

EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate F - Food and Veterinary Office

DG(SANTE) 2014-7234 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

BRAZIL

FROM 14 TO 27 OCTOBER 2014

IN ORDER TO EVALUATE THE OPERATION OF CONTROLS OVER THE PRODUCTION OF FRESH BOVINE MEAT DESTINED FOR EXPORT TO THE EUROPEAN UNION AS WELL AS CERTIFICATION PROCEDURES AND TO FOLLOW-UP PREVIOUS, RELEVANT AUDITS

Executive Summary

The report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Brazil from 14 to 27 October 2014. The objectives of the audit were to evaluate the operation of controls over the production of fresh bovine meat destined for export to the European Union (EU), as well as certification procedures and to follow the measures taken by the Brazilian authorities to address the recommendations made in audit reports DG(SANCO)/2013-6886-MR Final and DG(SANCO)/2011-6132-MR Final.

Despite some shortcomings being identified at both holding and processing establishment levels, the controls over the production of bovine meat destined for export to the EU are satisfactory.

A robust system for the provision of statutory official controls, verification of Food Business Operator (FBO) own procedures and enforcement action, as necessary, within clear time-scales was noted at all holdings and establishments visited.

Shortcomings were identified at one of the holdings visited, the majority of which were linked to the lack of FBO own controls in relation to the number of animals present on the holding and identification tags. Maintenance issues were noted at one of the establishments visited that had already been identified by the Competent Authority (CA) but had not been properly addressed at the time of the audit.

The Brazilian authorities have agreed to the need to implement microbiological testing requirements as set out in Regulation (EC) No 2073/2005, and amended their procedures accordingly whilst the audit was taking place. They undertook to continue working on the development of necessary documentation to be presented to the Commission services seeking approval for equivalence of their previous testing regime.

Regular and extensive monitoring of Shiga Toxin-producing Escherichia coli (STEC) is carried out by the FBO on final product to be exported to the EU and whilst no positives were found at any of the establishments visited, FBO procedures are in place for the diversion of positives to further processing or alternative markets, should the case arise.

Animal welfare controls at slaughterhouse level were found to be satisfactory and examples were seen of how welfare controls were integrated, including transport and handling on the holding of origin. It was noted that no official procedure had yet been developed for the examination and appointment of animal welfare officers or slaughterhouse personnel via appointed external training centres or designated CA procedures as required by Regulation (EC) No 1099/2009.

Based on previous criticism from Commission services and third countries of their Rapid Alert System for Food and Feed notification procedures, confirmed during this audit, the Brazilian authorities have recently amended their communication procedures seeking an improvement to internal investigatory efficiency and external communication.

The certification of bovine meat in the establishments was satisfactory for all consignments verified, including exports to Sweden and Finland. Officials were able to demonstrate full traceability to farms of origin and that the specific certificate conditions were met.

Two recommendations are made to the CA with a view to addressing the deficiencies identified during this audit.

Table of Contents

1 <u>Introduction</u>	1
OBJECTIVES	
3 Legal Basis	
4 BACKGROUND.	2
5 Findings And Conclusions	3
5.1 Legislation and Competent Authorities	
5.1.1 <u>Legal Basis</u> .	
5.1.2 <u>Findings</u>	3
5.1.3 <u>Conclusions</u>	5
5.2 Holding registration, Animal identification	5
5.2.1 <u>Legal Requirements</u>	5
5.2.2 <u>Findings</u>	6
5.2.3 <u>Conclusions</u>	7
5.3 <u>Listing of establishments</u> .	7
5.3.1 <u>Legal requirements</u> .	7
5.3.2 <u>Findings</u>	7
5.3.3 <u>Conclusions</u>	
5.4 Official controls at establishment level.	
5.4.1 <u>Legal requirements</u> .	
5.4.2 <u>Findings</u> .	
5.4.3 <u>Conclusions</u>	
5.5 Official certification.	
5.5.1 <u>Legal requirements</u> .	
5.5.2 <u>Findings</u>	
5.5.3 <u>Conclusions</u>	
5.6 RAPID ALERT SYSTEMS FOR FOOD AND FEED (RASFF).	
5.6.1 <u>Conclusion</u> .	
6 Overall Conclusions	
7 <u>Closing Meeting</u>	
8 Recommendations	
Annex 1 - Legal References	16

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation	
ACC	Aerobic Colony Counts	
CA(s)	Competent Authority(ies)	
CCA(s)	Central Competent Authority(ies)	
Certificadoras	Certifying entities at ERAS Holding Level	
ССР	Critical Control Point	
СР	Control Point	
DG SANCO	Health & Consumers Directorate General	
DIPOA	Department of Inspection of Products of Animal Origin (Departamento de Inspeção de Produtos de Origem Animal)	
EC	European Community(ies)	
E. coli	Escherichia coli	
ERAS	Livestock holdings approved for export to the EU and included in the TRACES list	
EU	European Union	
FBO(s)	Food Business Operator(s)	
FVO	Food and Veterinary Office	
GTA	Animal Movement Permit (Guia de Transito Animal)	
HACCP	Hazard Analysis of Critical Control Points	
MAPA	Ministry of Agriculture, Livestock and Food Supply (Ministério da Agricultura, Pecuária e Abastecimento)	
NI	Normative Instruction	
OV(s)	Official Veterinarian(s)	
RASFF	Rapid Alert System for Food and Feed	
SIGSIF	Brazilian Certification Database	
SIPOA	Inspection Service of Products of Animal Origin	
SISBOV	Cattle and Buffalo Identification and Certification System	
SISBOV coordination	Coordination of Traceability Systems (Coordenação de Sistemas de Rastreabilidade)	
SOP(s)	Standard Operating Procedures	
STEC	Shiga Toxin-producing Escherichia coli	
TRACES	European Commission's integrated computerised veterinary system	
Vistorias	Audits carried out by certificadoras at ERAS holdings	

1 Introduction

The audit took place in Brazil from 14 to 27 October 2014 as part of the planned audit programme of the Food and Veterinary Office (FVO). The audit team comprised two auditors from the FVO.

The audit team was accompanied by representatives from the Central Competent Authority (CCA), the Ministry of Agriculture, Livestock and Food Supply (*Ministério da Agricultura, Pecuária e Abastecimento, MAPA*).

The opening meeting was held on 14 October 2014 with the CCA in Brasilia. At this meeting the 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 objectives of the audit were to evaluate the operation of controls over the production of fresh bovine meat destined for export to the European Union (EU), as well as certification procedures and to follow the measures taken by the Brazilian authorities to address the recommendations made in audit report DG(SANCO)/2013-6886-MR Final. Actions taken following recommendations made in audit report DG(SANCO)/2011-6132-MR Final covering the production of gelatine were also covered.

The audit team reviewed in particular:

- the Competent Authority (CA) organisation and operation,
- the official controls over food business operators' (FBOs) compliance with general and specific rules on the hygiene of food of animal origin, and
- the correct implementation of the chain of certification.

In particular, controls over fresh bovine meat in the framework of Regulations (EC) No 178/2002, No 852/2004, No 853/2004, No 854/2004, No 882/2004, No 2073/2005 as well as Council Directives 92/118/EC and 98/83/EC and Commission Decisions 2003/779/EC and 2007/453/EC were subject to this evaluation. Evaluation of the animal health official controls regarding the issuing of animal movement permits (GTAs) by the State animal health CA was not part of the scope of this audit. In pursuit of these objectives, the audit itinerary included the following:

COMPETENT AUTHORITIES		COMMENTS	
Competent Authorities	Central	2	Opening and closing meetings
	Local	1	
FOOD PRODUCTION / PROCESSING / DISTRIBUTION – ACTIVITIES			
Slaughterhouses + Cutting plants		4	Combined with storage activities
Cold stores		4	Combined with storage activities
Holdings		4	Bovine holdings

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

Regulation (EU) No 206/2010 specifies that at present Brazilian bovine meat can be exported into the EU from TRACES approved holdings in the whole territory of the States of Minas Gerais, Espírito Santo, Goiás, Mato Grosso, Rio Grande do Sul, Santa Catarina, Paraná, São Paulo and part of the territory of the State of Mato Grosso do Sul.

At the time of the audit there were 1 622 holdings registered in the Cattle and Buffalo Identification and Certification System (SISBOV), as approved ERAS holdings (livestock holdings approved for export to the EU and included in the TRACES list). The current number of animals in the SISBOV system stands at 4 116 641 which roughly accounts for 2% of the bovine animals present in the territory of Brazil. In comparison with the year 2012 there has been a drop of around 20% in the total number of approved ERAS holdings, whilst the total number of bovine cattle in the scheme has remained stable.

Exports to the EU for fresh and frozen bovine meat in the year 2013 amounted to 65 879 tonnes with a value of 395 817 million Euro (source EU Commission Export Helpdesk) which represents an increase in the quantity of exports and their value.

Farmers are usually given a premium per animal by the processing establishments for being approved as ERAS holdings; this premium varies and in some States it is approximately 100 Brazilian Reais (33 Euro at the time of the audit) which represents around 5% premium over the amount normally paid for non-EU eligible animals. The extra costs incurred by farmers (eartags; costs of *certificadoras*) are calculated at around 40 Brazilian Reais. In some States the authorities also provide a subsidy of around 2.5% of animal value for being part of the ERAS scheme, whilst in others, farmers are abandoning the scheme as they move towards more profitable production (i.e. soya) with quicker turnovers.

The previous audit concerning the safety of fresh bovine meat in Brazil was carried out from 15 to 28 October 2013, the results of which are described in the audit report DG(SANCO)2013-6886.

Concerning Recommendation n° 2 of audit report 2011-6132, requesting that staff responsible for official controls of establishments in the gelatine chain respects the EU requirements as laid down in Regulation (EC) No 2074/2005 and Council Directive 96/93/EC, in order to ensure that the approval of establishments and export certification requirements are met, the Director of the *Departamento de Inspeção de Produtos de Origem Animal* - Department of Inspection of Products of Animal Origin (DIPOA) informed the audit team at the closing meeting that the necessary training will now take place in the first half of 2015.

These reports are available at the DG SANCO website:

http://europa.eu.int/comm/food/fvo/ir search en.cfm

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

Relevant legislation, circulars and normative instructions (NI) are in place and remain as described in previous audit reports.

The following updates have been made to CA procedures for the delivery of official controls at holding level, in response to audit report DG(SANCO)2013-6886:

- Circular CSR/SDA/MAPA N 02/2014 concerning the procedures of the certifying entities (*certificadoras*) for the control of the identification of bovines.
- Circular CSR/SDA/MAPA N 03/2014, that establishes the procedures for the verification of the control measures adopted by the *certificadoras* when checking the adjustment of stock, as provided for in NI 14/2006.

With regard to microbiological criteria; during this audit; Circulars 835/2006/CGPE/DIPOA and 665/2006/CGPE/DIPOA were in force. These specify testing frequencies and micro-organisms to be tested which differ from those laid down in Regulation (EC) No 2073/2005. The Brazilian authorities have contended, for many years, that their system is equivalent to that prescribed by EU legislation but, despite repeated recommendations made in previous audit reports, they have not completed validation studies, nor have they sent all necessary information to the Commission services to enable a determination of equivalence. However, during the closing meeting of this audit, the Brazilian authorities presented Memorandum No 371/CGPE/DIPOA/SDA (dated 24 October 2014), in which the DIPOA has requested, with immediate effect, that all EU beef exporting establishments align their microbiological testing frequencies and parameters with those set out in Regulation (EC) No 2073/2005. The Director of the DIPOA informed the audit team that once all necessary information to make their case of equivalence has been gathered the relevant EU Commission services will be contacted seeking acceptance so they can revert back to the testing regime as set out in Circulars 835 and 665 /2006/CGPE/DIPOA.

5.1.2.2 Competent Authorities

5.1.2.2.1 Organisation of Competent Authorities

Organisation of CAs remains as described in previous audit reports.

The Secretariat for the Protection of Animals and Plant Health of MAPA through its Departments of Animal Health and DIPOA, is responsible for animal health and public health. Likewise, it controls the Coordination of Traceability Systems (SISBOV) Unit which is in charge of the individual identification system of bovines and the overall control of traceability procedures, including

scheduled audits to appointed certificadoras.

The afore-mentioned services have a structure for the delivery of official controls at State level.

5.1.2.2.2 Competent Authorities powers, independence and authority for enforcement

In the establishments and holdings visited the audit team observed that the CA had sufficient enforcement powers, independence and authority to carry out the official controls necessary for the certification of fresh bovine meat to be exported to the EU. These powers covered FBOs and *certificadoras* carrying out "*vistorias*" at holding level.

5.1.2.2.3 Supervision

The *certificadoras* are audited regularly by the CA based on risk assessment, likewise a minimum of 10% of holdings are audited by the CA. Detailed instructions for supervisory controls of officials at establishments by the DIPOA have been in place for several years.

The audit team noted that the supervision of the activities of the official services carried out at establishment level were done as a minimum at the required frequency in accordance with the procedures in place and this included formalised follow up action when shortcomings had been detected.

At holding level, official controls over FBOs and *certificadoras* were done within the required time frames. Regular audits of the *certificadoras* are scheduled and carried out by the SISBOV coordination unit. The audit team was presented with documentation and examples of audits carried out on *certificadoras*, showing highlighted non-conformities, responses by *certificadoras* outlining actions to be taken within agreed deadlines and final official follow-up to verify conformance.

Currently 19 *certificadoras* are approved by the MAPA to audit the ERAS holdings. 4 audits of *certificadoras* had been scheduled for the year 2014; two and three audits of *certificadoras* had been performed in the years 2013 and 2012 respectively.

A re-evaluation of EU listed establishments must be done at least once every 18 months and usually covers not only EU requirements but requirements from other third countries as the establishments involved tend to be listed for multiple third countries. The re-evaluation includes FBOs' responsibilities and performance of the inspection services.

5.1.2.2.4 Organisation of control systems

The organisation of control systems in Brazil remains mainly as described in previous FVO reports.

The frequency of *vistorias* of ERAS holdings by the *certificadora* is set for feedlots every two months and for breeding holdings every six months.

The re-audits and audits for the inclusion of holdings in the ERAS list are performed by the CA. Risk-based criteria for the selection of holdings to be re-audited are used by the SISBOV coordinators at State level. The CA stated that the criteria used are:

- the number of animal movements:
- the quantity of animals slaughtered for export to EU;
- the *certificadora's* audit results; and
- non-conformities noted at slaughterhouse level;
- in addition, random selection is also performed.

The audit team noted that the Brazilian official control system at EU listed establishments includes a strong verification component. The officials perform a great number of daily "on the spot" verifications/inspections of FBO's obligations such as hygiene requirements and animal welfare. These controls are implemented with the daily deployment of officials at the different areas of the slaughterhouses. The system also includes a detailed audit component of the FBO's own control procedures, thus ensuring that many aspects of the EU requirements such as availability of all necessary documented procedures, compliance with some aspects of the carcass sampling requirements and adequacy of the Hazard Analysis of Critical Control Points (HACCP) based procedures are fully evaluated by the CA.

5.1.2.2.5 Documented control procedures

Documented control procedures are in place for:

- Certificadoras auditing holdings.
- CA staff carrying out official controls at holdings and establishments.

The CA has introduced documented control procedures that are detailed under the different headings of this audit report.

The audit team noted that, at the establishments and holdings visited, the official controls were documented in line with the national procedures, in one specific State (Rio Grande do Sul) it was noted that control procedures that went beyond the requirements set out by the MAPA had been implemented. Nevertheless, official documentation and follow up controls performed by the CA in order to verify corrective actions by FBOs were implemented in a standard manner across the different States and following official procedures and guidance.

5.1.3 Conclusions

A microbiological testing regime, that differs from the EU standard had been implemented without prior approval by the Commission services, and without the necessary documentation having been forwarded to enable assessment of equivalence. This has been corrected by the DIPOA with Memorandum No 371/CGPE/DIPOA/SDA of 24/10/2014 which mirrors EU microbiological criteria requirements.

The control system in Brazil provides satisfactory assurances regarding compliance with the EU requirements as set out in Article 46.1(h) of Regulation (EC) No 882/2004. The control system includes a robust "on the spot" verification/inspection component, underpinned by a frequent audit system of FBOs' compliance with EU requirements, and of the performance of official controls at holding and establishment level

Supervision and documented control procedures were found to be satisfactory.

5.2 Holding registration, 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 11.2 of the model certificates, in Part 2 of Annex II to the Regulation, sets out the animal health requirements to be met, including for bovine animals the requirement for the CA to have system(s) in place for holding registration and animal identification.

5.2.2 Findings

The system in place for the control of ERAS holdings remains as described in previous reports. *Vistorias* carried out by *certificadoras* were, in all cases done within the required time frames, likewise for official audits.

The audit team assessed the work of three different *certificadoras*, at the four ERAS holdings visited. Their performances was found to be, in the majority of cases, satisfactory. It was, however, noted that one of the *certificadoras* had yet to include, within his manual of procedures, the requirements stated in circular CSR/SDA/MAPA N 03/2014. Nevertheless, the specific check-list had already been added to the *vistorias*.

At three of the four holdings visited the FBO was able to provide accurate information on the number of animals present on the holding, and documentation showed the necessary correlation with information in the SISBOV system. The *vistorias* carried out by *certificadoras* and audits by the CAs provided the necessary controls and assurances regarding the fulfilment of the specific requirements for certification of beef products to the EU.

Nevertheless, at one large holding visited, which included feedlot facilities, the FBO was unable to provide an accurate number for animals that were present on the holding at the time of the FVO visit, including the number of animals already identified and those not yet tagged. Furthermore, eartags were missing or could not be accounted for; the overall situation was not helped by the fact that cattle eartags were taken from stock in a disorganised manner, further complicating the process of checking the inventory of eartags in stock and ascertaining which eartags had already been applied.

After a lengthy assessment of all available information, including GTA documents, the *certificadora* and official services were also unable to reach a final number of animals present on the holding at the time of the audit. The report of the previous audit carried out by the official services showed satisfactory results as did the two-monthly *vistorias* performed by the *certificadora*. The CA stated that for a holding of this size it usually takes three days and two Official Auditors to verify all available information and confirm compliance with the requirements for ERAS holdings.

On this same holding it was also noted that cattle eartags were being stored for another holding which was in the initial stages of the process of seeking approval as an ERAS holding. After the findings made during the visits, MAPA officials informed the audit team that an official audit had been rescheduled for the forthcoming month, to confirm full compliance with ERAS holding requirements

At three of the holdings visited, documented procedures were in place to ensure that withdrawal periods for veterinary medicines were complied with. At the remaining holding, no records were kept of the administration of veterinary medicines to the animals, instead a visual method was used (clipping of the hairs of the tail of animals that had been treated).

It was noted that no direct link exists between the GTA transport documentation and the fulfilment of the requirement concerning compliance with statutory 40 days permanence on the holding and 90 days in an authorised area. It was noted by the audit team that this was checked at slaughterhouse level when the pre-slaughter list is printed from the SISBOV system and afterwards against animal eartags.

When prompted about latest NIs amending NI14 (Circular CSR/SDA/MAPA N 2/2014, as described in page 3), the SISBOV representative at the State of Parana was unaware of its content and what it added

5.2.3 Conclusions

The comprehensive system in place in Brazil for holding registration and cattle identification provides sufficient guarantees to support the statements of Point 11.2 of the model certificate in Part 2 of Annex II to Regulation (EU) No 206/2010

The controls regarding holding registration, identification and registration of cattle and animal movement controls on the ERAS holdings were generally satisfactory. Nevertheless; very serious shortcomings on one holding (which had not been identified by the *certificadora* nor by the official services during official controls) demonstrate that the systems are not fully effective.

5.3 Listing of establishments

5.3.1 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.

5.3.2 Findings

The audit team noted that regular audits are performed for the specific requirements of importing countries (among them EU) with a minimum frequency of 1 audit every 1.5 years. In order to avoid conflicts of interest the official veterinarians (OVs) performing the audit re-evaluation of the establishments are not the officials carrying out the regular official controls at the specific establishment.

An internal system for the suspension of establishments to export to the EU is in place, when significant non-compliances are detected and for which FBO corrective action is required to lift such a suspension. The Brazilian Certification Database (SIGSIF) system bars those specific establishments from issuing export certificates for product to the EU, even though they remain on the list of approved establishments, until the CA confirms that the necessary corrective action has been taken. No specific time frames exists for the rectification of shortcomings that lead to the suspension, nor for the CA to issue a request to the Commission services to de-list the suspended establishment for EU exports.

5.3.3 Conclusions

A satisfactory procedure is in place for the listing of establishments and the maintenance of such a list. The internal suspension procedure ensures that listed establishments where significant non-compliances are found, are temporarily barred from exporting to the EU until such time that those deficiencies are addressed.

5.4 Official controls at establishment level

5.4.1 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 of fresh bovine meat into the EU are laid down in Model BOV of part 2 of Annex II to Regulation (EU) No 206/2010.

5.4.2 Findings

5.4.2.1 Ante-mortem inspection

Ante-mortem inspection was carried out in accordance with the EU requirements. Records were available. Results of ante-mortem inspection were well documented with inspection by CA personnel upon arrival of animals during working hours, and a final inspection prior to slaughter. In the majority of cases, official auxiliaries were present outside working hours acting as "spotters" of any issues for communication to the OV and, if necessary, requesting his urgent presence.

5.4.2.2 Post-mortem inspection

A working system of post-mortem inspection was noted with sufficient personnel and facilities provided for its performance. All official staff showed a good level of performance and understanding on the delivery of such official controls.

Findings at post-mortem inspection are recorded and the possibility exists for the results to be fed back to the owner of the animals. The audit team was informed that this was done on an *ad hoc* basis when they deviated from normal findings, and at the request to the owner of the animals.

A monthly summary of findings at post-mortem inspection is entered in the SIGSIF system from each approved establishment. A new system has now been developed for the addition of inspection results on a daily basis and is in the process of being rolled out.

5.4.2.3 FMD controls

In all slaughterhouses visited, appropriate FBO and CA procedures were in place for the control on the duration and temperature of the maturation, and on the pH controls of the meat at the end of the process. The feet and muzzle of slaughtered cattle were also inspected for the presence of vesicular diseases.

5.4.2.4 General and specific hygiene requirements

The majority of establishments visited were found to be satisfactory, with some issues requiring further attention due to the age of the buildings and facilities at the majority of establishments. This was more acute at one of the establishments visited where deficiencies were noted (e.g. rusty elements on the support of the slaughtering chain, flaking paint and mould in places where exposed carcasses were present, together with a cold store area used for products intended for the EU market in a poor state of repair, with leaking cold units and wall damages).

The official controls were found to be detailed and based on procedures that included several daily

checks at different parts of the establishment. Whilst the majority of findings made by the audit team had already been highlighted by the CA and included within enforcement and maintenance programmes, some had not or had not been attributed the necessary importance. This was specially so at the afore-mentioned establishment, as not all deficiencies had been identified by the CA. Moreover, persistence of the deficiencies and their nature casts doubts on the effectiveness of the enforcement programme.

Operational hygiene was found to be generally of good quality. Great care was given to the processing of carcasses to minimise contamination either from the de-hiding process or from gastrointestinal content. At one of the establishments, minor episodes of contamination were noted which the audit team considered to be linked to the high speed of the processing line and the limited space available to the operators at the working platforms.

Prophylactic measures such as animals being washed prior to slaughter with hyper-chlorinated water, and steam and suction point on the line addressing those areas of the carcass where non-visible contamination was more likely to be present were also in place in order to reduce the likelihood of contamination.

One noted shortcoming was the use of high pressure washers at final carcass wash in various establishments which could lead to cross contamination from splashing. When questioned by the audit team about this practice, which was not aligned to their overall satisfactory standards, the FBO responded that this procedure is done to ensure compliance with specific requirements of importing countries (i.e. Iran, Egypt) that required a complete absence of blood splashes or clots from the meat surface.

5.4.2.5 Hazard Analysis of Critical Control Points based systems

Circulars No 175/2005/CGPE/DIP0A and No 176/2005/CGPE/DIP0A define the procedures and the frequencies for official verification of FBOs' own-check programmes, including Standard Operating Procedures (SOPs), and HACCP-based programmes and water testing.

FBOs have Critical Control Points (CCPs) and Control Points (CPs) identified for their processes. Carcass contamination was consistently highlighted as a CCP with 100% monitoring taking place at the slaughter line prior to grading and final carcass wash. Carcass temperature control and livestock intake were covered as control points with a a regular level of monitoring.

Appropriate documentation was kept by the FBO showing the results of the monitoring and relevant corrective actions taken when deviations were detected.

CA personnel regularly carried out their own verification of the CCPs and CPs as part of their control over the FBO own Hazard Analysis of Critical Control Points (HACCP) based procedures but also to verify fulfilment with legal limits. There are regular checks over the FBO documentation and a clearly legible signature process exists that links such verification and follow up on actions to the personnel of the official services. Examples were seen of non-compliances being raised when the FBO failed to monitor as described in their HACCP plan or when deviations were found

CAs carried out a regular review of the FBO own HACCP based procedures and performed verification when amendments are made to them.

5.4.2.6 Microbiological testing

As previously described, the Brazilian authorities' guidances for the fulfilment of microbiological criteria sampling and analysis were different to those set out in Regulation (EC) No 2073/2005 whilst the audit was taking place. This, was, however, amended and the new guidance, aligned with EU requirements, entered into force on the last day of the audit.

All establishments visited followed the required sampling procedures which consists of:

- 50 samples for Aerobic Colony Counts (ACC) per semester from carcasses before chilling;
- 1 carcass sample every 300 carcasses for *Escherichia coli* (*E. coli*) continuously throughout the year;
- 1 annual cycle lasting for around 4 months of 82 samples for *Salmonella sp*.

In one State visited, alternative guidances had been given to the FBO (Memo 15/2014 of 20/01/2014 from Rio Grande do Sul State) that described the statutory microbiological test requirements for those establishments listed to export to the EU market. Such guidances were beyond the CCA requirements and aligned with EU requirements in regards to ACC and *Enterobacteriaceae* requirements.

At all establishments visited further microbiological tests were carried out on top of those legally required. This was carcass sampling for Shiga Toxin-producing *Escherichia coli* (STEC) per lot of animals slaughtered, daily sampling for *E. coli*; *E. coli* STEC, ACC and *Salmonella* of chilled meat to be exported to the EU.

All sampling and analysis methods were carried out following procedures which are audited by the Brazilian authority in charge of laboratories (Imetro) and used analysis methods that had been approved as equivalent by them. Furthermore, such accredited laboratories also take part in a quality assurance scheme run by the MAPA, with bi-annual assessment of capability to detect micro-organisms and action taken when failures are noted.

The majority of microbiological results observed were found to be well within the statutory limits and plotted for trend analysis. On those occasions where results were above the limits, examples of immediate action by the CA and full investigation by the FBO personnel were seen.

Regarding sampling of potable water: the required sampling frequency was implemented. This was done directly by the CA services, furthermore the FBOs also carried out their own water sampling programme on top of the official one. In all but one of the States visited, all the parameters as required by Directive 98/83/EC were included in the sampling programme; in the State of Rio Grande do Sul parameters such as Manganese, Sodium and Sulphate had not been included.

Routine monitoring of Chlorine was frequently done at all establishments visited and the level of Chlorine was found to be within the required limits

5.4.2.7 Traceability and identification marking

A number of traceability exercises were carried out using export certificates of chilled and frozen bovine meat destined to the EU. FBOs were able to make full traceability from final product to specific groups of animals brought in from ERAS approved holdings. Evidence could be seen of how the traceability system blocks the possibility of non-EU approved carcasses being diverted to EU processing at the cutting plant and how carcasses not fulfilling the Ph were also diverted from EU production

The CA carries out regular verification of traceability to enable them to sign export certificate documentation.

All boxes of chilled and frozen product are sealed with a breakable sticker which contains the identification number of the establishment and a serial number for control purposes. The CA could demonstrate how such stickers were kept under official control, and records were kept of the full inventory, with serial numbers of stickers used by the FBO every day.

Shortcomings were noted with regard to the readability of health-marks on the carcasses. Whilst they were fully legible when applied, by the time they had gone through the final carcass wash and stored in the chiller they had, in the majority of cases, become unreadable.

It was noted that the labels of packed beef product dispatched to the EU had the following wording: Slaughtered Brazil, Product of Brazil; and Brazilian beef, Origin Non-EU. The audit team was informed that this was a specific wording approved by the MAPA. All cattle had been born, reared and slaughtered in Brazil.

5.4.2.8 Animal welfare at the time of slaughter or killing

Animal welfare at the time of slaughter was found to be satisfactory. Animals were moved within the lairage and to the slaughtering area calmly and in line with the EU requirements. A penetrative captive- bolt system was used for stunning and a back-up system was immediately available on the spot at all establishments visited.

There was regular monitoring and verification by the FBO of relevant animal welfare parameters in the lairage and during the slaughtering process.

The CA carries out a daily verification process at the slaughterhouses and evidence could be seen of satisfactory verification of FBO own controls and documentation.

SOPs for animal welfare had been developed and implemented by the FBO, these were detailed and covered all the processes carried out at the establishment and went further as it covered handling at the holdings of origin, loading on to the trucks and transport to the slaughterhouse.

There was an appointed Animal Welfare Officer at all establishments visited and slaughterhouse personnel had received specific animal welfare training for the duties that they were performing, refresher training was also carried out. It was noted that Animal Welfare training for Animal Welfare Officers was either provided internally by FBO personnel or external organisations. Training of slaughterhouse personnel was usually done via cascade training by the Animal Welfare Officer. At the moment, there are no officially approved training programmes for the courses provided to FBO staff. There is nothing in place regarding the content and modalities of the independent final examination for those courses leading to certificates of competence as required by EU regulations.

The SOPs all stated that food was provided to the animals 24 hours after arrival but removed six hours prior to slaughter. This procedure is based on Brazilian Animal Welfare legislation which diverges with EU requirements that specify provision of food 12 hours after arrival.

5.4.2.9 Documentation of official controls

Extensive documentation covering official controls was present at the establishments visited, this covered daily checks covering all the different working shifts. Specific daily checks to be carried out each day (20% of total) were selected randomly via a computerised system. When non compliances were found; an official non compliance report was raised and the FBO was requested to develop a written action plan to address the deficiencies within agreed time-scales. Such deficiencies were consistently followed up.

Official Auditors from the State level carried out between four and six yearly audits covering both

the performance of FBOs and the CAs. Non compliances are raised and actions requested within an agreed time-frame. Monitoring and verification of non-compliances being addressed takes place.

5.4.3 Conclusions

A satisfactory delivery of ante- and post-mortem inspection by the CA was seen at all establishments visited by the CA. This was also the case in the majority of cases for the verification of FBO own controls with regard to their coverage, frequency and documentation. Official controls largely ensured that the general and specific requirements were met, notwithstanding the deficiencies noted in one establishment. Operational hygiene was found to be satisfactory at the majority of establishments visited.

HACCP based procedures were appropriately implemented by FBOs and so were the requirements for sampling and analysis for microbiological criteria, as set out by the Brazilian CA, which were only aligned to EU requirements at the end of this audit.

A satisfactory level of animal welfare was noted at all establishments visited and evidence was seen that at certain establishments procedures also covered transport to the lairage and the loading process at the holding of origin. Evidence was seen that slaughterhouse personnel dealing with live animals had been trained for the specific duties that they were performing, and that an Animal Welfare Officer had been appointed at all establishments visited. However, contrary to the requirements of Regulation (EC) No 1099/2009, the designated CA has yet to develop an official procedure to ensure that training courses with approved training programmes are available for personnel involved in killing and related operations, and that such personnel pass an independent final examination and receive the corresponding official certificate of competence.

The labelling of final beef products was partially in line with the requirements of Regulation (EC) No 1760/2000. This regulation requires the place of birth, rearing and slaughtering (when these are known) to be stated (instead of using the wording "Origin Non-EU"), when the three are the same it allows the wording "Origin", followed by the country in question, to be used instead.

5.5 Official certification

5.5.1 Legal requirements

Council Directive 96/93/EC lays down the general rules to be observed by third countries in issuing certificates required for exports to the EU, according to the specific EU veterinary legislation.

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.

Directive 96/93/EC lays down the general rules to be observed by third countries in issuing certificates required for exports to the EU, according to the specific EU veterinary legislation.

Decision 2003/779/EC lays down animal health requirements and the veterinary certification requirements for the import of casings from third countries. Additional attestations in relation to animal health requirements, to be included in the animal health certificates for imports of casings concerning the Bovine Spongiform Encephalities risk status of the country of origin, are given in Section C of Chapter C of Annex IX to Regulation (EC) No 999/2001.

5.5.2 Findings

The certification procedure remains as described in previous reports. Official export certificates are issued for every container at the processing establishment where the goods are loaded and sealed in the container. All relevant information is included in the certificate except the register of the vessels that will be used for sea transport as this is unknown at the time of issuing the certificate.

In all cases, issuing officials were able to trace back shipped final product to the holdings of origin and were able to demonstrate that all necessary supporting documentation were available. Two further assessments were made in regards to shipments going to Sweden and Finland and noted that the enhanced testing requirements in regards to *Salmonella sp.* had been met.

5.5.3 Conclusions

The certification procedures are satisfactory and provide equivalent guarantees to those laid down in Directive 96/93/EC

5.6 Rapid Alert Systems for Food and Feed (RASFF)

The audit team followed two specific RASFFs (Ivermectim above allowed limits from year 2013): follow up, communication, action being taken and the specific time-lines were assessed.

When a RASFF message is received, it is transmitted from central level to State level who then request an investigation by the local official services and the FBO. The outcome of this investigation and the actions being taken to reduce the likelihood of reoccurence, are then communicated back through State level to the central CA. In the case observed, this was completed within a satisfactory time scale (RASFF raised at EU Border Inspection Post on 30 April 2013, results of investigation transmitted to central level on 2 July 2013). However, the subsequent analysis and management of the case at central level was significantly delayed: the case had not been closed by the time of this audit and the outcome has not yet been communicated to the Commission services.

Further examples were seen of managerial actions being taken by the Brazilian Authorities covering establishments with repeated RASFF alerts due to STEC detection at Border Inspection Posts; these actions included requests for investigations to be made by the relevant FBO and CA State level: in one specific case this resulted in temporary suspension of the establishment from export to the EU market until a series of corrective actions had been taken

Due to concerns raised by a number of importing countries regarding the follow up and communication of RASFF in Brazil, and previous FVO recommendations; the DIPOA amended their internal procedures at the beginning of the year, focussing on the internal communication and management of RASFF alerts.

5.6.1 Conclusion

There is a clearly defined and developed system for the investigation and internal follow up of RASFF alerts. The procedures available have ensured that the CA and the FBO have dealt adequately with the RASFF notifications evaluated during the audit.

It was the view of the audit team that the whole chain of internal management and communications procedures audited, which had recently been amended, was highly bureaucratic and

administratively burdensome undermining the final resolution and communication of results of the investigation.

6 OVERALL CONCLUSIONS

Despite some shortcomings being identified at both holding and processing establishment levels, the controls over the production of bovine meat destined for export to the EU are satisfactory.

A robust system for the provision of statutory official controls, verification of FBO own procedures and enforcement action, as necessary, within clear time-scales was noted at all holdings and establishments visited.

Shortcomings were identified at one of the farms visited, the majority of which were linked to the lack of FBO own controls in relation to the number of animals present on the holding and identification tags. Maintenance issues were noted at one of the establishments visited that had already been identified by the CA but had not been properly addressed at the time of the audit.

The Brazilian authorities have agreed to the need to implement microbiological testing requirements as set out in Regulation (EC) No 2073/2005, and amended their procedures accordingly whilst the audit was taking place. They undertook to continue working on the development of necessary documentation to be presented to the Commission services seeking approval for equivalence of their previous testing regime.

Regular and extensive monitoring of STEC is carried out by the FBO on final product to be exported to the EU and whilst no positives were found at any of the establishments visited, FBO procedures are in place for the diversion of positives to further processing or alternative markets, should the case arise.

Animal welfare controls at slaughterhouse level were found to be satisfactory and examples were seen of how welfare controls were integrated, including transport and handling on the holding of origin. It was noted that no official procedure had yet been developed for the examination and appointment of animal welfare officers or slaughterhouse personnel via appointed external training centres or designated CA procedures as required by Regulation (EC) No 1099/2009.

Based on previous criticism from Commission services and third countries of their RASFF notification procedures, confirmed during this audit the Brazilian authorities have recently amended their communication procedures seeking an improvement to internal investigatory efficiency and external communication.

The certification of bovine meat in the establishments was satisfactory for all consignments verified, including exports to Sweden and Finland. Officials were able to demonstrate full traceability to farms of origin and that the specific certificate conditions were met.

7 CLOSING MEETING

A closing meeting was held on 27 October 2014 with the CCA, the MAPA. At this meeting the 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 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 actions 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.	Regarding animal welfare requirements at the time of killing; to ensure that a procedure is developed to approve programmes of training courses for personnel involved in killing and related operations, with independent final examinations and delivering relevant certificates of competence, as required by Articles 7 and 21 of Regulation (EC) No 1099/2009.
2.	To carry out a thorough review of controls (both official and by certificadora) on ERAS holdings (livestock holdings approved for export to the European Union and included in the TRACES list) to determine the extent to which the shortcomings found at one holding visited during this audit are prevalent and to enhance the control systems in order to ensure that all ERAS holdings have effective traceability.

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=2014-7234

Annex 1 - Legal References

Legal Reference	Official Journal	Title
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. 999/2001	OJ L 147, 31.5.2001, p. 1-40	Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 882/2004	The state of the s	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 852/2004	p. 1, Corrected and	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	p. 55, Corrected and	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		Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

Legal Reference	Official Journal	Title
Reg. 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
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. 206/2010	OJ L 73, 20.3.2010, p. 1–121	Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements
Dir. 92/118/EEC	OJ L 62, 15.3.1993, p. 49-68	Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC
Dir. 96/22/EC	OJ L 125, 23.5.1996, p. 3-9	Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of β-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC

Legal Reference	Official Journal	Title
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
Dec. 2007/453/EC	OJ L 172, 30.6.2007, p. 84-86	2007/453/EC: Commission Decision of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk