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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

ARGENTINA

FROM 03 TO 15 SEPTEMBER 2014

IN ORDER TO EVALUATE THE OPERATION OF CONTROLS OVER THE PRODUCTION OF AND CERTIFICATION PROCEDURES FOR FRESH EQUINE MEAT AND CASINGS DESTINED FOR EXPORT TO THE EUROPEAN UNION

Executive Summary

The report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Argentina from 3 to 15 September 2014. The objectives of the audit were to evaluate the operation of controls over the production of fresh equine meat and natural animal casings for human consumption destined for export to the European Union (EU), as well as certification procedures. This audit was carried out at the same time as FVO audit DG(SANCO)/2014-7226 to evaluate the operation of controls over the production of and certification procedures for fresh bovine meat destined for export to the EU.

The Argentinian Competent Authorities (CAs) are well defined and are in general able to ensure an official control system that altogether provides compliant or equivalent measures to those in EU legislation. Official controls on identification of animals and on their movements were generally capable of satisfying the animal health guarantees provided in the certificate for fresh equine meat. Official controls in casing establishments were capable of satisfying the guarantees provided in the relevant certificate.

Official controls in relation to ante- and post-mortem, general and specific hygiene requirements, Hazard Analysis of Critical Control Points-based systems, microbiological criteria, traceability and identification marking, animal welfare at the time of slaughter were overall satisfactory, albeit with some deficiencies. Whilst such deficiencies do not undermine the reliability of the statements in the relevant certificates for the export to the EU of natural animal casings and of fresh equine meat, corrective action is required. The certification procedures in place ensure that the rules and principles applied by the Argentinian certifying officers offer guarantees at least equivalent to those laid down in Council Directive 96/93/EC.

The vast majority of the actions taken by the Argentinian CCA in response to the recommendations of reports DG(SANCO)2012-6347 and DG(SANCO)2011-6143 have been implemented. Some are still in progress, in particular, the re-evaluation of establishments and the registration of medicinal treatments.

Whilst the system in place for the distribution and use of veterinary medicinal products and controls thereof, are quite different in comparison with EU requirements, the fact that anabolic compounds are not authorised for equidae provides assurances that the provisions of Council Directive 96/22/EC are satisfied and this is supported by the absence of non-compliant results in the national residue monitoring plan. However, the CA's delayed introduction of mandatory treatment records for equidae and evidence that unrecorded off-label treatments of equidae with veterinary medicinal products had taken place in the premises visited by the FVO audit team undermine the reliability of the vendors' declarations concerning use of such products.

A number of recommendations have been made to the CA with a view to enhancing the control system in place.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	**Explanation**
CA(s)	Competent Authority(ies)
CCA(s)	Central Competent Authority(ies)
CCP(s)	Critical Control Point(s)
DG(SANCO)	Health & Consumers Directorate General
EC	European Community(ies)
EU	European Union
FBO(s)	Food Business Operator(s)
FVO	Food and Veterinary Office
HACCP	Hazard Analysis of Critical Control Points
Hygiene Package	Regulations (EC) No 852/2004, No 853/2004 and No 854/2004
SENASA	National Service for Agriculture and Food Quality (S*ervicio Nacional de Sanidad Y Calidad Agroalimentaria)*
SAGPyA	Department of Agriculture, Livestock, Fisheries and Food (*Secretaría de Agricultura, Ganadería, Pesca y Alimentos*)
DIRTE	Individual Document for Recording Treatments of Equidae - *Documento Individual para el Registro de Tratamiento de Equideos*
CREHA	National Program for the Control of Residues, Contaminants and Hygiene in Food of Animal Origin (CREHA Animal) - *Plan de Control de Residuos e Higiene de los Alimentos*
DT-e	Electronic Movement Document - *Documento de Transito Electronico*
SIGSA	Animal Health Management Integrated System - *Sistema Integrado de Gestion de la Sanidad Animal*
Collection centre(s)	Include *"acopios*", collection centres which can only send horses to slaughterhouses and "*tenedores*", holdings which can send horses to *acopios* and /or to other holdings
VMPs	Veterinary Medicinal Products
RENSPA	National Sanitary Register of Producers - *Registro Nacional Sanitario de Productores Agropecuarios*

1 Introduction

The audit took place in Argentina from 3 to 15 September 2014 as part of the planned audit programme of the Food and Veterinary Office (FVO). The audit team comprised two auditors from the FVO. This audit was carried out at the same time as FVO audit DG(SANCO)/2014-7226 to evaluate the operation of controls over the production of and certification procedures for fresh bovine meat destined for export to the EU.

Most observations and conclusions of this audit were similar to those of FVO audit report DG(SANCO)2014-7226. Descriptive elements and observations made in report DG(SANCO)2014-7226 are not duplicated in this report except where necessary. Where appropriate, cross-references are provided to report DG(SANCO)2014-7226.

The FVO audit team was accompanied by representatives from the Central Competent Authority (CCA), the National Service for Agriculture and Food Quality (*Servicio Nacional de Sanidad Y Calidad Agroalimentaria* - SENASA) from the Argentinian Department of Agriculture, Livestock, Fisheries and Food - *Secretaría de Agricultura, Ganadería, Pesca y Alimentos* (SAGPyA).

The opening meeting was held on 3 September 2014 with the CCA in Buenos Aires. At this meeting the FVO audit team confirmed the objectives of, and itinerary for the audit, and additional information required for the satisfactory completion of the audit was requested.

2 Objectives

The main objective of the audit was to evaluate the official controls in Argentina related to the production of fresh equine meat and of natural animal casings for human consumption intended for export to the European Union (EU) and the certification procedures for their export to the EU.

In addition, the FVO audit team assessed the implementation of the measures taken by the Argentinian Competent Authorities (CAs) to address the recommendations of previous FVO audit reports, in particular reports DG(SANCO)/2011-6143 and report DG(SANCO)/2012-6347.

The FVO audit team in particular reviewed:

- the controls systems in place over the production of horse meat intended for export to the EU, including animal welfare at slaughter, sampling programmes and testing for *Trichinella*;
- the control systems in place for the production of natural animal casings intended for export to the EU;
- the traceability system in place for the production of horse meat, including controls over the registration of holdings, animal identification and the movements of animals necessary for the certification in accordance with the requirements of Commission Regulation (EU) No 206/2010;
- the system for certification of horse meat and of casings in relation to the requirements of Council Directive 96/93/EC.

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

COMPETENT AUTHORITIES			Comments
Competent Authorities	Central	2	Opening and closing meetings with the CCA
	Regional	3	Three Regional and four local CAs were met at establishments level
	Local	4	one local CA office
FOOD PRODUCTION / PROCESSING / DISTRIBUTION – ACTIVITIES			
Slaughterhouses, Cutting premises, Cold stores		2	Establishments with integrated activities
Casing establishment		1	
Laboratories		2	Within slaughterhouses, testing for the presence of *Trichinella*
Horse collection centres		3	Supplying horses for slaughter to the slaughterhouses visited
Holdings		2	Breeding / fattening premises, supplying *equidae* to collection centres visited
Veterinary Medicinal Products retailers		3	

3 Legal Basis

The audit was carried out under the general provisions of 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.

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

4 Background

According to information provided by the CCA, the number of *equidae* slaughtered for human consumption in Argentina was 2 229 409 in 2012 and 2 338 873 in 2013. There is no domestic consumption of equine meat and all the meat produced is exported. The amount of fresh equine meat exported to the EU was 11 900 tonnes in 2012 and 5 900 tonnes in 2013. The amount of casings exported was 7 800 tonnes in 2012 and 3 900 tonnes in 2013.

Information regarding the animal health situation in Argentina can be found at the World Organisation for Animal Health (OIE) website:

http://www.oie.int/wahis_2/public/wahid.php/Wahidhome/Home

Further specific information regarding the animal health situation in relation to horses in Argentina can be found in the FVO report DG(SANCO)/2011-6143.

The previous FVO audit concerning the production of fresh equine meat and casings was performed from 29 March to 8 April 2011 (report DG(SANCO)2011-6143). FVO audit DG(SANCO)/2012-6347, from 30 May to 11 June 2012, covered the production of bovine, rabbit and hare meat. Because certain recommendations of this audit concerned control system issues, these have been followed up in the current audit as well as in audit DG(SANCO)/2014-7226 where appropriate. FVO reports are accessible at:

http://ec.europa.eu/food/fvo/ir_search_en.cfm

The action plans received from the Argentinian authorities at desk analysis provided satisfactory guarantees in response to the recommendations of both reports. The action plans are available at the website above.

5 Findings And Conclusions

5.1 Legislation and Competent Authorities

5.1.1 Legal basis

Article 46.1 of Regulation (EC) No 882/2004 stipulates that official controls by Commission experts in third countries shall verify compliance or equivalence of third country legislation and systems with EU feed and food law, and EU animal health legislation. These controls shall have particular regard to points (a) to (e) and (g) of the aforementioned Article.

5.1.2 Findings

5.1.2.1 Legislation

Some changes have been introduced in Argentinian legislation since the last FVO audits on the same subjects. The main relevant legislation in place at the time of this audit was the following:

- SENASA *Resolución* No 666/2011, requiring treatment records to be maintained on holdings.

- SENASA *Resolución* No 146/2010 creating a national regulatory framework for the provisions of equines for slaughter.

- SENASA *Resolución* No 783/2011, replacing *Resolución* No 856/2010 from 1 November 2011, laying down provisional procedures to implement *Resolución* No 146/2010 until definitive legislation will be in place. Draft legislation aimed at strengthening the identification of horses is currently at public consultation stage. The CCA stated that at least six months will be required before it can be published.

- SENASA *Resolución* No 458/2012 approving the National Program for the Control of Residues, Contaminants and Hygiene in Food of Animal Origin (*Plan de Control de Residuos e Higiene de los Alimentos* - CREHA *Animal*).

- SENASA *Resolución* No 617/2005 laying down requirements for movements of horses not for slaughter.

5.1.2.2 Competent Authorities

5.1.2.2.1 Organisation of Competent Authorities

The organisation of the CAs remains as described in previous FVO reports and in particular, report DG(SANCO)/2011-6143.

5.1.2.2.2 Competent Authorities powers, independence and authority for enforcement

Powers, independence and authority for enforcement of the CAs remain as described in report DG(SANCO)/2011-6143. The FVO audit team noticed that, in two particular instances, enforcement actions were slow or not taken:

- In one establishment, where unidentified horses had been found in the stables of the slaughterhouse, actions against the supplying collection centres, the slaughterhouse operator and the accredited veterinarians who had signed the documentation, had started and were ongoing. However, the notification of a legal proceeding against the slaughterhouse operator was sent only two months after the finding. See also 5.2.2 Findings - "Animal Identification" and 5.5.1.1 "Ante-mortem inspection" of this report.

- In another region, a "pilot project" had been put in place by a slaughterhouse operator to recover and rear foals from pregnant mares presented for slaughter. This plan, in breach of several pieces of national legislation, had been running for nearly two years. Although all officials were aware of this, it had not been officially presented to the CA and CCA. An official inspection was performed only in July 2014 but there was no evidence of enforcement actions. See also section 5.2.2 Findings – "Movement controls" below.

5.1.2.2.3 Supervision

The system for supervision of the different levels of the CA remains as described in report DG(SANCO)/2011-6143. The FVO audit team reviewed examples of monthly supervisions performed by the Regional CA over the activities of the veterinary service in the establishments visited, and one management control carried out by the CCA over a Regional CA. The following observations were made:

- The frequency set for the regional supervision was respected; such controls and the follow-up were generally well documented, albeit with some exceptions.

- Supervision performed by newly appointed regional supervisors on the veterinary service of one establishment in June 2014 detected a number of shortcomings which had not been previously reported.

- In a slaughterhouse in a different region, in July 2014 the supervisors detected deficiencies not identified or not reported by the veterinary service, including the presence of unidentified horses. One week later, the CCA visited the same establishment during a management control over the Regional CA and found a number of additional non-compliances. As a result, production and certification were suspended for one week.

5.1.2.2.4 Training of staff in performance of official controls

In response to a recommendation in report DG(SANCO)/2012-6347 to improve official controls, the CA provided evidence that *ad-hoc* training has been provided to officials in charge of performing the re-evaluation of the EU listed establishments.

The FVO audit team did not assess the training courses attended by the CA staff. Nevertheless the FVO audit team noted that the officials interviewed during this audit had adequate knowledge of the EU requirements.

5.1.2.2.5 Resources

Sufficient resources have been deployed to carry out the implementation of the system of controls in relation to the export of meat and casings to the EU.

5.1.2.2.6 Organisation of control systems

The organisation of the control systems in Argentina remains as described in previous FVO reports.

5.1.2.2.7 Documented control procedures

Updated procedures, relevant for the scope of this audit, have been issued in response to FVO recommendations:

- Circular No 4014 concerning the assessment of establishments requesting to be listed to export to the EU and for the re-evaluation of those already listed, has been updated twice on the basis of the experience acquired during this process. The current version (Circular No 4014/B) includes a broader scope and procedures for the suspension and withdrawal of certification as well as a template for corrective actions. There is no procedure yet to document the follow-up of corrective actions following such assessments.

- Memorandum No 052/2013 of 6.5.2013 provides check-lists for inspections in holdings with live animals approved for EU export.

- Circular No 4046/12 on the implementation of Regulation (EC) No 2073/2005 has been amended. A Guidance, which was envisaged to be in place by 31.3.2013 in response to a previous FVO report, has been drafted and is currently under discussion within the regional CAs.

In one region, a form had been drafted to document the follow-up activities in case of non-compliances detected during regional supervision.

5.1.2.2.8 Official controls on imports

In Argentina there is no import of live horses for slaughter destined for the EU market.

Casings are imported into Argentina from third and EU countries for calibration; those imported from third countries are not sent to the EU market.

Conclusions on Competent Authorities

The Argentinian CAs are well defined and are in general able to ensure an official control system that altogether provide compliant or equivalent measures to those in EU legislation.

5.2 CONTROLS ON LIVE HORSES AND ANIMAL IDENTIFICATION

5.2.1 Legal requirements

The veterinary certification requirements for the introduction into the EU of fresh meat are laid down in Regulation (EU) No 206/2010. Point II.2 of the relevant model certificate, "EQU" in part 2 of Annex II to the Regulation, sets out the animal health requirements to be met for horse meat and in particular requires guarantees concerning the origin of the animals. 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, and in particular Article 29, are eligible for export to the EU. These conditions imply that there should be a system for animal identification.

5.2.2 Findings

Official controls in horse collection centres are performed by SENASA animal health officials from the local offices. Such controls are performed with a check-list drafted by the CCA in Memorandum 052/2013 of 06.05.2013. These controls are aimed at the verification of compliance with the requirements of *Resolución* No 146/2010 and No 783/2011, and, in particular, should focus on: documentation (request of registration of the collection centre; documents accompanying incoming and outgoing animals; invoices for the purchase of ear-tags and register of movements); animals present (number, their identification, hot-branding); presence, use and records of veterinary medicinal products (VMPs); and should include a traceability exercise.

There is no established frequency or criterion for the selection of the collection centres. However, such official controls are generally combined with sampling for the residue monitoring plan and the selection of premises for this purpose is determined at central level. The frequency of official controls performed in the last two years varied between once every two years to four times in one year. Official controls were generally well documented and only minor deficiencies had been found.

The documentation, records and identification of the animals present were generally in line with national requirements, with only minor shortcomings. One exception was observed in one collection centre, as detailed in the following section “movement controls”.

Holding registration

Holdings keeping animals from all species are required to be registered in the National Sanitary Register of Producers (*Registro Nacional Sanitario de Productores Agropecuarios* – RENSPA).

On the basis of *Resolución* No 146/2010 all suppliers of horses to slaughterhouses must be included in the “National Register of Holdings Supplying Equidae for Slaughter” (*Registro Nacional Único de Establecimientos Proveedores de Équidos para Faena*). This additional registration is granted following an application in which the operator commits to complying with the relevant requirements of national legislation concerning slaughter horses, including those concerning the administration of VMPs. There are two types of horse suppliers which can be included in this register: collection centres (“*acopios*”) which can send horses only to slaughterhouses, and

production units ("*tenedores*") which can send horses to an *acopio*, to a slaughterhouse or to other holdings. Stricter animal health requirements apply to *tenedores*, such as testing for Equine Infectious Anaemia and vaccinations against Equine Influenza and *Encephalomyelitis*. For the purpose of this report, the term "collection centre(s)" refers to both *acopios* and *tenedores*.

The collection centres and the holdings visited were registered in compliance with national legislation. One holding visited had been included in the register of *tenedores* due to a clerical error.

In response to a recommendation of report DG(SANCO)/2011-6143, between 2011 and June 2014, the local animal health offices of the CA inspected 381 collection centres and their main suppliers. Several of these collection centres were de-listed either as a result of the inspection or for inactivity. Forty-one non-compliances were detected. At the time of this audit 199 collection centres remained on the special register.

Animal identification

Currently equine animals born and reared in Argentina for purposes other than slaughter are not required to be identified, as a general rule. However, national legislation on animal health requires that when horses are moved they are accompanied by a health certificate in which the horses' features are described with an outline diagram. Hot branding is also used and the register of hot brands certifies the horse ownership, but not all Argentinian horses are hot branded. In addition, verification of such hot brands is not part of the SENASA official tasks in slaughterhouses. Draft framework legislation for the identification of certain categories of horses (e.g. sport horses and pets) by means of a microchip will eventually exclude such horses from slaughter.

In Argentina horses are not considered to be food producing animals until they have been designated for this purpose. *Resolución* No 146/2010 and *Resolución* No 783/2011 require that slaughter horses are identified by means of an individual ear-tag which is applied when they arrive in the collection centres. Slaughter horses must also be hot branded with the letter "F" on the right rump before being moved to a collection centre or to a slaughterhouse.

According to the above-mentioned national legislation, slaughterhouse operators may only receive individually identified horses. Service Order No 09/10 establishes procedures and actions to be taken in case of unidentified horses delivered to a slaughterhouse. The FVO audit team noticed that:

- In one slaughterhouse visited the FBO had procedures in place and could document the own controls performed on horse identification, both at delivery and during slaughter. Such controls were verified by the veterinary service of the establishment.

- In another slaughterhouse the FBO had no procedures in place to check the identification of animals and had accepted unidentified animals (see also sections 5.1.2.2.2 and 5.5.1.1).

Movement controls

According to *Resolución* No 783/2011, movements of slaughter horses to collection centres are allowed only if animals are accompanied by a movement document (*Documento Electrónico de Transito* - DT-e). The integrated management system for animal health (*Sistema Integrado de Gestión Animal* – SIGSA) is the IT application in place since January 2014 that feeds the database containing the information regarding the holding registrations, the number of animals present and their movements. The DT-e is issued by the local animal health offices through the SIGSA system.

Slaughter horses moved to collection centres are also accompanied by sworn statements from the vendor. The individual sworn statement contains, *inter alia,* the outline diagram describing the animal and a declaration that: the animal was born in Argentina; it was not treated with VMPs in the last 180 days; in case of treatment, the withdrawal period has been respected; what type of products were used and the dates of treatment and of withdrawal; and that only authorised VMPs were used.

When horses are moved from a collection centre to a slaughterhouse, they must be accompanied by a DT-e and by individual documents for the registration of treatments (*Documento Individual para el Registo de Tratamiento de Equideos* - DIRTE). The DIRTE also contains the digits of the applied ear-tag, verified and signed by an accredited veterinarian. The accredited veterinarian must also complete a section of the sworn statement with the ear-tag number, thus linking the two documents.

Collection centres are also obliged to keep a register of movement of animals. This was available in the three collection centres visited. The registers of movements and the relevant supporting documentation were correctly filled in and traceability exercises on some animals, where these were performed, were satisfactory. The supporting documentation reviewed by the FVO audit team in the slaughterhouses visited concerning delivered and slaughtered animals was also satisfactory. The holding visited had a movement register in place although not obligatory, but it contained several mistakes.

A particular situation concerning a slaughterhouse, a collection centre and a fattening unit belonging to the same operator was noted by the FVO audit team. The slaughterhouse operator had put in place two years ago a "pilot project" to recover foals from pregnant mares sent to slaughter. This project, which was in breach of several national legal provisions, had not been officially presented to the SENASA, although all officials were aware of it. The implementation of this project entailed the following:

- Mares in the last trimester of pregnancy, delivered to the slaughterhouse and to the attached collection centre, were temporary excluded from slaughter until birth and weaning of their offspring. According to national legislation the slaughter of animals during the last trimester of pregnancy is not allowed, although they can be legally transported, but animals can only remain in the slaughterhouse lairages for a maximum for ten days.

- At weaning, the foals were identified with a microchip and with a certificate reporting their features (outline diagram) and systematically treated off-label with a product containing ivermectine. The same treatment was administered also to the pregnant mares. Such treatments were not recorded on any document or register.

- After weaning, the mares were slaughtered while the foals were moved to the FBO's fattening unit, a field at a different location, without any movement document. This is in breach of national legislation requiring that live animals cannot be moved from a slaughterhouse, and requiring that horses cannot be moved from a collection centre to a destination other than a slaughterhouse. At the time of the FVO visit, there were 286 foals in the fattening unit. Since the implementation of the project, the slaughter of foals had not yet started.

It was only during an inspection performed in July 2014 that the SENASA officials found discrepancies in the number of animals present in the fattening field and blocked any movement to and from this holding. At the time of the FVO audit, information on any further action was not available and, in particular, a decision concerning the destination of the foals had not yet been

taken.

The FVO audit team also noted that the CA inspections failed to identify that the distance separating the collection centre from the slaughterhouse pens where pregnant mares were kept did not meet national legislation requirements (500 meters prescribed). There was no blue print to identify which fields pertained to the slaughterhouse and which ones to the assembly centre.

Conclusions

Official controls on identification of animals and on their movements were generally adequate and capable of satisfying the animal health guarantees provided in the certificate for fresh equine meat. However, official controls on one FBO failed to enforce national requirements concerning animal movements and medical treatments and failed to identify other non-compliances with national provisions. Nevertheless, because the horses involved had not yet been slaughtered, there was no risk for human health.

5.3 Controls on veterinary medicinal products and residues

5.3.1 Legal requirements

The veterinary certification requirements for the introduction into the EU of fresh meat are laid down in Regulation (EU) No 206/2010, Annex II, part II, certificate "EQU". In its point II.1.7 the CA has to provide guarantees covering live animals and products thereof provided by the residue plan submitted in accordance with Directive 96/23/EC, and in particular, Article 29 thereof.

5.3.2 Findings

Distribution and use of VMPs

The general system of authorisation, distribution and use of VMPs (including official controls) and the monitoring of residues has been described in report DG(SANCO)/2011-6143 and in more detail in report DG(SANCO)/2011-8903 (monitoring of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products). The text below provides an update and is specific to the subject of this audit.

A recommendation in report DG(SANCO)/2011-6143 concerned the reliability of the guarantee that horses are not treated with essential substances (Annex to Commission Regulation (EC) 1950/2006[1]) during the 180 days prior to slaughter. One of the actions indicated by the CCA in their response was that the register of treatments specified in *Resolución* No 666/2011 would be mandatory from 15.3.2012 for all holdings keeping animals for human consumption destined for the EU and, in particular, from 1.1.2011 for the equine species. However, the distribution of these registers from the local SENASA offices is not yet finalised and is still ongoing, with priority given to EU cattle holdings and to dairy holdings. Horse holdings are provided with such registers at the

1 Substances essential for the treatment of equidae as well as substances which bring added clinical benefit compared to other treatment options available for equidae. Such substances may be used, for the specific disease conditions, treatment needs or zootechnical purposes specified in the Annex, where no medicinal product authorised for equidae or referred to in Article 11 of Directive 2001/82/EC would yield equally satisfactory results in terms of successfully treating the animal, or where they provide a clinically relevant advantage based on improved efficacy or safety or a major contribution to treatment avoiding unnecessary suffering for the animal, or ensuring the safety of those treating the animal.

time of sending their first consignment of live horses to collection centres. The representative of one Regional CA indicated that, until the time of this FVO audit, the register of treatments had been supplied to more than 5 700 holdings in that region.

One of the two holdings visited had the register of treatments in place. Records showed that a group of 30 horses had been treated off-label with ivermectin but the withdrawal period was not recorded. Such animals, which were not identified, were kept in a separated pen and, according to the owner, would be kept there for six months following the treatment before being moved to a collection centre.

Foals and mares kept in another holding and in the associated collection centre and slaughterhouse were treated with anthelmintic products, including ivermectin off-label, antibiotics and other VMPs, but such treatments were not recorded. Foals had not yet been slaughtered while mares, which according to the FBO had been treated only during the last trimester of pregnancy, were only slaughtered after the weaning of their offspring, i.e. at least six months after the treatment. Nevertheless, it could not be excluded that some of these animals might have been slaughtered during the withdrawal period.

In Argentina the trade of substances with androgenic, oestrogenic or progestagenic effect, of ketamine and those with beta-agonistic or thyrostatic action is strictly regulated and their use in animals intended for human consumption is prohibited. In Argentina there are no anabolic agents on the market for use in horses.

The majority of other VMPs can be purchased without a prescription. These include VMPs commonly used in horses, such as phenylbutazone and several anthelmintic products, most of which bear a label clearly mentioning the prohibition of use in horses for human consumption. Farmers and accredited veterinarians interviewed, acknowledged that such anthelmintic products were commonly used in holdings which have supplied horses to collection centres for slaughter. However, the CAs and the operators of the sites visited stated that treated horses are segregated for at least six months prior to slaughter. None of the DIRTE and sworn statements reviewed by the FVO audit team reported any treatments with VMPs.

In none of the three pharmacies visited by the FVO audit team was there evidence of official controls performed by the Provincial Veterinary Councils. The CA stated that such controls are generally performed only following complaints or suspicions.

Monitoring of residues

In the sites visited the FVO audit team noted that the plan "CREHA *Animal*" was implemented, with samples distributed during the year. The available results were all compliant.

Conclusions

Whilst the system in place for the distribution and use of veterinary medicinal products and controls thereof, is quite different in comparison to EU requirements, the fact that anabolic compounds are not authorised for *equidae* provides assurances that the provisions of Directive 96/22/EC are satisfied and this is supported by the absence of non-compliant results in the national residue monitoring plan. However, the CA's delayed introduction of mandatory treatment records for *equidae* and evidence that unrecorded off-label treatments of *equidae* with VMPs had taken place in the premises visited by the FVO audit team undermine the reliability of the vendors' declarations

concerning use of such products.

5.4 Listing of establishments

5.4.1 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.

5.4.2 Findings

A recommendation in report DG(SANCO)/2012-6347 and repeated from report DG(SANCO)2011-6143 concerned the reviewing of establishments listed for EU export. In their response the CCA established a re-evaluation programme for all establishments listed for EU export. At the time of this audit, this re-evaluation had been performed in 83 meat establishments, with 16 still to be visited. A letter was sent in July 2014 to the Commission Services requesting amendment of the relevant published lists. The re-evaluation of 24 listed casing establishments resulted in only 11 compliant plants. The CCA stated that the communication to the Commission to amend the list had not yet been made.

In the three establishments visited the re-evaluations had taken place in 2013 and were well documented. In both slaughterhouses the re-evaluation visits resulted in the temporary suspension of the production and / or certification.

Conclusions

While actions are well advanced, the recommendation of reports DG(SANCO)2011-6143 and DG(SANCO)2012-6347 concerning listing of establishments is not yet fully addressed. Delays in notifying the Commission of changes resulted in suspended establishments remaining listed for long periods of time.

5.5 Official controls at establishment level

5.5.1 Legal requirements

Article 12 of Regulation (EC) No 854/2004 lays down that the CA of a 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 relevant EU requirements, in particular those of Regulation (EC) No 853/2004, or with requirements that were determined to be equivalent. It also lays down 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.

The animal and public health and veterinary certification requirements for the introduction into the EU of equine fresh meat are laid down in in Regulation (EU) No 206/2010, Annex II, part II, certificate “EQU”, and those for casings are laid down in Annex IA to Commission Decision 2003/779/EC, model certificate “CAS”.

5.5.2 Findings

5.5.2.1 Ante-mortem inspection

At both slaughterhouses visited, ante-mortem inspections were well documented and were repeated every 12 (in one slaughterhouse) or 24 hours (in another slaughterhouse).

As mentioned also in sections 5.1.2.2.2 (enforcement) and 5.2.2 (animal identification), in one slaughterhouse the veterinary service had failed to notice, despite a repeated ante-mortem inspection, that 20 horses out of 48 in two consignments did not have ear-tags. Traceability exercises performed by the FVO audit team confirmed that the meat from such horses had been excluded from the EU market.

In the same slaughterhouse the records of ante mortem inspections of the animals present during the FVO visit did not mention any finding concerning injured animals. However, one horse in a group observed by the FVO audit team had an open wound on a front leg and some others had bruises. An extensive bruise with a huge haematoma on the rump of one horse was later seen during post-mortem.

The results of the necropsy performed on the animals dead on arrival (DOA) in one slaughterhouse (35 DOA out of more than 23 000 animals slaughtered from 1.1.2014 to 2.9.2014) showed that most deaths were possibly due to inadequate conditions of transport (e.g. limb or rib fractures, spleen rupture) or that some animals had pre-existing conditions which were aggravated during the transport (e.g. cachexia, intestinal or uterine torsions and ruptures, asphyxia). The CCA explained that loading densities and duration of transport are not set in legislation but only in guidance. Legal actions against transporters could be taken by the animal health local offices following information received by the veterinary service of the slaughterhouse. There was no evidence of actions taken.

5.5.2.2 Post-mortem inspection

In both slaughterhouses visited, post-mortem inspections were generally acceptable, albeit with some exceptions (i.e., insufficient inspection of some lymph nodes after incision in one establishment, no inspection of the intestines in the other). Post mortem inspections were performed by personnel of the CA which in one slaughterhouse were assisted by FBO staff.

Procedures in place to identify, on the line, carcasses from white and grey horses and to inspect them for melanosis were implemented and were adequate.

A recommendation in report DG(SANCO)/2011-6143 was to ensure that the procedure used for *Trichinella* testing is in line with the requirements of Commission Regulation (EC) No 2075/2005. In their response, the CCA indicated that laboratories were requested to be supplied with 100x magnification equipment, have updated procedures and undergo further training and a series of proficiency tests.

In both slaughterhouses visited, the laboratories were adequately equipped; the examination for *Trichinella* was performed by qualified slaughterhouse staff with procedures in line with those of Regulation (EC) No 2075/2005. Evidence of proficiency tests performed in the last three years was available.

Procedures were in place to release carcasses after the results of *Trichinella* tests were made

available to the veterinary services of the slaughterhouse.

5.5.2.3 General and specific hygiene requirements

The infrastructures of the three establishments visited were old with some maintenance issues, which were adequately identified and followed-up by the CAs; where necessary, maintenance plans were in place. In the casing establishment visited not all maintenance problems had been identified during the official controls.

Operational hygiene was overall satisfactory in the three establishments visited. Corrective actions had been implemented by the FBOs following CAs' remarks during previous official controls. However, in one slaughterhouse the inadequate layout of the slaughter line had not been identified by the CAs. Because of the insufficient space, carcasses were in contact with each other and were touching equipment, platforms and offal trays. Frequent contact between carcasses and platforms or other infrastructure was noted also in the other slaughterhouse.

5.5.2.4 HACCP-based systems

Hazard Analysis Critical Control Points (HACCP)-based procedures were in place in all establishments visited. Some deficiencies identified by the CAs during official controls had been corrected by the FBOs and evidence of follow-up was available.

The FVO audit team randomly assessed some parts of the HACCP-based procedures in the establishments visited. These were satisfactory, albeit with some minor deficiencies which had not been identified during official controls:

- In one casing establishment the FBO's procedures did not describe the microbiological tests performed and their frequency.

- In one slaughterhouse the procedures for traceability were out of date with obsolete EU legislation described, and not reflecting what was actually implemented.

- In another slaughterhouse the sampling method for carcasses described was different from the method implemented.

In response to a recommendation in report DG(SANCO)2012-6347 that water testing is performed in line with the requirements of Council Directive 98/83/EC, the CA reviewed the parameters and frequency of water testing described in their Circular No 2731. However, the CCA explained that a complete physical-chemical analysis can only be performed by the National Water Institute (*Instituto Nacional de Agua* –INA) which has insufficient laboratory capacity to carry out more than one test per year for each establishment. Not all chemical parameters are performed yet, due to insufficient laboratory capacity.

Where the water testing was assessed by the FVO audit team, it was noted that microbiological and physical-chemical tests were performed by both the FBO and the CA. Results were available and were in line with the parameters of Directive 98/83/EC. The results of the tests performed by one FBO on the quantity of residual free chlorine were always the same, because of the rapid test used which had a limited range. The FBO stated that a new kit with an extended range had recently been purchased but was not yet in use.

5.5.2.5 Microbiological testing

Microbiological sampling took place in all establishments visited, including in the casing establishment although it is not obligatory. Where these were assessed by the FVO audit team, the available results were favourable. In one slaughterhouse there was no trend analysis of the results.

5.5.2.6 Traceability and identification marking

Traceability exercises were part of the CA official controls. The exercises carried out by the FVO audit team in the three establishments visited were satisfactory. Evidence of exercises of traceability and recall requested by the Regional CAs were available in all establishments visited.

In both cutting plants the documentation of processed carcasses did not include the slaughter date. The FBOs declared that all carcasses were cut on the day following the slaughter. Carcasses were identified by the herd number and by the slaughter progressive number (in one establishment) or by the progressive number only (in the other establishment). However, errors could not be excluded as animals belonging to the same herd might be slaughtered for various reasons on different dates and carcasses might receive the same progressive number as those from the previous day.

In the casing establishment visited, the identification of products and of containers was adequate both in the storage rooms and during processing, except for a few drums for the national market. However, these were in a separate area.

5.5.2.7 Animal welfare at the time of slaughter or killing

Council Regulation (EC) 1099/2009 on the protection of animals at the time of killing is not yet fully implemented:

- The Argentinian CCA has organised training on animal welfare and certificates of competence had recently been provided, but only to the animal welfare officers and to the heads of the veterinary services of slaughterhouses. The CA stated that further training sessions for the FBO staff handling live animals will be organised.

- Animals are provided with bedding and feed only after a period of 24 hours in the lairages whereas the EU Regulation requires that animals are provided with feed and bedding after 12 hours.

In both slaughterhouses visited, lairaging, handling of animals, stunning and related operations were adequate and in line with the requirements of Regulation (EC) 1099/2009.

5.5.2.8 Documentation of official controls

Official controls were well documented including follow-up of remedial actions requested, with only a few exceptions and, in particular, the lack of evidence of follow-up of the CCA re-evaluations. There is no obligation to report to the CCA on the results of the follow-up of such re-evaluations. Nevertheless, follow-up was documented in two out of three establishments visited.

Conclusions

Official controls in relation to ante- and post-mortem, general and specific hygiene requirements,

HACCP-based systems, microbiological criteria, traceability and identification marking, animal welfare at the time of slaughter were satisfactory, albeit with some deficiencies. Whilst such deficiencies do not undermine the reliability of the statements in the relevant certificates for the export to the EU of natural animal casings and of fresh equine meat, corrective action is required.

A recommendation from report DG(SANCO)/2011-6143 concerning *Trichinella* testing has been satisfactorily addressed whilst a recommendation from report DG(SANCO)/2012-6347 concerning water testing is not yet fully addressed, although in progress.

5.6 Official certification

5.6.1 Legal requirements

Council Directive 96/93/EC states that during inspections or audits, the Commission shall ensure that the rules and principles applied by third countries' certifying officers offer guarantees at least equivalent to those laid down in this Directive.

The specific animal health, public health and veterinary certification requirements for the introduction into the EU of products of animal origin intended for human consumption, are laid down in the product specific Commission Regulations.

5.6.2 **Findings**

The procedures for certification for export to the EU remain as described in previous FVO reports.

In the three establishments visited the FVO audit team assessed some provisional and final certificates and the supporting documentation. This assessment was satisfactory.

Conclusions

The certification procedures in place ensure that the rules and principles applied to the Argentinian certifying officers offer guarantees at least equivalent to those laid down in Directive 96/93/EC.

6 Overall Conclusion

The Argentinian CAs are well defined and are in general able to ensure an official control system that altogether provide compliant or equivalent measures to those in EU legislation. Official controls on identification of animals and on their movements were generally adequate and capable of satisfying the animal health guarantees provided in the certificate for fresh equine meat. Official controls in casing establishments were adequate and capable of satisfying the guarantees provided in the relevant certificate.

Official controls in relation to ante and post-mortem, general and specific hygiene requirements, HACCP-based systems, microbiological criteria, traceability and identification marking, animal welfare at the time of slaughter were satisfactory, albeit with some deficiencies. Whilst such deficiencies do not undermine the reliability of the statements in the relevant certificates for the export to the EU of natural animal casings and of fresh equine meat, corrective action is required. The certification procedures in place ensure that the rules and principles applied by the Argentinian certifying officers offer guarantees at least equivalent to those laid down in Directive 96/93/EC.

The vast majority of the actions taken by the Argentinian CCA in response to the recommendations of reports DG(SANCO)2012-6347 and DG(SANCO)2011-6143 have been implemented. Some are still in progress, in particular, the re-evaluation of establishments and the registration of medicinal treatments.

Whilst the system in place for the distribution and use of veterinary medicinal products and controls thereof, are quite different in comparison to EU requirements, the fact that anabolic compounds are not authorised for *equidae* provides assurances that the provisions of Directive 96/22/EC are satisfied and this is supported by the absence of non-compliant results in the national residue monitoring plan. However, the CA's delayed introduction of mandatory treatment records for *equida*e and evidence that unrecorded off-label treatments of *equidae* with veterinary medicinal products had taken place in the premises visited by the FVO audit team undermine the reliability of the vendors' declarations concerning use of such products.

7 Closing Meeting

A closing meeting was held on 15 September 2014 with the CCA, the SENASA. At this meeting the FVO audit team presented the findings and preliminary conclusions of the audit and advised the CCA of the relevant time limits for production of the report and their response.

The representatives of the CCA acknowledged the findings and conclusions presented by the FVO audit team. In addition, information on action already taken and planned, in order to address particular findings in the establishments visited, was provided.

8 Recommendations

An action plan, describing the action(s) 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 25 working days of receipt of the report.

N°.	**Recommendation**
1.	To ensure that lists of establishments approved for export to the European Union are kept up-to-date as required by Article 12 of Regulation (EC) No 854/2004.
2.	To rectify the shortcomings identified in this report in order to ensure that establishments listed for export to the EU comply with the requirements of Regulations (EC) No 852/2004 and (EC) No 853/2004 as indicated in the relevant certificates.
3.	To ensure that veterinary medicine treatment records are kept on holdings eligible to supply slaughter horses for the European Union market, in line with Article 10 of Council Directive 96/23/EC and Annex I, part A(III), 8(b) to Regulation (EC) No 852/2004.
4.	To ensure that all requirements of Regulation (EU) No 1099/2009, in particular concerning certificates of competence for slaughterhouse staff and the provision of

N°.	Recommendation
	bedding and feed, are met.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2014-7296

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. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
Reg. 2075/2005	OJ L 338, 22.12.2005, p. 60-82	Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for Trichinella in meat

Legal Reference	Official Journal	Title
Reg. 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
Reg. 1099/2009	OJ L 303, 18.11.2009, p. 1-30	Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing
Reg. 1950/2006	OJ L 367, 22.12.2006, p. 33-45	Commission Regulation (EC) No 1950/2006 of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae
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 ß-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. 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