food and Feed of positive results of phenylbutazone in horse meat dispatched to the EU: as a follow-up measure, the FBO undertook at his own initiative to test all slaughtered horses for this substance (no other anti-inflammatory or antimicrobial substances are included in the screening). Although the number of positive results had decreased since the testing regime was implemented, a few positive results (1-2/week over an average of 200 horses slaughtered/week) still occur in animals for which the previous owner had declared the absence of medical treatment in the EID. As a consequence, the information contained in several of the EIDs checked by the audit team, is likely to have been unreliable/incorrect, when considered in the light of the testing results of the FBO. The FBO applies financial penalties to these owners. In the other horse slaughterhouse, the FBO does not test the carcases. When positive results are detected in official samples taken by the VIC, the supplier is black-listed and cannot supply horses for slaughter anymore.

78. The VIC can take, in the framework of the residues surveillance programme run by the CFIA, some official samples from horse carcases (on average, 15 to 20 carcases are sampled in a month). In case of positive results, the CFIA animal health teams are informed and can carry out a follow-up visit at the holding of origin to investigate the source of the residues. However, the programme has been described as "educational" and not enforceable, thus not leading to any sanction to the farmer, although a note on the EID warns the declarant about possible penal actions in case of incorrect/false declaration.

79. Positive results for phenylbutazone found by the FBO (see paragraph 77), are not systematically passed to the VIC. The CFIA representatives informed the audit team that in this case, the task of the VIC is to ensure that the FBO takes the corrective measures foreseen in his procedures, and that CFIA inspectors are not legally entitled to enter the holdings concerned for investigation purposes.

80. Nonetheless, the audit team noted that Provincial legislation offer a possible tool for enforcement in case of residues violations in animals brought for slaughter. For instance (see paragraph 4), Provincial legislation in Québec (*Loi sur la protection sanitaire des animaux*), in case of supply to a slaughterhouse with animals the meat of which contains residues of VMPs above the MRLs, allows provincial authorities to impose fines from 250 CAD to 2,500 CAD. However, the use of this tool would need strong collaboration and coordination between CFIA (responsible for controls at slaughterhouses) and provincial authorities (responsible for controls at holdings level), not currently envisaged.

### *5.5.2 Specific requirements for slaughterhouses*

***Ante-mortem inspection***

*81.* The MHMOP requires that the FBOs must have effective control programmes and procedures to ensure claims made on the EIDs they accept may be considered valid. Verification takes place through documentary checks upon arrival at the abattoir: incomplete or erroneous EIDs lead to phone calls to the owner or transient agent to amend the documentation, while the animal is retained and not allowed to be slaughtered until the correct documentation has reached the abattoir. In some cases financial penalties by the FBO are considered.

82. The FBO must have signed agreements with owners and transient agents allowing the CFIA animal health inspectors to verify the accuracy of information during on-the-spot visits. So far this verification task has not been implemented (the same finding has been noted in the 2014 audit). There is no enforcement by CFIA, which limits its action to the verification that the FBO has implemented the actions as described at paragraph 77.

83. The audit team verified a number of EIDs, noting that several of them had been received with inaccurate/mistaken statements and had been corrected following phone contacts between the FBO and the owners. Sometimes, transient agents had been requested to ensure the follow-up of invalid EIDs. In order to verify the accuracy of the EIDs, transient agents were in one establishment requested to interview previous owners whilst in other establishments this was done by the FBO staff. CFIA staff was not systemically informed of the non-compliances and the record keeping by the FBO was generally poor (only corrections on the EIDs).

84. The *ante-mortem* inspection was carried out appropriately by VIC/OVs in all abattoirs visited, and all findings were documented on the pen cards.

***Post-mortem inspection***

85. Equivalent CA procedures (MHMOP + CETA) require all horse carcases destined for export to the EU to be tested for *Trichinella spp.* The test is carried out by FBO staff in on-site laboratories; results are periodically checked by the VIC and in any case at the time of certification of the consignments destined to the EU (the only export market that requires testing). Staff in charge of tests had a certificate of proficiency and participated in inter-laboratory testing organised by the NRL in Saskatoon every six months. Since 2016, liquid pepsin has been used instead of granular pepsin, but the correlation of its strength with that of the granular pepsin previously used has not yet been demonstrated.

86. Some cases were seen where a staff member in one establishment had failed the proficiency test; follow-up documentation was available to demonstrate then the same staff participated and passed successfully in a new proficiency test within one month.

87. Generally, *post-mortem* inspection was performed correctly, but records were kept only in case of condemnation of entire carcases, and not for all cases of findings. Records of partial condemnation were kept by the FBOs for commercial reasons.

***Animal welfare controls at slaughter***

88. No animal welfare concerns were found in any of the establishments visited; horses and bison were stunned with a rifle and captive bolt pistols were present as the backup stunning equipment.

89. The physical condition of all horses seen was satisfactory.

### *5.5.3 General hygiene requirements applicable to all establishments*

90. The establishments visited were generally in line with the requirements with only minor non-compliances identified by the audit team, e.g.:

    a. extensive and incorrect use of hoses for washing tools and aprons led to splashing over the carcases;

    b. edible offal (hearts, kidneys and livers) remained too long at ambient temperature in the offal room before packing and chilling;

    c. handling of cardboard boxes and unprotected meat by the same operators;

    d. insufficient segregation of EU and non-EU products in the freezer;

    e. possibility of dirty carcases contaminating clean ones before being diverted for trimming.

### *5.5.4 HACCP and microbiological testing*

91. The Canadian traceability and health/identification requirements for exports to the EU are described in Chapter 11 of the MHMOP; Section 11.7.3.6.8 "Traceability requirement" and Section 11.7.3.5 "Special marking and packaging requirements".

92. The FSEP manual requiring HACCP standards to be implemented in all CFIA registered establishments under the MIR is mandatory since November 2005. The HACCP programmes have to be evaluated regularly by the on-site VIC/FPI and the RVO/FPS, as part of their official controls.

93. Once every two years HACCP System Design Tasks are conducted by a CFIA team led by a FSEP Specialist Inspector to evaluate in depth the HACCP programme in accordance with Chapter 18, Section 18.4.4 of the MHMOP. This task is performed more frequently in the case of new HACCP programmes, follow-up to a food safety recall, failure to meet microbiological performance standards or failure to meet CFIA pathogen control policy requirements.

94. The Canadian carcass sampling for pathogen reduction follows requirements established by the MHMOP and CETA similar to the US requirements. With regard to control of *Salmonella*, 58 consecutive samples (swabs) are taken from consecutive slaughter days targeting the most important species: this annual testing programme is completed if the results are considered to be acceptable, i.e. no more than two positive results out of the 58 samples tested.

95. One sample per 300 horses slaughtered is to be taken for *E. coli* testing: one FBO visited respected this frequency, whilst the other was sampling one carcase per slaughter day, irrespective of the size of the slaughter batch. Sampling for total bacterial counts do not provide for Canadian requirements.

96. The sampling of carcasses for *Salmonella* testing was verified in one horse slaughterhouse visited; all the test results were favourable and in line with the CA findings. In the same establishment water samples were taken monthly and tested for total bacterial count, *E. coli, faecal streptococci/enterococci* and total coliforms with satisfactory results. The chlorination level of the water from the own well was in line with Canadian standards, but well above EU ones.

97. All FBOs had traceability systems in place to trace back meat to the animal or groups of animals. In the cases audited the production of the EU eligible meat was carried out before any non EU eligible production would start, and in all cases but one the EU eligible carcasses/meat were properly identified and stored separately from the non- EU eligible carcasses/meat. Reconciliation was possible in all the cases evaluated by the audit team.

**Conclusions on production of horsemeat destined for export to the EU and its control.**

98. The production of horse meat intended for export to the EU in general complies with the equivalent Canadian requirements and the additional EU ones.

99. However, there are substantial weaknesses in the enforcement of national rules with regard to documentation (EIDs) accompanying horses to slaughter, in particular those requiring animals not having been treated with prohibited substances in food-producing animals (e.g. phenylbutazone) or in which withdrawal periods of allowed VMPs have not been respected. In particular, there are no official checks to verify the authenticity of the EIDs or whether the horses actually match the identifications registered on the EIDs.

100. The information contained in several of the EIDs checked by the audit team, in conjunction with the testing results of the FBO, appeared incomplete and unreliable. This affects the reliability of the guarantees provided by the CA that horses slaughtered in Canada for export to the EU have not been treated with substances which are not permitted in the EU, or for which the withdrawal periods had not been complied with.

## 5.6 OFFICIAL CERTIFICATION

### Legal requirements

Article 6 of Directive 96/93/EC.

Article 14 of Regulation (EC) No 854/2004.

Articles 14 and 18 of Regulation (EC) No 206/2010.

Annex 5-I of the CETA.

### Findings

101. Documented procedures are in place concerning the certification of the products covered by the scope of the audit and intended to be exported to the EU. Similar procedures are followed in relation to certifying EU eligibility of products on the domestic transfer documents. Certification of fresh meat is done by the on-site VIC.

102. Although required by the Canadian legislation, the FBOs visited had no written procedures for preparing the documentation needed for certification. However, the audit team noted that the VICs had the necessary supporting documentation made available at the time of certification of consignments for export to the EU.

103. Certificates seen by the audit team in the establishments visited (both for farmed game meat and horse meat) were all correctly completed. Traceability of the meat being certified was possible back to the holding of origin.

**Conclusions on official certification**

104. Certification procedures are adequate, and are applied as planned.

## 5.7 CONTROL OF USE OF VETERINARY MEDICINAL PRODUCTS

### Legal requirements

Point II.1.7 of the model certificate "EQU"**.**

### Findings

#### *5.7.1 Veterinary medicinal products and residues in relation to horse meat*

105. The health certificate for horse meat requires the horses, the meat of which is destined to the EU, to stay six months in a third country where the administration to domestic solipeds of thyrostatic substances, stilbenes, stilbene derivatives, their salts and esters, estradiol 17ß and its ester-like derivatives is prohibited, and where the administration of substances having estrogenic, androgenic or gestagenic action and ß agonists is only allowed for specific therapeutic or zootechnical treatments.

106. The CFIA published a list of VMPs including withdrawal periods which may be used in horses intended for food (annex E7 to Chapter 17 of the MHMOP), where various formulations of phenylbutazone, estradiol 17ß and anthelmintics contain a warning on the label and/or package insert "not to be used in horses for food production", as well as a list of 'essential substances" for horses with a default 180 day withdrawal period (annex E6 to Chapter 17 of the MHMOP), in line with Commission Regulation (EC) No 1950/2006.

107. Health Canada has published a list of VMPs being used in horses (for instance, various formulations of phenylbutazone, estradiol and anthelmintics contain a warning on the label and/or package insert "not to be used in horses for food production"), and a list of VMPs considered essential medicines. The Health Canada website also indicates the withdrawal periods for most of them, as well as national MRLs for pharmacologically active substances.

108. Concerning game animals, no specific VMPs are available and it is common to have off-label use of VMPs approved for cattle.

109. In response to 2014 audit, the CCA stated that any VMP used within the last 180 days prior to slaughter must be declared by the owner and that they will work with the horse industry to strengthen the ways and the means of ensuring that animal identification and treatments records are credible and complete for these 180 days before slaughter.

110. The work of the CFIA done together with the horse industry to strengthen the system has not resulted in tangible actions: tests carried out by one FBO met during the audit demonstrate that EIDs are not always reliable and do not always correctly record the VMP status of the relevant animal.

#### *5.7.1.1 Veterinary medicinal products*

111. Whilst in the EU horses are food producing animals until and unless they have been signed out of the food chain, in Canada horses are by default not considered to be food producing animals until they have been designated for this purpose.

112. Veterinary clinics and agricultural supply stores (except in Québec, where such stores do not sell VMPs subject to veterinary prescription) are the main sales points for VMPs for horses. These are mainly supplied by wholesale distributors.

113. VMPs that contain substances contained in the Prescription Drug List are only available on prescription. However, except than in Québec, where they are all under veterinary prescription, various antimicrobials and anthelmintics are available over-the-counter in agricultural supply stores([4]).

114. Annex E5 to Chapter 17 of the MHMOP contains a list of substances not permitted for use in horses for food production. This list contains, *inter alia*, chloramphenicol,

[4] In their response to the draft report, the CCA stated that this was valid at the time of the audit. Since December 2018, this does not apply to category 1-2-3 antimicrobials across Canada.

nitrofurans, beta-agonists, nitroimidazoles, stilbenes, thyrostats, chlorpromazine, dapsone, antibiotics for growth promotion purposes, boldenone, estradiol, resorcyclic acid lactones and steroidal hormonal implants for growth promotion purposes, which is largely in line with the banned and prohibited substances in the EU.

115. Licenced free practice veterinarians are permitted to import veterinary and human medicinal products from third countries for "own use" in food producing animals; however, Health Canada informed the audit team that a specific single use licence from Health Canada is required to do so.

116. The approved feedlot visited kept treatment records per age-cohort (a lot of horses) distributed over various pens. The VMPs used and the withdrawal periods observed were in line with CFIA recommendations.

117. The two wholesalers of VMPs visited by the audit team were licensed by Health Canada. The premises had been inspected at the required frequency (every three years). Non-conformities noted during those inspections had been corrected by the company and this had been verified by Health Canada. Standardised inspection reports were used.

118. The retail outlet visited by the audit team was licensed and annually inspected by the provincial authority in line with provincial requirements. Standardised checklists/inspection reports were used. The content of the inspections was limited to checking the storage facilities, the expiry dates and registration numbers on the products in stock, and the qualifications of the sales staff.

119. Retail outlets are authorised to sell several antimicrobials (e.g. tetracycline, tylosin and monensin) and antiparasitics (e.g. avermectin) over-the-counter. The chain of the retail outlet visited had an efficient computerised programme allowing tracing back of farmers and VMPs sold. The representatives of the Alberta provincial authority stated that the legislation is being amended, restricting the list of VMPs being sold at retail level. However, certain VMPs will continue to be sold through this channel([5]).

#### *5.7.1.2 Monitoring of residues*

120. Canada follows the guidelines of the *Codex Alimentarius* Commission (CAC/GL 16-1993 “Codex guidelines for the establishment of a regulatory programme for control of veterinary drug residues in foods”). The residue monitoring plan follows a fiscal year, from April to March. Few positive results had been found in horse meat (see DG(SANTE)/2016-8896 for more details).

[5] In their response to the draft report, the CCA stated that this was valid at the time of the audit. Since December 2018, this does not apply to category 1-2-3 antimicrobials across Canada.

**Conclusions on the use of veterinary medicinal products**

121. The effectiveness of follow-up of non-compliant results has been variable. Whilst the CFIA puts the responsibility for follow-up of non-compliances largely on the shoulders of the slaughterhouses, CFIA does not perform inspections on holdings keeping horses on the basis of the agreement between FBO and slaughterhouses' owners, to verify and ensure the effectiveness of the follow-up investigations and corrective actions. As observed in earlier audits, the CFIA is in this regard hampered by a lack of direct powers over primary producers and transient agents.

122. No concrete actions have been put in place by both CFIA and horse industry to verify that EIDs are reliable and correctly record the VMP status of the relevant animal. CFIA does not adequately enforce the relevant regulatory obligations in this respect.

123. Several antimicrobials and antiparasitics are available over-the-counter to farmers; the provincial legislation is currently being amended, limiting the number of VMPs being sold without veterinary prescription, but certain VMPs will remain available over-the-counter.

## 6 OVERALL CONCLUSION

The different CAs involved in the official controls of the production and certification chain of horse and game meat are clearly designated, and well organised. A comprehensive set of operating procedures for controls, underpinned by appropriate and adequate reporting tools, is in place. Certification procedures were found to be adequate.

The production of farmed game meat intended for export to the EU generally complies with the relevant Canadian and Union requirements, including the requirement that all carcases fit for export to the EU undergo laboratory testing for CWD and originates from herds in which, according to the federal and provincial surveillance programmes, CWD has not been suspected or confirmed. Some shortcomings in respect of the obligation to keep accurate and reliable records of medical treatments at holding level were identified.

While all slaughterhouses visited generally met the general and specific hygiene requirements, the CA does not ensure that the lists of establishments approved for export to the EU are kept up to date and accurately reflect the activities currently carried out, or that the establishments fulfil all conditions for listing. As such, the CA's actions implemented in response to the same point raised during the 2014 audit have not been sufficiently effective.

The audit identified certain issues in relation to the reliability of the controls over both imported and domestic horses destined for export to the EU, with the exception of horses kept in feedlots for a minimum of six months. The system does not provide full guarantees that horses have not been treated with illegal substances within the last 180 days before

slaughter, or that the withdrawal periods of VMPs had been respected. The official follow-up of non-compliant results is limited: whilst the CA puts the responsibility for corrective actions and follow-up of non-compliances largely on the shoulders of the slaughterhouses, it does not carry out inspections of holdings keeping horses to verify and ensure the effective implementation of corrective actions. The CA's action is, in this regard, hampered by a lack of direct powers over primary producers, and transient agents. The absence of cooperation and coordination with the provincial authorities, which do have such enforcement powers, constitutes a missed opportunity. The same finding was noted during the 2014 audit.

Several antimicrobials and antiparasitics are available over-the-counter; the provincial legislation is currently being amended, limiting the number of VMPs being sold without veterinary prescription.

## 7 CLOSING MEETING

A closing meeting was held on 24 September 2018 with the CCA. At this meeting, the preliminary findings of the audit were presented by the audit team and discussed.

The representatives of the CCAs acknowledged the findings presented by the audit team and offered some additional information.

## 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 to correct the deficiencies found should be presented to the Commission, within 60 working days of receipt of the report.

| No. | Recommendation |
|---|---|
| **1.** | To ensure that the establishments are approved for export to the EU only if they are subject to regular review to assess their compliance with all the conditions for listing, as required by Chapter 18 of the MHMOP, and that the lists of establishments approved for export to the EU are kept up-to-date, fully reflecting the activities carried out and communicated to the Commission as required by Article 12.(3) of Regulation (EC) No 854/2004.<br><br>*Recommendation based on conclusion No 45*<br>*Associated finding No 43* |
| **2.** | To develop tools for cooperation and coordination between federal and provincial authorities, to enforce existing legislation (both at federal and Provincial level) in case horses are brought to slaughterhouses when withdrawal periods after administering VMPs have not elapsed, or in the event |

| No. | Recommendation |
|---|---|
| | of prohibited substances being discovered.<br><br>*Recommendation based on conclusion No 38*<br>*Associated findings Nos 4, 19, 20, 79 and 80* |
| **3.** | To develop a reliable system to ensure that documentation (EIDs) accompanying horses to slaughter is reliable and correctly records the VMP status of the relevant animal, and to ensure that follow-up of non-compliances (residues) has an equivalent effect to the requirements of Articles 16-19, 22 and 23 of Council Directive 96/23/EC.<br><br>*Recommendation based on conclusions No 99,100, and 122*<br>*Associated findings Nos 72, 74, 77, 83, 109, and 110* |
| **4.** | To ensure that, in accordance with Canadian federal and provincial legislation, accurate and reliable medical records are kept at game farms level, to adequately support the declaration of the owner in the documents accompanying the animals to slaughter.<br><br>*Recommendation based on conclusion No 65*<br>*Associated finding Nos 56* |

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

http://ec.europa.eu/food/audits-analysis/rep_details_en.cfm?rep_inspection_ref=2018-6458

**ANNEX 1 – LEGAL REFERENCES**

| Legal Reference | Official Journal | Title |
|---|---|---|
| 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. 1760/2000 | OJ L 204, 11.8.2000, p. 1-10 | Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97 |
| 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 |

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| Reg. 1169/2011 | OJ L 304, 22.11.2011, p. 18-63 | Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 |
| 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. 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. 2015/1375 | OJ L 212, 11.8.2015, p. 7–34 | Commission Implementing Regulation (EU) 2015/1375 of 10 August 2015 laying down specific rules on official controls for Trichinella in meat |
| 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 |

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| 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 |