FINAL REPORT OF AN AUDIT

CARRIED OUT IN

BRAZIL

FROM 21 TO 31 MAY 2013

IN ORDER TO EVALUATE THE CONTROL OF RESIDUES AND CONTAMINANTS IN LIVE ANIMALS AND ANIMAL PRODUCTS INCLUDING CONTROLS ON VETERINARY MEDICINAL PRODUCTS

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.
Executive Summary
This report describes the outcome of a Food and Veterinary Office (FVO) audit in Brazil, carried out between 21 and 31 May 2013, as part of the published programme of FVO audits on the monitoring of residues in live animals and animal products in European Union (EU) Member States and in third countries.

The objective of the audit was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, in order to assess whether these systems offer adequate assurance that the products and animals for which Brazil is currently listed in the Annex to Commission Decision 2011/163/EU (as amended) as having an approved residue monitoring plan (PNCRC) (bovine, equine, poultry, aquaculture and honey) are within the specified residue limits laid down in EU legislation. Since the authorisation, distribution and use of veterinary medicinal products and feed additives have an impact on the monitoring of residues, the national rules governing the control systems in these areas were also part of the audit. Following a request made by Brazil that the Commission consider permitting the importation of fresh pig meat into the EU, the audit focused mainly on the pig sector and, in particular, the functioning of the ractopamine-free segregated production (RFP) scheme in the State of Santa Catarina. The audit also assessed the impact of actions taken in response to the recommendations made following the previous FVO audit on residues (DG(SANCO)2011-8862) (2011 FVO audit).

It is concluded that the PNCRC is generally designed and implemented in line with Directive 96/23/EC. The system in place to ensure that samples are analysed in ISO 17025 accredited laboratories using only validated methods is effective and the competent authorities can have confidence in the reliability of analytical results produced by the laboratory network. The ongoing development of analytical methods has increased the scope of testing for a range of substances compared with that described in the 2011 FVO audit report and the availability of additional methods during 2013 is expected to ensure that the PNCRC better reflects the usage patterns of veterinary medicinal products in Brazil and include all of the compulsory substance groups for the relevant commodities which are specified in Council Directive 96/23/EC.

With regard to the follow-up of non-compliant results, there is a comprehensive system in place for the prompt follow-up of residue violations. However, the policy of involving food business operators in the follow-up investigations, often some time before any official action is taken, combined with limitations in the scope of the investigations carried out and in the measures and/or sanctions which may be imposed, has the potential to compromise the effectiveness of follow-up and the ability of the competent authority to identify the reasons for illegal use of substances. In this respect the system for follow-up is not equivalent to the requirements of Council Directive 96/23/EC (Articles 13, 16-18, 23, 24, 27 and 28).

The system governing the authorisation, distribution and use of veterinary medicinal products has not changed significantly since the 2011 FVO audit. The fact that veterinary medicinal product treatment records are only required to be kept for certain species of food producing animals and that, in contrast to the EU, there is no official guidance on minimum withdrawal periods to be observed following 'off-label' use of veterinary medicinal products, there is an increased risk that animals sent for slaughter and products derived therefrom, will contain residues at concentrations in excess of MRLs. With regard to controls on the use of veterinary medicinal products, whilst inspections are carried out regularly at veterinary medicinal product wholesalers, retailers and feed mills (including those producing medicated feed), the continuing absence of official controls concerning the use of veterinary medicinal products on farms and by veterinary practices has the potential to weaken guarantees offered by the PNCRC concerning the residues status in commodities which may be exported to the EU.
Since the 2011 FVO audit, the procedures for the operation of the RFP scheme and their implementation have been strengthened and many of the elements which could theoretically enable the split-system to function satisfactorily are now in place. Although there has been a decline in the number of detections of ractopamine in the official sampling programme since these changes were made, the fact that 13% of samples taken from pigs from the RFP scheme at slaughter in 2013 were found to contain this substance and no cause for the contamination has been identified, indicates that the system in place is not yet sufficiently robust to guarantee that products from such pigs are derived only from animals which have not received ractopamine at any time during their life, as required by Article 11.2 of Directive 96/22/EC.

The report makes a number of recommendations to the Brazilian competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.
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<tr>
<td>CCα / CCβ</td>
<td>Decision Limit / Detection Capability</td>
</tr>
<tr>
<td>CCRC</td>
<td><em>Coordenação de Controle de Resíduos e Contaminantes</em> – Co-ordination of the control of residues and contaminants</td>
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<tr>
<td>CGAL</td>
<td><em>Coordenação Geral de Apoio Laboratorial</em> – General Co-ordination of Laboratories</td>
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<tr>
<td>CIDASC</td>
<td><em>Companhia Integrada de Desenvolvimento Rural de Santa Catarina</em> - animal health service of the State of Santa Catarina</td>
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<tr>
<td>DDA</td>
<td><em>Departamento de Defesa Agropecuária</em> - Divisions of Agriculture and Livestock Defence</td>
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<tr>
<td>DFIP</td>
<td><em>Departamento de Fiscalização de Insumos Pecuários</em> – Department of Livestock Input Inspection</td>
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<tr>
<td>DG(SANCO)</td>
<td>Health and Consumers Directorate-General</td>
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<tr>
<td>DIPOA</td>
<td><em>Departamento de Inspecao de Produtos de Origem Animal</em> - Department of Inspection of Products of Animal Origin</td>
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<tr>
<td>DSA</td>
<td><em>Departamento de Saude Animal</em> - Department of Animal Health</td>
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<tr>
<td>EC</td>
<td>European Community</td>
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<tr>
<td>EEC</td>
<td>European Economic Community</td>
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<tr>
<td>ELISA</td>
<td>Enzyme-linked immuno-sorbent assay</td>
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<td>EU</td>
<td>European Union</td>
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<td>FVO</td>
<td>Food and Veterinary Office</td>
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<tr>
<td>GTA</td>
<td><em>Guia de transito animal</em> (animal movement document)</td>
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<tr>
<td>INMETRO</td>
<td><em>Instituto Nacional de Metrologia, Normalização e Qualidade Industrial</em> – Brazilian National Accreditation Body</td>
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<tr>
<td>ISO</td>
<td>International Organisation for Standardisation</td>
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<tr>
<td>LC-MS/MS</td>
<td>Liquid Chromatography-(Tandem) Mass Spectrometry</td>
</tr>
<tr>
<td>LOD, LOQ</td>
<td>Limit of Detection, Limit of Quantification</td>
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<tr>
<td>MAPA</td>
<td><em>Ministério da Agricultura, Pecuária e Abastecimento</em> – Ministry of Agriculture, Livestock and Supply</td>
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<tr>
<td>ML</td>
<td>Maximum Level</td>
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<tr>
<td>MRL</td>
<td>Maximum Residue Limit</td>
</tr>
<tr>
<td>MRPL</td>
<td>Minimum Required Performance Limit</td>
</tr>
<tr>
<td>PCBs</td>
<td>Polychlorinated biphenyls</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
</tr>
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<td>----------</td>
<td>-----------------------------------------------------------------------------</td>
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<tr>
<td>PNCRC</td>
<td><em>Plano Nacional de Controle de Resíduos e Contaminantes</em> - National Plan for Control of Residues and Contaminants</td>
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<tr>
<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
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<td>RFP</td>
<td>Ractopamine-free production</td>
</tr>
<tr>
<td>SDA</td>
<td><em>Secretaria de Defesa Agropecuária</em> – Secretariat of Animal and Plant Protection</td>
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<tr>
<td>SEFIP</td>
<td><em>Serviço de Fiscalização de Insumos Pecuários</em> – Service of Fiscalization of Livestock Inputs</td>
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<tr>
<td>SFA</td>
<td><em>Superintendência Federal de Agricultura, Pecuária e Abastecimento</em> - Federal Superintendence of Agriculture, Livestock and Supply</td>
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<tr>
<td>SIF</td>
<td><em>Serviço de Inspeção Federal</em> – Federal Inspection Service</td>
</tr>
<tr>
<td>SIPOA</td>
<td><em>Serviço de Inspeção de Produtos de Origem Animal</em> – Service of Inspection of Animal Origin Products</td>
</tr>
<tr>
<td>SISRES</td>
<td><em>Sistema de Informações Gerencias de Resíduos</em> (database)</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
</tr>
<tr>
<td>SSA</td>
<td><em>Serviço de Saúde Animal</em> - Service of Animal Health</td>
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1 INTRODUCTION

The audit took place in Brazil from 21 to 31 May 2013. The audit team comprised two inspectors from the Food and Veterinary Office (FVO) and one expert from a European Union (EU) Member State. The audit was undertaken as part of the FVO's audit programme, evaluating control systems and operational standards in the residues sector.

Representatives from the central competent authority responsible for control of residues in animals and animal products accompanied the audit team during the audit. An opening meeting was held on 21 May 2013 with the central competent authority responsible for implementing residue monitoring in live animals and animal products and representatives of the competent authority responsible for the authorisation of veterinary medicinal products. At this meeting, the objectives of, and itinerary for, the audit were confirmed and the control systems were described by the authorities.

2 OBJECTIVES

The objective of the audit was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, in order to assess whether these systems offer adequate assurance that the products and animals concerned are within the specified residue limits laid down in EU legislation. Since the authorisation, distribution and use of veterinary medicinal products and feed additives have an impact on the monitoring of residues, the national rules governing the control systems in these areas were also part of the audit. Following the request made by Brazil that the Commission consider permitting the importation of fresh pig meat into the EU, the audit focused mainly on the pig sector and, in particular, the functioning of the ractopamine-free segregated production (RFP) scheme in the State of Santa Catarina. The audit also assessed the impact of actions taken in response to the recommendations made following the previous FVO audit on residues (DG(SANCO)2011-8862) on the ability of the competent authorities to deliver the required standards in the sectors for which Brazil is currently listed in the Annex to Commission Decision 2011/163/EU (as amended) as having an approved residue monitoring plan (bovine, equine, poultry, aquaculture and honey).

The table below lists sites visited and meetings held in order to achieve that objective.

<table>
<thead>
<tr>
<th>Meetings/Visits</th>
<th>n</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Competent Authorities</td>
<td></td>
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<tr>
<td>Central</td>
<td>2</td>
<td>Opening and closing meetings at the Ministry of Agriculture, Livestock and Supply (MAPA)</td>
</tr>
<tr>
<td>Regional</td>
<td>1</td>
<td>Meetings at the State MAPA offices in the State of Santa Catarina</td>
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<tr>
<td>Laboratories</td>
<td>3</td>
<td>Visits to two Governmental laboratories (LANAGROs)</td>
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<tr>
<td>Farms</td>
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<td>Visit to two pig farms in the segregated RFP scheme</td>
</tr>
<tr>
<td>Establishments</td>
<td>3</td>
<td>Visits to a pig slaughterhouse and two feed mills</td>
</tr>
<tr>
<td>Other sites</td>
<td>1</td>
<td>Visit to a retailer of veterinary medicinal products</td>
</tr>
</tbody>
</table>
3 LEGAL BASIS

The audit was carried out under the general provisions of EU legislation, and in particular:


A full list of the legal instruments referred to in this audit report is provided in the Annex and refers, where applicable, to the last amended version.

4 BACKGROUND

4.1 COUNTRY STATUS IN RELATION TO EU-APPROVAL OF RESIDUE MONITORING PLANS

Commission Decision 2011/163/EU indicates that Brazil’s residue monitoring plan is approved in accordance with Council Directive 96/23/EC for bovine, equine, poultry, aquaculture and honey. The central competent authority has requested that the Commission services consider permitting the importation of pig meat from the State of Santa Catarina into the EU and a residue monitoring plan for this commodity has been submitted.

4.2 SUMMARY OF PREVIOUS FVO AUDIT RESULTS

The Brazilian control system for residues of veterinary medicines and contaminants in food of animal origin has been evaluated by the FVO in six residues audits carried out since 1999. The most recent of these audits, carried out in 2011 (DG(SANCO)/2011-8862 MR Final), hereafter referred to as the 2011 FVO audit report, also assessed the RFP scheme. The reports of all of these audits have been published on the website of the Directorate – General for Health and Consumers here: http://ec.europa.eu/food/fvo/index_en.cfm.

The 2011 FVO audit report concluded that the planning, implementation, laboratory testing and supervision of the residue monitoring programme (PNCRC - Plano Nacional de Controle de Resíduos e Contaminantes) was largely satisfactory. However, the effectiveness of the arrangements in place could be enhanced further by increasing the scope of the analytical tests to better reflect the usage patterns of veterinary medicinal products and by ensuring that relevant substance groups are included in the PNCRC. Improvements had been made to the comprehensive and complex system in place for the follow-up of residue violations although it continued to be weakened by the limited legal powers to apply measures or sanctions and the practice of notifying farmers in advance of on-farm investigations. The relative ease with which veterinary medicinal products could be obtained and used coupled with the limited requirements for treatment records were considered to make it difficult for farmers to ensure compliance with withdrawal periods and consequently increase the possibility of residues violations.

The 2011 FVO audit report further concluded that progress had been made in drafting legislation, protocols and procedures on which the RFP scheme was based but it was at an early stage of development and despite prompt actions being taken when non-compliances were detected, the
The competent authority was not yet in a position to demonstrate that the pigs produced in the RFP scheme had not been treated with ractopamine at any time in their lives.

4.3 Rapid Alert System for Food and Feed (RASFF) Notifications for Products of Animal Origin from Brazil Concerning Residues

Since the 2011 FVO audit there have been 34 RASFF notifications for residues of veterinary medicinal products, comprising 27 cases of ivermectin in beef, three detections of semicarbazide (the marker residue of nitrofurazone) in bovine stomachs, two cases of doramectin in beef, one case of doxycycline in chicken and one case of albendazole in beef.

4.4 Production and Trade Information

According to data provided by MAPA, in 2012 Brazil exported the following products of animal origin to the EU: bovine (115,079 tonnes (16% of national production)), poultry (272,306 tonnes (0.25% of national production)), equine (2,000 tonnes (approximately 10% of slaughtered animals)), aquaculture (8,300 tonnes (2010) (0.005% of national production)) and honey (approximately 5,000 tonnes (2011) (11% of national production)). In addition, approximately 3,500,000 tonnes of porcine products were produced nationally in 2012. Pig meat is not currently exported to the EU.

5 Findings and Conclusions

5.1 Residue Monitoring

The organisation and role of the competent authorities with responsibilities for topics falling within the scope of this audit is unchanged from those described in the 2011 FVO audit report. The diagram below shows the organisation and relevant functions of the competent authorities involved at Federal and State level.

Two of the competent authorities involved operate at the federal level. The CCRC (Coordenação de Controle de Resíduos e Contaminantes – Co-ordination of the control of residues and contaminants) is the main co-ordination body for planning and implementation of the PNCRC and for follow-up of non-compliant results. The CGAL (Coordenação Geral de Apoio Laboratorial – General Co-ordination of Laboratories) is responsible, inter alia, for the approval and supervision of laboratories responsible for analysing samples for the PNCRC. Tasks include approval of analytical methods based on validation data provided by the laboratories and carrying out periodic audits to confirm compliance with the relevant MAPA requirements.

The states visited during this audit, and 26 others, operate under DDAs (Departamentos de Defesa Agropecuária - Divisions of Agriculture and Livestock Defence) which are organised within SFAs (Superintendencias Federal de Agricultura, Pecuária e Abastecimento – Federal Superintendencies of Agriculture, Livestock and Supply). A detailed description of the different arrangements in place in the remaining 18 states is given in the 2011 FVO audit report.

The competent authorities and their roles in overseeing the RFP scheme have not changed from those described in the 2011 FVO audit report: SEFIP (Serviço de Fiscalização de Insumos Pecuários – Service of Fiscalization of Livestock Inputs) is responsible for controls on feed production, the animal health service of Santa Catarina (Companhia Integrada de Desenvolvimento Rural de Santa Catarina – CIDASC) for controls on farms and SIF (Serviço de Inspeção Federal –
Federal Inspection Service) / SIPOA (Serviço de Inspeção de Produtos de Origem Animal – Service of Inspection of Animal Origin Products) for controls at slaughterhouses.

5.2 PLANNING OF THE RESIDUE MONITORING PLAN

Legal Requirements

Third countries which export live animals or animal products to the European Union are obliged to submit to the European Commission a specific plan setting out the guarantees which it offers as regards the monitoring of the groups of residues and substances referred to in Annex I to Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products.

The residue plan should take account of the results of monitoring from the previous year and should be revised annually and updated at the request of the Commission, particularly when checks carried out by the Commission render it necessary. Article 29 of said Directive states that guarantees must have an effect at least equivalent to those provided for in the Directive and must, in particular, meet the requirements of Article 4 and specify the particulars laid down in Article 7 and meet the requirements of Article 11(2) of Directive 96/22/EC. Articles 3 to 7 of Council Directive 96/23/EC deal with the requirements for residue monitoring plans. The levels and frequencies of sampling for residues are specified in Annex IV to Council Directive 96/23/EC and Commission Decision 97/747/EC.
Article 11 of Regulation (EC) No 178/2002, laying down the general principles and requirements of food law, specifies that food and feed imported into the EU for placing on the market within the EU shall comply with the relevant requirements of food law or conditions recognised by the EU to be at least equivalent thereto. In relation to maximum levels of residues and contaminants in food, Regulation (EC) No 470/2009 of the European Parliament and of the Council lays down Maximum Residue Limits (MRLs) for residues of pharmacologically active substances in food which are listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010. Regulation (EC) No 396/2005 lays down maximum residue levels of pesticides in or on food and feed of plant and animal origin. Commission Regulation (EC) No 1881/2006 lays down Maximum Levels (MLs) for contaminants in food. Minimum Required Performance Limits (MRPLs) are defined in Article 4 of Commission Decision 2002/657/EC.

In accordance with Article 29 of Council Directive 96/23/EC, Commission approval of every third country’s residue monitoring plan is necessary if that country is to remain on the list of third countries from which EU Member States may import animals and animal products. The list of countries and commodities with approved residue monitoring plans is in the Annex to Commission Decision 2011/163/EU.

Findings

The planning process for the PNCRC is as described in the 2011 FVO audit report. Normative Instruction No. 42 of 20 December, 1999 provides the main legal basis for the PNCRC. The audit team noted that:

- The PNCRC for 2013 covers the commodities for which Brazil is listed in the Annex to Commission Decision 2011/163/EU. In addition, plans for pigs, milk and eggs are also included. The plan for fishery products covers both wild caught and farmed species.

- The substance groups to be tested for each commodity in the 2013 PNCRC are in accordance with the requirements of Directive 96/23/EC, with the exception of non-steroidal anti-inflammatory drugs in pig muscle which are not being included. According to information provided by CGAL, analytical methods for this substance group and a broader range of coccidiostats in this matrix have been validated and are shortly expected to be approved for use in the PNCRC. The development of these new methods is part of an ongoing programme which has resulted in an increased scope of testing in the PNCRC for commonly used substances since the 2011 FVO audit. Once the analytical methods planned to be introduced during 2013 are in place, recommendation No. 1 of the 2011 FVO audit report will be addressed.

- The PNCRC for 2013 is broadly similar to the one for 2012, although there is a planned increase in the number of samples to be taken to check for antiparasitic substances in bovine liver and muscle (605 planned compared with 435 planned in 2012), mainly due to an increase in testing for abamectin, doramectin, ivermectin, eprinomectin and moxidectin in bovine muscle. There was also an increase in the monitoring of residues of other anti-parasitic substances (organophosphates, carbamates and pyrethroids) in bovine muscle covering a total of 117 new analytes for analysis held by LANAGRO Goiás. In addition, there has been an increase in the number of poultry samples to be tested for a broad range of coccidiostats (510 samples planned for 2013 compared with 110 samples planned for 2012).

In its response to the draft report, the competent authority clarified that ostriches, goats and sheep are also part of the PNCRC.
• As noted in the 2011 FVO audit report, both pig muscle and urine are tested for ractopamine. According to the 2013 PNCRC, it is planned to check for this substance in 60 samples of muscle based on the 'Reference Limit to Take Regulatory Action' of 10 μg/kg, in accordance with the MRL for ractopamine in this matrix adopted by the Codex Alimentarius. An additional 30 samples of pig muscle will be tested for this substance based on a reference level of 1 μg/kg in accordance with other (non-EU) market requirements for ractopamine-free pig meat. The same number of samples of bovine muscle and urine will also be checked against the same limits.

• Following a review of the results of the official sampling programme for the RFP scheme by the competent authorities in 2012, it was concluded that the results showed the ability to detect ractopamine in pig urine would not be affected if official samples were collected only in the slaughterhouse rather than also on-farm. As a result, from 2012 official samples of pig urine have only been collected at slaughter and the food business operators in the RFP scheme were informed in November 2012 that they should include sampling of pig urine on-farm to check for ractopamine in their own-check programmes.

• The 2013 PNCRC includes 152 (three times more than were scheduled in 2012) samples of urine (at slaughter) from pigs reared within the RFP scheme to be checked for ractopamine based on an action level of 1 μg/L, although all confirmed findings above the decision limit for the analytical method (CCα of 0.17 μg/L) would be considered as non-compliant.

• The PNCRC does not currently include any analysis of feed to check for ractopamine. According to the CGAL, a suitable method is currently being developed and should become available at the end of 2013. The audit team checked the progress made to date and the findings are described in the section 5.6.3.²

• Each year the PNCRC is published in the Official Gazette, including detailed data on the substances to be analysed and the commodities to be sampled. The PNCRC for 2013 was published on 31 May 2013 (OJ No. 103, 6-13). According to the competent authority, Article 37 of the Brazilian Constitution obliges the competent authority to publish information including the PNCRC³, even though this may undermine the element of surprise in official controls required by Annex II of Council Directive 96/23/EC. As a result, the competent authority stated that it is not possible to address recommendation No. 2 of the 2011 FVO audit report.

**Conclusions on planning of the residue monitoring plan**

The PNCRC is generally designed in line with Directive 96/23/EC and the on-going development of analytical methods has increased the scope of testing for a range of substances compared with that described in the 2011 FVO audit report. The availability of additional methods during 2013 is expected to ensure that the PNCRC better reflects the usage patterns of veterinary medicinal products in Brazil and that all compulsory substance groups for the relevant commodities which are

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² In its response to the draft report, the competent authority stated that it considered routine sampling of feed to monitor for the presence of ractopamine would not significantly strengthen the RFP scheme but its use as a confirmatory tool when investigating deviations was recommended.

³ In its response to the draft report, the competent authority confirmed that pursuant to the article 37 of the Brazilian Constitution, considering the principle of publicity in public administration, in connection with providing transparency in its actions, MAPA should publicise its actions and disclose every year the Normative Instruction with the commodities and scope of analysis.
specified in Directive 96/23/EC will be included.

### 5.3 Implementation of the Residue Monitoring Plan

#### Legal Requirements


#### Findings

The system for the implementation of the PNCRC has not changed since the 2011 FVO audit report. In summary, CCRC manages the database Sistema de Informações Gerencias de Resíduos (SISRES) which is used to generate weekly sampling schedules (except for live cattle – which is planned on a monthly basis). These sampling plans can be downloaded directly by officials of the SIFs (Serviço de Inspeção Federal – Federal Inspection Service) who are responsible for taking samples in all establishments which are subject to federal inspection including slaughterhouses and fish processing plants. Sampling on cattle farms is carried out by officials of the SSA (Serviço de Saúde Animal - Service of Animal Health) and authorised veterinary inspectors. SFA officials responsible for managing the PNCRC at state level provide information to the CCRC regarding establishments which can be included, or excluded, from the randomised weekly sampling plans.

The audit team noted that:

- **Normative Instruction No 42** of 20 December, 1999 provides detailed rules for the implementation of the PNCRC. In addition, a Manual for sampling within the PNCRC was issued by CCRC in 2010.

- Weekly sampling plans produced in the SISRES database specify deadlines by which the samples should be taken and submitted to the laboratory. Samples which are either taken, or arrive at the laboratory past the deadlines cannot be registered in SISRES and are rejected. Information concerning the collection of samples and any rejections by the laboratories are monitored via the SISRES database and, where necessary, CCRC may adjust the sampling plans for subsequent weeks to help ensure that the planned sample numbers given in the PNCRC are achieved in practice.

- Following the detection in 2013 of ractopamine in 13 samples of pig urine, which were

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4 In its response to the draft report, the competent authority explained that including or removing facilities from the sampling plan is performed by DIPOA.
subsequently found to have been taken wrongly from animals not reared in the RFP scheme, SFA officials have recently been required to provide CCRC with information regarding the planned slaughter of pigs from the RFP scheme so that these animals can be specifically targeted in the weekly sampling plans if required. During the visits, the audit team was able to check that these arrangements are functioning as intended.

- It could be seen from the results of the 2012 PNCRC, that the samples analysed for each commodity and substance group either fulfilled or exceeded the number planned. In the case of antiparasitic substances in cattle, which were the main subject of RASFF alerts issued since the 2011 FVO audit, it can be seen that a total of 692 samples were analysed compared with 435 planned.

- According to the results of the 2012 PNCRC, all 50 samples of urine planned to be taken from pigs in the RFP scheme were analysed. However, in the testing laboratory visited, the audit team confirmed that only 17 of the 50 samples had actually been received and analysed. The competent authority stated that the shortfall in sampling was due to a review of the RFP scheme, a pause between production cycles and the move to replace on-farm sampling of pig urine with samples taken at slaughter (see section 5.2.).

- The competent authority confirmed that since the 2011 FVO audit report steps have been taken to ensure that officials fulfil their responsibilities for arranging the delivery of official samples to the laboratory by suitable means and to make sure that food business operators are not involved in this process. As such, recommendation No. 3 of the 2011 FVO audit report has been addressed.

- The officials met in the slaughterhouses visited were aware of the sampling requirements and had adequate sampling materials and seals for this task. All samples which were seen arriving at the laboratory visited were packed and sealed in accordance with the national instructions.

Conclusions on implementation of the residue monitoring plan

As seen in 2011, there is a comprehensive system in place for supervising the implementation of the PNCRC which helps to ensure that the programme is satisfactorily executed.

5.4 Follow-up of non-compliant results

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive. Measures to be taken by competent authorities in response to the finding of non-compliant residues results are described in Articles 13, 16, 17, 18, 19, 23, 24, 27 and 28 of Council Directive 96/23/EC.

5.4.1 Non-compliant results in the residue monitoring plans

Findings

The procedures in place for the follow-up of non-compliant results and the typical sanctions which
would be imposed when non-compliant results are detected remain largely unchanged from those described in 2011 FVO audit report. In summary, MAPA Directive No 396 of 23 November 2009 provides the legal basis for the follow-up of non-compliant results in the PNCRC, including follow-up sampling of the next five batches of animals sent for slaughter or products sent for processing (e.g. honey) from the establishment of origin of the non-compliant result.

SDA/MAPA Order No 132 of 2012 provides for the temporary suspension of the issuing of Animal Movement Permits (Guia de transito animal - GTA) for farms implicated in non-compliant results detected in the PNCRC. Where these violations involve authorised veterinary medicinal products, the issuing of GTAs can be suspended for a period of time equivalent to the withdrawal period of the product concerned. If it is not possible to identify the actual veterinary medicinal product used (for example due to the absence of treatment records), the GTA-suspension period should be the maximum withdrawal period for authorised veterinary medicinal products of the same category of product. In case of unauthorised veterinary medicinal products or illegal substances being detected, the above Order stipulates that the issuing of GTAs for that farm should be suspended for a period of six months. In most cases no follow-up samples would be taken during the period when the issuing of GTAs for the farm is suspended. Once GTAs are allowed to be issued again the next five production batches sent for slaughter or processing would be sampled.

The results of the 2012 PNCRC which were published in Normative Instruction No 7 of 27 March 2013, show that a total of 25 samples were non-compliant (excluding 44 non-compliances for inorganic contaminants (arsenic) in wild fish). A similar level of non-compliances (21 - excluding 21 non-compliances in wild fish) was found in the 2011 PNCRC. During this two year period, the highest number of non-compliances concerned avermectins in bovines (2.6% of liver and 0.65% of muscle samples were non-compliant in 2012 compared with 2% and 1.99% of liver samples being non-compliant in 2011). In the 2012 PNCRC, 7.4% of farmed shrimp samples were non-compliant for nitrofurans (semicarbazide) and 6.6% of honey samples were also non-compliant for nitrofurans (three for nitrofurazone and one for furazolidone). No non-compliances were detected for these commodities / substance groups in the 2011 PNCRC. The audit team noted that:

- Documentation relating to follow-up cases seen by the audit team showed that the non-compliant results were notified promptly to all relevant levels of the competent authorities involved. Details of non-compliant results and the farms of origin were also notified to inspectors in other slaughterhouses in case animals from that farm were to be presented for slaughter elsewhere, in which case the animals should be sampled and detained pending the receipt of the test results.

- Since the 2011 FVO audit, the system for communicating non-compliant results has been streamlined with information being transmitted electronically and further standardised procedures have been introduced. In addition, identification details of the farm or establishment of origin are now included directly on the sampling form. This means that in case of non-compliant results inspectors no longer need to request such details from the slaughterhouse or processing establishment where sampling took place.

- As described in the 2011 FVO audit report, the official inspector in the establishment where the non-compliant sample was taken is required to inform the food business operator concerned of the result and to request that they carry out an investigation to identify possible causes for the non-compliance. The food business operators are required to present an action plan describing corrective and preventive measures which will be taken to address any shortcomings identified and must also trace any product from the batches involved.
• In a number of follow-up cases checked by the audit team, by the time the official follow-up farm visits took place, the farmers stated they had already been informed by the slaughterhouse of the non-compliant result and/or had already been visited by representatives of the integrated company. In one case, involving detection of β-bolde-none in pig urine, the official investigation was initiated nearly two weeks after one already carried out by the farmer, his technical adviser and supervisor. In another case of sulphamethazine detection in pigs, at the time of the official follow-up inspection the farmer stated that he had already been recently approached by technicians from the slaughterhouse (an integrated company) whose goal was to identify the cause of the violation. In a third case concerning the detection of tilmicosin in pigs, the official on-farm investigation was carried out two days after the non-compliance was notified. However, representatives of the integrated company had already visited the farm the previous day and collected feed samples for analysis as they suspected cross-contamination in the feed mill could have given rise to the residue. In this respect recommendation No. 5 of the 2011 FVO audit report that follow-up investigations be performed without prior notice being given to farmers by the industry has not been addressed.

• In the vast majority of cases reviewed by the audit team the official follow-up investigations were not effective at identifying the source of contamination or the reason for the non-compliant results. In some cases the absence of treatment records on the farms impaired the effectiveness of follow-up investigations. In other cases, relevant factors such as potential contamination of feed were considered in the official follow-up investigations and official feed samples were collected on the farm, or at the supplying feed mill. However, these samples were not always analysed owing to a lack of suitable validated analytical methods (eg. testing for chloramphenicol in tilapia feed). In another example seen, official feed samples were collected during the follow-up inspection but only from batches of feed produced after the residue was detected. These samples were sent for analysis for sulphonamides, tetracyclines and quinolones, but not for tilmicosin which had been detected in the original non-compliant result.

• In case of repeated violations (e.g. a non-compliant result in one of the five subsequent production batches sampled) the audit team noted that no additional measures or sanctions are applied, apart from repeating the standard measures of temporarily suspending the issuing of GTAs and sampling a further five production batches. A draft MAPA Normative Instruction has been prepared which foresees the possible application of sanctions or penalties in case of non-compliant PNCRC results and reviewing the current provisions of Normative Instruction No 42 of 20 December 1999. It is not known when this draft Normative Instruction will be formally agreed and enter into force. In this respect recommendation No. 4 of the 2011 FVO audit report has only been partially addressed.

5.4.2 Non-compliant results in the RFP scheme

Findings

As described in the 2011 FVO audit report, food business operators are required to carry out an investigation in response to 'detections' of ractopamine (above CCα 0.17µg/L but below 1.0µg/L) while an official follow-up investigation will be carried out where 'violations' (levels ≥ 1.0µg/L) are...
Ractopamine was not detected in any of the 17 official samples collected from pigs in the RFP scheme in 2012. At the time of this audit, 63 of the 152 official samples of pig urine planned to be taken under the 2013 PNCR had been analysed. The results showed violations (above 1.0 µg/L) had been detected in 11 samples while there had been nine detections (levels between 0.17µg/L and 1.0 µg/L). Documentary evidence was provided to show that 10 of the violations and three detections related to samples which were mistakenly taken from animals which were not in the RFP scheme. The competent authority stated that steps have been taken to avoid such problems in the future (see section 5.3.). The audit team noted that:

- The follow-up files seen by the audit team showed that the relevant competent authorities and food business operators had been informed promptly of the non-compliant sample results, as for other non-compliances in the PNCRC.

- All except one of the detections of ractopamine in RFP scheme animals were found in pigs from one of the two integrated companies currently in the scheme. The SIF inspector had requested that the food business operator conduct an investigation to identify the source of the contamination and to provide an action plan to address any shortcomings found.

- According to representatives of the integrated company concerned, the farms where the non-compliant animals were reared were inspected and the farmers interviewed to verify that no ractopamine had been used on the farm. In addition, ractopamine had not been detected in own-check analyses of certain batches of feed at the point of loading for dispatch from the feed mill to the affected farms. No reason for the contamination had been identified and the company concerned proposed in its action plan to strengthen the own-check sampling of feed at the point of loading into trucks to verify that it was free from ractopamine.

- The scope of the follow-up investigations carried out by the food business operator was limited as the samples of batches of feed delivered to the farms, which the operator stated were retained by farmers during the production cycle, had not been checked for the presence of ractopamine. As such, it was not possible to see if feed had been contaminated during transportation or storage on farm or if there had been sporadic presence of ractopamine in raw materials used to produce feed. According to the food business operator, the possibility that materials used to produce feed may have been contaminated had only recently been considered during a meeting with the competent authorities to discuss the non-compliances. It was additionally noted that although the company concerned had validated the method for its own check sampling of pig urine on farm, that routine sampling had not yet been carried out, even though this had been required since November 2012. CIDASC had identified this shortcoming during the official follow-up investigation carried out shortly before this audit.

- Documents provided to the audit team, showed that the food business operator had been notified of a non-compliant sample result containing 1.47µg/L of ractopamine ten days

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6 In its response to the draft report, the competent authority states that ractopamine was found in samples from four of the 15 farms in the RFP scheme and noted that the sampling methodology is based on taking five samples from each property in the RFP scheme and when there are any likely detections, these should be considered as one sole non-conformity and not as five.

7 In its response to the draft report, the competent authority states that there are already validated research, monitoring and investigation methods for active ingredients in livestock feed, including to confirm the presence of ractopamine.
before CIDASC carried out the official investigation. During the official follow-up investigation, no evidence was found that ractopamine had been used. No official samples of pig urine or feed were collected as, in the latter case, there is no suitable analytical method available\(^8\).

- A detailed investigation had been carried out by SEFIP in the feed mill supplying feed to the farms where non-compliances had been detected. A comprehensive inspection report had been produced along with requirements for corrective actions to address shortcomings identified. These included strengthening the own-check procedures in place to verify that feed would be free from ractopamine.

- According to MAPA, the farm supplying the animal in which 1.47µg/L of ractopamine had been detected in its urine, has been suspended from the RFP scheme. Additional penalties may be imposed on the integrated company concerned owing to the number of non-compliant samples detected in 2013 but this would be dependent on the outcome of an appeal which was currently being considered\(^9\).

5.4.3 Non-compliant results reported under the RASFF

Findings

The procedures in place for the follow-up of non-compliant results reported under the RASFF are set out in SDA/MAPA *Ordinance No. 53* of 17 March 2009 and there has been no change in this respect since the 2011 FVO audit report. The audit team noted that:

- A database is maintained at central level concerning the state of follow-up actions taken pursuant to RASFF notifications (and also notifications received from other countries).

- Once RASFF notifications are received, these are promptly communicated from DIPOA to SIPOA, requesting that the establishment involved immediately initiates an investigation to identify the cause of the non-compliance, describe and adopt measures taken to prevent further violations and assess any need for complementary actions to guarantee compliance with EU standards.

- Where RASFFs involved detections of prohibited substances (e.g. nitrofurans in bovine stomachs) SIPOA was additionally requested to provide details of the farms of origin if possible to facilitate further investigations. The results of the company’s investigations on possible causes and corrective actions taken are also to be assessed by local SIF and SIPOA staff.

- The audit team examined a number of follow-up files, including the case of doxycycline in chickens reported in November 2012. In this case, the slaughterhouse postulated that the farmer might have used a veterinary medicinal product containing doxycycline without a

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\(^8\) In its response to the draft report, the competent authority stated that the analysis of livestock feed is not deemed essential on a routine basis but rather as an investigative tool to confirm the presence of ractopamine in livestock feed. The validation of an appropriate analytical method has now been concluded.

\(^9\) In its response to the draft report, the competent authority stated that the properties that produced and supplied pigs which were deemed not to be in conformity with the requirements of the RFP scheme were suspended from the scheme and the production chain in question was considered unfit to produce pigs without ractopamine, pursuant to MVE 028/2013 (15/05/2013) and Information 40/2013 (06/08/2013).
proper prescription, or that feed premixes or raw materials might have been contaminated. However, the official DIPOA report of 30 January 2013 considered that the investigative tools used by the company were inadequate to identify the reasons for any non-conformities, and that possible contamination via feed had received insufficient attention.

- The audit team also saw evidence of repeated RASFFs involving product emanating from the same establishments (e.g. 17 clopidol notifications from one poultry establishment and 12 from another and 21 ivermectin notifications from one beef establishment). An internal MAPA risk assessment paper had been elaborated to consider the case of repeated RASFF notifications involving ivermectin in beef originating from a single establishment.

Conclusions on follow-up investigations/actions

There is a comprehensive system in place for the prompt follow-up of residue violations. However, the practice of involving food business operators in the follow-up investigations, often some time before any official action is taken, and limitations in the scope of the investigations carried out and in the measures and/or sanctions which may be imposed, collectively have the potential to compromise the effectiveness of follow-up, particularly in relation to identifying the reasons for illegal use. Consequently the system does not have an effect equivalent to that provided for by (Articles 13, 16-18, 23, 24, 27 and 28 of) Council Directive 96/23/EC.

5.5 Ractopamine-Free Production (RFP) Scheme of pig meat for future potential export to the EU

Legal Requirements

According to Article 11.2 of Council Directive 96/22/EC, the EU Member States shall prohibit the importation of farm or aquaculture animals and meat or products from animals to which substances referred to in, inter alia, Annex II, List B (beta-agonists) have been administered, unless those substances were administered in compliance with the provisions and requirements laid down in Articles 4, 5 and 7 and the withdrawal periods allowed in international recommendations have been observed.

Findings

Following the 2011 FVO audit, a number of measures have been taken by the competent authorities to remedy the weaknesses identified in the operation of the RFP scheme. The most important of these was to require from 2011 onwards, that all feed used in the RFP scheme should come from feed mills which used only materials which are entirely free of ractopamine. A review of the results of the official sampling programme for the RFP scheme carried out by the competent authorities in 2012 showed that there had been a significant reduction in the number of findings of ractopamine following the change to dedicated ractopamine-free feed production. The draft results of a second review carried out in 2013 generally supported these findings as no ractopamine was detected in 86% of samples from pigs receiving feed from dedicated ractopamine-free producers and only 1% of the samples contained levels above 1µg/L. For comparison, the review found that 24% of samples taken from pigs receiving feed from non-dedicated producers which do not use ractopamine, were found to contain levels above 1.0µg/L whereas all samples of urine from pigs receiving feed from feed producers using ractopamine contained levels above 1µg/l – with a median concentration of 114.5µg/L. On the basis of these results, the competent authority considered that it should be possible to identify any deliberate use of ractopamine as a growth promoter if the
manufacturers’ instructions for use have been followed. However, the competent authority did not know how rapidly the levels of ractopamine in urine would decline to levels below 1µg/L if feed containing this additive were withheld for longer periods before slaughter.

Since the 2011 FVO audit, a number of changes have been made to strengthen the requirements for food business operators participating in the RFP scheme. Most notably, these include a more in-depth verification that farms in the RFP scheme fulfil the relevant requirements set down in the relevant CIDASC Service Instruction described below. The audit team noted that:

- Currently, there are two integrated companies in the RFP scheme, each with a feed mill and slaughterhouse and with nine farms (five piglet producers and four weaning to finish farms) in one and six (one piglet producer and five finishing farms) in the other. The total capacity of the farms is approximately 27,000 animals. One of the farms is currently suspended from the scheme owing to the detection of ractopamine in pigs (1.47µg/L) in 2013.

- In Brazil, seven formulations of the beta-agonist ractopamine from five manufacturers / importers are authorised to be used as additives in pig feed. According to the competent authority, these additives may only be supplied directly to feed mills and data regarding the import and sales are collected on an on-going basis, although these are not currently analysed. Documentation seen by the audit team showed that it would be possible to trace batches of ractopamine to the first purchaser if necessary and, as such, this addresses recommendation No. 10 of the 2011 FVO audit report.

- Since 2012, the official sampling as a means to verify compliance with the requirements of the RFP scheme has been restricted to collecting urine from such animals at slaughter. Food business operators have been required to include on-farm sampling of pig urine in their own-check programmes since November 2012. Similarly, in the absence of official sampling of feed to check for ractopamine, producers of feed for the RFP scheme are also required to carry out own-check analysis of their feed to confirm the absence of ractopamine. Non-compliant results in the own-check programmes are required to be notified to the competent authorities. However, it was noted that one of the integrated companies in which all but one of the confirmed findings of ractopamine originated in 2013, had validated a testing programme for analysing samples of pig urine but it had not yet initiated routine testing as required. It had also not notified the competent authorities of non-compliant sample results for heavy metals and veterinary medicines detected in its own-check sample programmes in its slaughterhouse, as required. The competent authority was not aware of the scope of own-check testing carried out by the other integrated company in the RFP scheme.

- Although ractopamine was not detected in the 17 official samples taken under the 2012 PNCRC, in 2013 to date, there have been confirmed findings of ractopamine in 13% of samples (seven out of 54 samples, excluding an additional 13 confirmed findings in samples which were subsequently identified as being taken from pigs from farms which are not part of the RFP scheme). Follow-up investigations have been carried out but, no reason for the contamination has been identified (see section 5.4.). As such, recommendation No. 6 of the 2011 FVO audit report has not been addressed.

**5.5.1 Feed production**

Findings
According to the competent authority, only those feed mills that can demonstrate they only produce feed using materials which are shown to be ractopamine-free may be authorised by MAPA to participate in the RFP scheme. Only those feed mills in the RFP scheme may supply feed to farms in the scheme and operators must be able to demonstrate, through documentation, that this requirement is respected. The audit team noted that:

- Both feed mills visited had been subject to regular official controls carried out by SEFIP based on a comprehensive checklist which include specific checks to identify any use of products containing ractopamine and to verify that the operator’s own-check programmes are implemented as required. Reports of the inspections were available and actions had been required to address any shortcomings identified.

- According to the operators of both feed mills visited, only ractopamine-free feed had been produced in these establishments since 2011 and each had dedicated transport for deliveries to farms in the RFP scheme.

- A detailed analysis of the risks that raw materials might be contaminated with ractopamine had been carried out by one of the feed mills visited. This was supported by an own-check sampling plan, the results of which had highlighted the relatively high risk of contamination of a number of materials used in feed, most notably meat meal derived from pigs. In one case, ractopamine was found in a product which was not used routinely. The manufacturer had been notified and measures taken to eliminate the source of this contamination. Suppliers of materials used in feed production had been asked to state that ractopamine was not used in their products and the robustness of these statements was verified by routine own-check sampling.

- According to the operator of the second feed mill visited, following detections of ractopamine in official samples in 2011/12, steps had been taken to identify possible sources of contamination and the use of pig meat meal in feed was stopped in 2012. In addition, suppliers of pre-mixes and other ingredients had been required to provide statements confirming that they did not use ractopamine in their manufacturing process, or that adequate measures were in place to prevent cross-contamination of ractopamine-free products. A programme to regularly check batches of feed for the presence of ractopamine at the point of loading for dispatch to farms was in place.

- All except one of the official samples in which ractopamine had been identified in animals from the RFP scheme to date in 2013 (see above) had come from pigs on farms supplied by the second feed mill visited. Follow-up investigations had so far not identified the potential sources of contamination and, in its action plan, the operator proposed to test all batches of feed for the presence of ractopamine at the point of loading for dispatch to the farms. However, limitations in the scope of these investigations meant that other sources of contamination had not been considered and could not necessarily be prevented by increasing the frequency of own-checks as proposed (see section 5.4.).

- The standard operating procedures (SOPs) for the own-check analyses were examined in the second feed mill visited. Two test methods were described for animal feed: one using a lateral flow device had a limit of detection (LOD) of 0.5 g/kg. The second method was based on an enzyme-linked immuno-sorbent assay (ELISA) method which had an (LOD) of 2µg/kg. An SOP for the analyses of ractopamine in muscle and liver was presented, based on the use of a different ELISA method, which had an LOD of 0.25µg/kg. The SOP for
ractopamine in urine gave an LOD 0.6µg/L with sample extraction and 1.5µg/L when no extraction was performed. No in-house validation files were presented for these methods.

5.5.2 Farms

Findings

The requirements which farms wishing to participate in the RFP scheme shall comply with, and the system of official controls to ensure that these are fulfilled are set down in, a CIDASC Service Instruction, the fourth version of which was published in January 2013. A comprehensive Official Verification Manual includes, inter alia, check-lists to be used for these official controls and details of the measures/sanctions to be taken in case of non-conformities.

In order to be eligible to join the RFP scheme, farms must apply for an alpha-numeric identification code, which forms the basis for the traceability of animals (which must be identified with ear tags or tattoos or other approved methods) throughout the segregated production chain. The farmers are required to maintain up-to-date animal balance control data (incoming, births, deaths and outgoing animals) and to ensure that this information matches that in the CIDASC official system and to keep copies of the GTAs for a minimum period of three years.

The integrated company to which the farm belongs is, inter alia, responsible for providing farmers with a manual of procedures explaining the steps to taken if animals are sick, including the identification or segregation of animals receiving individual treatments, instructions on the completion of records concerning use of veterinary medicinal products and vaccines and checks to be carried out when receiving inputs or animals on to the farm. The Service Instruction stipulates that, as a pre-requisite of participating in the RFP scheme, records of the use of veterinary medicinal products and data concerning movements of animals into and off the farm and mortality (animal balance control data) must remain permanently on the farm and be made available whenever requested by the competent authority.

Before being permitted to participate in the RFP scheme, an official inspection is carried out on the farm to verify compliance with the relevant requirements set down in the Service Instruction. Once farms have been accepted into the RFP scheme, they are subject to official controls at least once a year for issues relevant to the scope of this audit or once in each production cycle for certain maintenance issues, to check that the relevant requirements continue to be fulfilled. Farmers must provide an action plan to address deficiencies identified during these controls and failure to do so may lead to the farm being suspended from the RFP scheme. The audit team noted that:

- According to information provided by CIDASC, all farms participating in the RFP scheme have been assigned unique alpha-numeric codes. Evidence was seen that these numbers were used as required to provide traceability of animals through the chain. All animals seen by the audit team on the farms visited were identified using coded ear tags, as required by the Service Instruction. One of the integrated farms visited used red tags to clearly distinguish re-tagged animals from those with the original (cream coloured) tags. According to CIDASC, on farm controls include cross-checks to verify the farmers' statements regarding the use of replacement tags.

- On the farms visited by the audit team, records were available for the delivery of feed. Examples seen included a declaration that the feed was ractopamine-free and that the feed had been produced in one of the two feed mills in the RFP scheme. In addition, the use of
veterinary medicinal products had been recorded, as required, and prescriptions were available concerning the incorporation of medicines into feed.

- The farms visited by the audit team had been checked by CIDASC during February 2013 and deficiencies concerning the use of veterinary medicinal products had been noted in the inspection reports. On one farm, the treatment records were not present as required (it was stated that these had accompanied the pigs to the slaughterhouse) and deficiencies were noted concerning some prescriptions for medicated feed in which it was stated that amoxicillin and ivermectin should be used but the feed actually contained florfenicol. Records for the use of veterinary medicinal products were on the farm when visited by the audit team. Representatives of the integrated company concerned stated that the animals had received the correct medication and that the feed mill had been instructed to check more carefully the prescriptions and the feed formulations accompanying the dispatch invoices.

- On the second farm visited, the CIDASC inspection identified that, inter alia, veterinary medicinal product treatments had not been recorded on the farm since 29 December 2012 and no records of veterinary prescriptions for mass medication or records of animal feed purchases or deliveries were present on the farm at the time of the inspection. This farm was suspended from the RFP scheme when no action plan to address the identified deficiencies was received by CIDASC within the requested deadline. Once the action plan had been received and assessed as being satisfactory the suspension was lifted, but without any official verification on the farm that the identified deficiencies had been corrected.

- CIDASC found no pigs at the time of inspection of one of the farms visited whereas there should have been 300 present according to their database. Apparently, the discrepancy was due to the farmer not routinely notifying mortality figures to CIDASC. Corrective measures had been taken to address this issue. Animal balance data were provided to the audit team in this farm, in which all movements of animals onto or off the farm were noted.

5.5.3 Slaughterhouses

Findings

The audit team noted that:

- The establishment visited by the audit team was slaughtering pigs based on draft procedures intended to ensure the segregation of RFP scheme animals throughout the entire process. In order to be eligible to be slaughtered under the terms of the RFP scheme, all pigs must be identified by an ear tag or tattoo and the details must be entered in the GTA accompanying the animals to slaughter. According to CIDASC, any pigs arriving with replacement ear tags must be segregated and would not be eligible for slaughter for the EU market.

- As part of the demonstration slaughter seen by the audit team, the food business operator checked and recorded the number of each ear tag after stunning. At the bleeding stage, the carcasses were identified using slap-marks which enabled the split carcasses of RFP scheme animals to be identified during storage and subsequent processing. Any animals without an ear tag were slap-marked with an 'X' to indicate that the animal could not be considered as being from the RFP scheme and measures were in place to ensure the carcass was segregated from the others during storage and processing. Official veterinarians were responsible for verifying that the procedures in place had been followed correctly.
• An exercise to trace and potentially recall pig meat dispatched by the slaughterhouse visited was carried out in February 2013 following the detection of ractopamine in pigs from the RFP scheme. A report of the exercise was provided showing that it was possible to link the batch number of dispatched products to the day of slaughter, as required by national law. According to the food business operator, this system could be refined further by the allocation of a specific letter to each farm eligible to export animals to the EU.

Conclusions on Ractopamine Free Production Scheme of pig meat for future potential export to the EU

Since the 2011 FVO audit, the procedures for the operation of the RFP scheme and their implementation have been strengthened and many of the elements which could theoretically enable the split-system to function satisfactorily are now in place. Although there has been a decline in the number of detections of ractopamine in the official sampling programme since these changes were made, the fact that 13% of samples taken from pigs from the RFP scheme at slaughter in 2013 were found to contain this substance and no cause for the contamination has been identified, indicates that the system in place is not yet sufficiently robust to guarantee that products from such pigs are derived only from animals which have not received ractopamine at any time during their life, as required by Article 11.2 of Directive 96/22/EC.

5.6 LABORATORIES

Legal Requirements


5.6.1 General description

Findings

The system in place for the co-ordination and supervision of the laboratory network involved in analysing samples for the PNCRC is largely as described in the 2011 FVO audit report. CGAL has a legal mandate to co-ordinate the National Agricultural Laboratory Network which currently consists of six official MAPA (LANAGRO) laboratories and 11 private laboratories which have been approved to carry out analysis for the PNCRC. The analytical capabilities for each laboratory are available on the MAPA website and this information is used as the basis for selecting which of the laboratories to contract to analyse samples for the PNCRC. This task is currently being undertaken by 11 of the 17 approved laboratories (five LANAGRO and six private). The LANAGRO laboratories fulfil some of the functions of a reference laboratory and, in addition to analysing samples, are responsible for method development and validation, dissemination of
knowledge, provision of training and for undertaking research.

Prior to being used for the PNCRC, methods need to be approved by CGAL, based on a positive evaluation of the SOPs and the validation dossiers. Normative Instruction No. 1 of 2007 requires that the laboratories be accredited to ISO 17025. The CGAL service for auditing and authorisation audits the laboratories annually.

MAPA also specifies that approved laboratories must validate methods according to a MAPA protocol, participate in regular proficiency testing, have a manual of procedures, and follow MAPA reporting instructions. A harmonised quality manual (Manual Garantia Analítica) which describes all procedures regarding, inter alia, sample reception, validation, quality control and calculations has been put in place. The audit team noted that:

- All approved laboratories in the network are accredited to ISO17025 by the Brazilian Accreditation Body - INMETRO (Instituto Nacional de Metrologia, Normalização e Qualidade Industrial).

- Since the 2011 FVO audit, considerable progress has been made in developing and validating new analytical methods for a range of analyte-matrix combinations and there is a plan in place for further developments in the next few years.

- According to data provided by CGAL, all laboratories analysing samples for the PNCRC have participated in a range of relevant proficiency tests during the last three years with largely satisfactory results (z-scores). Where the z-scores were unsatisfactory, investigations were carried out to identify and correct the cause.

- A project (573408/20084 CTAGRO – residues and contaminants in food) to supply guidance, equipment, facilities and supplies was extended until the end of 2012. A study plan has also been developed for a project to prepare reference materials of urine containing ractopamine. However, at the time of this audit, reference materials for urine and muscle were not available.

- MAPA provided the SOP for an analytical method using LC-MS/MS to detect ractopamine in pig muscle (MET/LRM/PL/026 v1 dated 16 April 2013) which has been developed by the LANAGRO in Pedro Leopoldo, which could potentially be used for the PNCRC in future. The CCα value for pig muscle was 0.11µg/kg while the CCβ was 0.12µg/kg. It was noted that the fragment ions for confirmation are not very specific (loss of water) and no validation file was provided.

5.6.2 On-the-spot visits to the laboratories

5.6.2.1 LANAGRO-SP in Campiñas, State of São Paulo

Findings

The laboratory in Campiñas was visited during all FVO residue audits since 2003. It was visited during this audit as it is, inter alia, responsible for analysing Group A5 substances including ractopamine in samples of urine taken from pigs in the RFP scheme. In addition, in 2012 and 2013 the laboratory was responsible for analysing: Group A1 and A4 (diethylstilbestrol and zeranol) in bovine liver; Group A2 (thiouracil, methylthiouracil, propylthiouracil and tapazol) in porcine urine;
Group A6 chloramphenicol in honey, nitrofurans in pig, equine and poultry muscle; Group B3a (organochlorine pesticides including PCBs) in fat from cattle, equine, pigs and poultry; Group B3c (arsenic, cadmium, lead and mercury) in muscle and kidney from cattle, poultry, pigs, equine and fish. The audit team noted that:

- The laboratory is accredited to ISO 17025 and most of the analytical methods are included in the scope of accreditation. According to an overview of the methods provided by MAPA, the analytical method for ractopamine in pig urine was in place as from 21 June 2012 and has been accredited. There have been several extensions to the scope of accreditation, in 2011 and most recently on 19 March 2013. Validated analytical methods are available for Groups A1, A2 and A4 although these are not yet included in the scope of accreditation.

- Five administrative non-conformities were found during an audit of the laboratory carried out by SAC/CGAL on 20-21 September 2012. An action plan to remedy these was provided and finalised on 14th February 2013.

- The laboratory participated in seven proficiency tests during 2011, four in 2012 and a further two during 2013 to date. These included two for beta-agonists in urine. Although the results (z-scores) of the proficiency tests were satisfactory in 2011, three false positive results were generated for clenbuterol (twice) and for salbutamol in one of the proficiency tests in 2012. An investigation was carried out which identified the source of contamination in reconstituted samples. Staff were briefed on measures to avoid contamination in future and analysis of new samples showed no contamination was present. According to the laboratory, there was a minimal risk that PNCRC samples would have been affected by this source of contamination as these are not reconstituted.

- The analytical methods for ractopamine in pig urine (MET RDV/004/005 dated 9 September 2011) was examined by the audit team. The method uses deconjugation and ractopamine-d3 is used as the internal standard. Appropriate quality control samples are implemented in the method and quality control charts for quality assurance samples were present and showed the method performed well. However, it was noted that the fragment ions chosen for confirmation could be more selective (one fragment is a loss of H₂O). The method was validated according to the MAPA procedure (Annex II to Normative Instruction No 24 of 2009). The validation file was comprehensive and showed that the CCα value for porcine urine was 0.17µg/kg while the CCβ was 0.24µg/kg.

- In March 2013, the laboratory provided training to three private laboratories in the laboratory network to disseminate the above method.

- The laboratory is currently validating a method for ractopamine in pig muscle but this has not yet been completed.

- The method for analysis of chloramphenicol in honey was also examined by the audit team. The MAPA procedure for method validation had been followed and the CCα calculated to be 0.06µg/kg while the CCβ was µ0.11µg/kg. Only three samples had been analysed using this method in 2012.

- The harmonised procedures for sample reception were followed in practice and it could be seen that each were assigned a laboratory number which guaranteed the source of the samples were not known to the staff performing analyses. Records were available of
samples which were rejected which included a number which had arrived outside the deadlines for sample submission specified in the sampling schedules.

5.6.2.2 SLAV-LANAGRO-RS in Florianopolis, State of Santa Catarina

Findings

The SLAV is an advanced laboratory of LANAGRO RS. The laboratory is not involved in analyses for the PNCRC but was visited as, according to CGAL, it is in the process of developing an analytical method to detect ractopamine in feed using LC-MS/MS. It is expected that the method will be used for the testing of official feed samples by the end of 2013. The audit team noted that:

- Suitable analytical equipment and technical staff have recently been moved to the laboratory.
- A comprehensive study plan (POP ALA/SLAV/13/01) was available for the development and validation of the LC-MS/MS method for ractopamine in feed.
- The draft method (MET ALA/SLAV/09/01) uses clenbuterol-d9 as an internal standard. For accurate quantification a deuterated analogue internal standard is preferred and it is anticipated that ractopamine-d3 will be acquired in the future. The lower limit of detection to be achieved was set at 12.5µg/kg.

Conclusions on laboratories

There is an effective system in place to ensure that samples for the PNCRC are analysed in laboratories accredited to ISO 17025 and which use validated methods and participate regularly in proficiency tests. As such, the competent authorities can have confidence in the reliability of analytical results produced by the laboratory network.

5.7 VETERINARY MEDICINAL PRODUCTS AND MEDICATED FEEDINGSTUFFS

5.7.1 Authorisation, distribution and use of veterinary medicinal products

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive and must, in particular, meet the requirements of Article 4 and specify the particulars laid down in Article 7 thereof and meet the requirements of Article 11(2) of Directive 96/22/EC.

According to Article 11(2) of Council Directive 96/22/EC, Member States may not import live animals or animal products from third countries which authorise the use of stilbenes or thyrostats in
food producing animals. Member States are also prohibited from importing products of animal origin for human consumption if the animals from which such products have been derived have been treated at any time with either thyrostatic substances, stilbenes, stilbene derivatives, their salts and esters, oestradiol 17β and its ester-like derivatives, and beta-agonists if administered for the purposes of growth promotion.

The relevant provisions in EU law governing the marketing authorisation of veterinary medicinal products are laid down in Articles 5-15, 21-30, 58-62 and 83 of Directive 2001/82/EC and for certain products authorised on an EU-wide basis, in Articles 30-40 of Regulation (EC) No 726/2004. Provisions governing the distribution and use of veterinary medicinal products are laid down in Articles 65-71 of Directive 2001/82/EC. Veterinary medicinal products which are authorised for use in food producing animals may only contain pharmacologically active substances which are listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010. Article 67(aa) of Directive 2001/82/EC requires that veterinary medicinal products for food producing animals are only dispensed to the public under a veterinary prescription unless exempted under the conditions laid down in Article 2 of Commission Directive 2006/130/EC.

In respect of medicated premixes conditions governing their distribution and use are laid down in Articles 2, 8 and 9 of Council Directive 90/167/EEC. Production of medicated feedingstuffs can only take place in establishments which have been authorised for the production of feedingstuffs containing additives in accordance with Articles 9, 10, 11 and 13 of Regulation (EC) No 183/2005 and the production process must satisfy the conditions laid down in Annexes I and II to that Regulation.

Findings

The system for the authorisation, distribution and use of veterinary medicinal products for food producing animals has been described in the 2011 FVO audit report. Since then, Normative Instruction No 10 of 27 April 2001 concerning the use of anabolic steroids in cattle has been revoked by Normative Instruction No 55 of 1 November 2011 prohibiting the import, production, sale and use of natural or artificial substances which act as hormonal anabolic steroids for the purpose of growth and weight gain in cattle. Normative Instruction No 14 of 17 May 2012 also prohibits the import, manufacture and use of spiramycin and erythromycin-containing substances as a performance-enhancing zootechnical feed additive while Act No 1 of 1 November 2012 suspended the import and sale of two performance-enhancing additives based on β-agonists for cattle. MRLs continue to be set in line with Codex Alimentarius guidelines and based on data from marker residue depletion studies.

Normative Instruction No 36 of 7 June 2002 concerning the sale of controlled substances (e.g. anaesthetics, sedatives, hormones) has been replaced by Normative Instruction No 25 of 8 November 2012 which extends the number of controlled substances from 17 to over 130 (grouped, inter alia, as narcotics, psychotropic substances, sedatives and anabolic steroids). By means of Normative Instruction No 13 of 19 April 2013, the date for entry into force of Normative Instruction No 25 of 2012 has been set as 1 January 2014, by which time a computerised system is expected to be implemented for registering veterinary prescriptions for such controlled substances. Normative Instruction No 48 of 28 December 2011 also prohibits the use in beef cattle, kept in confined or semi-confined holdings, of avermectin products having a withdrawal period of more than 28 days. The audit team noted that:

- Manufacturers, wholesalers and retailers of veterinary medicinal products are required to be
licensed by MAPA to carry out these activities. The retailer visited by the audit team had been recently inspected and was duly licensed for the current year, with such licences being renewed annually.

- Lists of authorised veterinary medicinal products are published on the MAPA website, while further details, including accompanying product information, can be consulted via a publicly available website, developed by the Brazilian veterinary pharmaceutical industry in partnership with the central competent authorities.

- All veterinary medicinal products seen by the audit team at the retailer, farms and feed mills visited were labelled in accordance with the relevant national requirements and were within the expiry date.

- As described in the 2011 FVO audit report, treatment records are only required to be kept on certain cattle farms and certain pig farms in the RFP scheme. MAPA advised that current legislation does not establish or provide for supervisory actions concerning the use of veterinary medicinal products on farms. In this respect recommendation No. 7 of the 2011 FVO audit report has not been addressed.

- Records of treatments with veterinary medicinal products were available on the two pig farms visited by the audit team (both farms are within the RFP scheme). Based on the documentation available, withdrawal periods had been properly observed following treatments, whether by mass medication in feed or via individual treatments.

- Food chain information must also accompany pigs in the RFP schemes to slaughter which includes details of any veterinary medicines administered including any single animal treatments, during the entire production cycle, the date(s) of treatment and the withdrawal period. Checks had been carried out to verify this had been done properly.

- As in the 2011 FVO audit report, there are no rules concerning the off-label use of veterinary medicinal products and veterinarians and farmers can legally use products in other species and for different indications from which they are authorised. No guidance concerning such off-label use and the application of any withdrawal periods has been issued and MAPA stated that, in this regard, veterinarians and farmers are responsible for their own actions although official action would be taken if a non-compliant sample result was detected which could result in the veterinarian involved being referred to the Federal Veterinary Professional Regulation Council. In this respect recommendation No. 8 of the 2011 report has been partially addressed.

Conclusions on authorisation, distribution and use of veterinary medicinal products

The system governing the authorisation, distribution and use of veterinary medicinal products has not changed significantly since the 2011 FVO audit. As treatment records are only required to be kept for certain food producing animals (different from the situation in the EU - Article 10 of Directive 96/23/EC), and there is a lack of official guidance regarding permitted 'off-label' use of veterinary medicinal products (again different from the situation in the EU - Article 11 of Directive 2001/82/EC), there is an increased risk that animals sent for slaughter and products derived therefrom may contain residues in excess of MRLs. This potentially undermines the extent to which guarantees provided by the PNCRC regarding the residue status of products of animal origin which could be exported to the EU, may be considered equivalent to those provided for by EU
legislation.

5.7.2 Controls on the distribution and use of veterinary medicinal products

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive and must, in particular, meet the requirements of Article 4 and specify the particulars laid down in Article 7 which provides for legislation on the use of (pharmacologically active) substances listed in Annex I to the Directive and, in particular, provisions on their prohibition or authorisation, distribution and placing on the market and the rules governing their administration. Article 10 of Council Directive 96/23/EC lays down the veterinary medicines record keeping requirements for livestock owners.

The relevant provisions in EU law governing competent authorities' obligations to carry out inspections throughout the distribution chain of veterinary medicinal products in order to verify compliance with the provisions of the EU code relating to veterinary medicinal products (Directive 2001/82/EC) are laid down in Articles 65, 66, 68, 69 of that Directive. With regard to ensuring that the production of medicated feedingstuffs is in accordance with Council Directive 90/167/EEC, the rules governing control functions by the competent authorities are laid down in Articles 4, 9 and 13 of said Directive.

Findings

The system of controls in place on the distribution and use of veterinary medicinal products is as described in the 2011 FVO audit report. The audit team noted that:

• The competent authority provided details of controls performed during 2012 on the distribution and use of veterinary medicinal products. Similar to the situation described in the 2011 FVO audit report, these controls were performed in feed mills, veterinary medicinal product wholesalers and pharmacies but not on farms or in veterinary practices. In this respect recommendation No. 9 of the 2011 FVO audit report has not been addressed. The audit team was informed that veterinarians do not sell veterinary medicinal products directly to farmers but rather only purchase those products used in the course of their own work.

• In 2012, only 723 out of a planned total of 2,002 inspections of feed mills were carried out due to budgetary limitations. Following these inspections, a total of 248 notices of infraction were issued, which the competent authority stated often related to deficiencies in labelling and analytical guarantees concerning the products.

• During the same period, it was planned to carry out 3,865 inspections of veterinary medicinal product wholesalers and pharmacies, and a total of 4,303 inspections were actually carried out, with 1,240 notices of infraction being issued. According to the competent authority, the most commonly detected non-compliances included unregistered or expired veterinary medicinal products being sold, products not being kept refrigerated when required and retailers operating without a valid licence.

• In the state visited, the audit team saw that inspectors received regular notifications from the
central competent authority concerning unauthorised products to be seized and that these notifications were followed up during official inspections.

- In the veterinary medicinal product retailer visited, prescriptions were received for the sale of products containing controlled active substances (anaesthetics, sedatives etc.). Retailers also submitted regular quarterly reports to the state authorities with data concerning the sale of such controlled products.

- The operators of the feed mills visited had put in place procedures to verify the effectiveness of the mixing operations when incorporating veterinary medicinal products in feed and in order to verify that measures to reduce carry over between batches were effective. Documentary evidence was provided showing that these checks were carried out on a regular basis. The implementation of these procedures was checked during official controls carried out by SEFIP.

- One company participating in the RFP scheme had prepared a list of active substances that could be used on their farms, provided that authorised products were available and that the products were used so as to guarantee that any residue levels were within permitted limits.

Conclusions on official controls on the distribution and use of veterinary medicinal products

Whilst inspections are carried out regularly at veterinary medicinal product wholesalers, retailers and feed mills (including those producing medicated feed), the continuing absence of official controls concerning the use of veterinary medicinal products on farms and by veterinary practices has the potential to weaken guarantees offered by the PNCRC concerning the residues status and usage of veterinary medicinal products in commodities which may be exported to the EU.

5.8 FOLLOW-UP OF RELEVANT RECOMMENDATIONS MADE IN PREVIOUS FVO REPORT ON RESIDUES (DG SANCO 2011-8862 MR FINAL)

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<thead>
<tr>
<th>No</th>
<th>Recommendation</th>
<th>Findings</th>
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<tr>
<td>1.</td>
<td>Ensure that all relevant data are considered for planning of the residue monitoring plan, taking into account the requirements as laid down in Article 7 of Council Directive 96/23/EC and that the scope of testing under the PNCRC is broadened, in particular for anabolic steroids, non-steroidal anti-inflammatory drugs and other veterinary medicinal products which are frequently used in animal production.</td>
<td>This recommendation has been addressed satisfactorily (see section 5.2.).</td>
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<td>2.</td>
<td>Ensure that food business operators are not informed in advance of the scope of testing under the residue monitoring plan (i.e. by not publishing the details of the scope of testing) in order to ensure that the element of surprise in the checks is constantly maintained, in accordance with the requirements of Annex III to Council Directive 96/23/EC.</td>
<td>This recommendation cannot be addressed due to legal reasons. (see section 5.2.).</td>
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3. Ensure that the transport of official samples is carried out under appropriate conditions as laid down in Point 1.1. of the Annex to Commission Decision 98/179/EC (i.e. transport not organised by the food business operator) in order that all such samples arrive at the laboratory and, insofar as it is possible, arrive in appropriate condition for analysis.  
   This recommendation has been addressed satisfactorily (see section 5.3.).

4. Ensure that the follow-up of non-compliant results has an effect equivalent to those provided for by (Articles 13, 16-18, 23, 24, 27 and 28 of) Council Directive 96/23/EC i.e. that adequate measures are taken to prevent re-occurrence of residue violations.  
   This recommendation has not been satisfactorily addressed (see section 5.4. and recommendation no. 1 of this report).

5. Ensure that follow-up investigations are carried out without prior notice being given to farmers as laid down in Article 12 of Council Directive 96/23/EC.  
   This recommendation has not been satisfactorily addressed (see section 5.4. and recommendation no. 2 of this report).

6. Ensure that the system in place to guarantee that pigs have never received beta agonists for growth promotion purposes is capable of and actually achieves this objective in order to provide guarantees equivalent to the requirements of Article 11(2)(a)(ii) of Council Directive 96/22/EC.  
   This recommendation has been partially addressed (see section 5.5. and recommendation no. 3 of this report).

7. Ensure that medicines records are kept for all animal species from which products are exported to the EU, with an equivalent effect to the requirements laid down in Article 10 of Council Directive 96/23/EC.  
   This recommendation has not been addressed (see section 5.7.1. and recommendation no. 4 of this report).

8. Given that off-label use of veterinary medicinal products can and does occur in Brazil, ensure that sufficiently long withdrawal periods are put in place in such cases, in order to ensure that food of animal origin exported to the EU does not contain residues at concentrations in excess of EU MRLs (where applicable).  
   This recommendation has not been satisfactorily addressed (see section 5.7.1. and recommendation no. 6 of this report).

9. Ensure that controls on the distribution and use of veterinary medicinal products are carried out throughout the distribution chain – including farms - in order to support guarantees offered by the residue monitoring plan thus providing guarantees at least equivalent to those foreseen in Council Directive 96/23/EC.  
   This recommendation has not been addressed (see section 5.7.2. and recommendation no. 5 of this report).

10. Consider strategies to tighten controls on the distribution of ractopamine in order to ensure that (illegal) use of this substance does not occur in species other than pigs, thus...  
    This recommendation has been addressed (see section 5.5.).
minimising the possibility of animal products being exported to the EU which do not comply with the provisions of Article 11 of Council Directive 96/22/EC.

6 **OVERALL CONCLUSIONS**

It is concluded that the PNCRC is generally designed and implemented in line with Directive 96/23/EC. The system in place to ensure that samples are analysed in ISO 17025 accredited laboratories using only validated methods is effective and the competent authorities can have confidence in the reliability of analytical results produced by the laboratory network. The on-going development of analytical methods has increased the scope of testing for a range of substances compared with that described in the 2011 FVO audit report and the availability of additional methods during 2013 is expected to ensure that the PNCRC better reflects the usage patterns of veterinary medicinal products in Brazil and include all of the compulsory substance groups for the relevant commodities which are specified in Council Directive 96/23/EC.

With regard to the follow-up of non-compliant results, there is a comprehensive system in place for the prompt follow-up of residue violations. However, the policy of involving food business operators in the follow-up investigations, often some time before any official action is taken, combined with limitations in the scope of the investigations carried out and in the measures and/or sanctions which may be imposed, has the potential to compromise the effectiveness of follow-up and the ability of the competent authority to identify the reasons for illegal use of substances. In this respect the system for follow-up is not equivalent to the requirements of Council Directive 96/23/EC (Articles 13, 16-18, 23, 24, 27 and 28).

The system governing the authorisation, distribution and use of veterinary medicinal products has not changed significantly since the 2011 FVO audit. The fact that veterinary medicinal product treatment records are only required to be kept for certain species of food producing animals and that, in contrast to the EU, there is no official guidance on minimum withdrawal periods to be observed following 'off-label' use of veterinary medicinal products, there is an increased risk that animals sent for slaughter and products derived therefrom, will contain residues at concentrations in excess of MRLs. With regard to controls on the use of veterinary medicinal products, whilst inspections are carried out regularly at veterinary medicinal product wholesalers, retailers and feed mills (including those producing medicated feed), the continuing absence of official controls concerning the use of veterinary medicinal products on farms and by veterinary practices has the potential to weaken guarantees offered by the PNCRC concerning the residues status in commodities which may be exported to the EU.

Since the 2011 FVO audit, the procedures for the operation of the RFP scheme and their implementation have been strengthened and many of the elements which could theoretically enable the split-system to function satisfactorily are now in place. Although there has been a decline in the number of detections of ractopamine in the official sampling programme since these changes were made, the fact that 13% of samples taken from pigs from the RFP scheme at slaughter in 2013 were found to contain this substance and no cause for the contamination has been identified, indicates that the system in place is not yet sufficiently robust to guarantee that products from such pigs are derived only from animals which have not received ractopamine at any time during their life, as required by Article 11.2 of Directive 96/22/EC.
7 Closing Meeting

A closing meeting was held on 31 May 2013 with representatives of the central competent authority. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The competent authorities expressed disagreement with the preliminary conclusions presented concerning the RFP scheme.

8 Recommendations

The competent authorities are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below, within twenty five working days of receipt of this audit report.

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<td>1.</td>
<td>Ensure that the follow-up of non-compliant results has an effect equivalent to those provided for by (Articles 13, 16-18, 23, 24, 27 and 28) of Council Directive 96/23/EC.</td>
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<td>2.</td>
<td>Ensure that farmers are not made aware of non-conformities before the official follow-up investigations are carried out as required by Article 12 of Council Directive 96/23/EC.</td>
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<td>3.</td>
<td>Ensure that the system in place to guarantee that pigs have never received beta-agonists for growth promotion purposes is capable of and actually achieves this objective in order to satisfy the requirements of Article 11(2)(a)(ii) of Council Directive 96/22/EC.</td>
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<td>4.</td>
<td>Ensure that medicines records are kept for all animal species from which products are exported to the EU, with an equivalent effect to the requirements laid down in Article 10 of Council Directive 96/23/EC.</td>
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<td>5.</td>
<td>Ensure that controls on the distribution and use of veterinary medicinal products are carried out throughout the distribution chain – including farms - in order to support guarantees offered by the residue monitoring plan thus providing guarantees at least equivalent to those foreseen in Council Directive 96/23/EC.</td>
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<td>6.</td>
<td>Given that off-label use of veterinary medicinal products can and does occur in Brazil, ensure that sufficiently long withdrawal periods are put in place in such cases, in order to ensure that food of animal origin exported to the EU does not contain residues at concentrations in excess of EU MRLs (where applicable).</td>
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The competent authority's response to the recommendations can be found at:

## Annex 1 - Legal References

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<td><strong>Monitoring and sampling of residues in food of animal origin</strong></td>
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<td><strong>Approval of residue monitoring plans submitted by third countries</strong></td>
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<td><strong>Validation of analytical methods for residues and Minimum Required Performance Limits</strong></td>
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<td><strong>Bans on the use of hormones and beta-agonists for growth promotion in food producing animals</strong></td>
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<td><strong>Maximum Residue Limits for veterinary medicinal products in food of animal origin</strong></td>
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**maximum Residue Levels for pesticide residues in food of animal origin**

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**Maximum Levels for contaminants in food**

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**Authorisation of veterinary medicinal products**

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**Medicated feedingstuffs and additives**

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**Sampling methods and methods of analysis for contaminants in foodstuffs**

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