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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

MEXICO

FROM 08 TO 17 NOVEMBER 2011

IN ORDER TO EVALUATE THE MONITORING 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 Mexico, carried out between 8 to 17 November 2011, 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 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. The audit assessed the performance of the competent authorities and other officially authorised entities involved in residues and veterinary medicinal product controls and the legal and administrative measures put in place to give effect to the relevant EU requirements.

It is concluded that the residues monitoring plan (RMP) is generally designed in line with Council Directive 96/23/EC and some improvements have been made since the last FVO mission in 2008, however its effectiveness is undermined by an overall limited scope of testing and an inadequate sampling frequency for eggs. Sampling under the RMP has been generally carried out as planned, however the inadequate sealing and safeguarding of samples has the potential to negate their legal validity. Whilst follow-up actions in case of detection of residues are triggered, also in cases where substances without national permissible limits are found, the procedures differ significantly from the approach taken in the EU and are in general not effective in revealing the causes for residue violations and in preventing their recurrence.
Notwithstanding the progress made in the performance of the laboratory relative to the 2008 FVO mission, the shortcomings in the validation of analytical methods undermine the effectiveness of the residue monitoring plan.
Whilst an adequately designed prescription system for veterinary medicinal products has been put in place, the shortcomings concerning treatment records, MRLs and setting of withdrawal periods have the potential to weaken guarantees on the residues status of food of animal origin exported to the EU. Furthermore, weak official controls on the distribution and use of veterinary medicinal products undermine confidence in the effectiveness of the residue control system. With regard to the competent authority assurances, given in 2009 under the 'horse action plan' on identification, traceability and keeping of treatment records for equine animals, some improvements have been noted relative to the situation described in the report of 2010 FVO mission on horse meat production, but overall there have been no significant changes to this situation. The key components of the 'horse action plan' have not all been implemented and, as a result, the guarantees given on horse meat exports to the EU are insufficient to guarantee that equivalent standards to those provided for by EU legislation are applied.
Overall, in respect to commodities currently exported to the EU, the audit identified several shortcomings in the application of residues and veterinary medicines controls. Several of them were present also at the time of previous FVO residue missions in 2008 and 2005, and most of the recommendations from the report of the 2008 FVO residue mission have not been adequately addressed - despite the commitments made by the competent authority in the action plan provided in response to these recommendations. In particular, hormones are still authorised for growth promotion in horses.

The report makes a number of recommendations to the Mexican competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.

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Abbreviations and definitions used in this report

Abbreviation	Explanation
AOZ and AMOZ, AHD and SEM	Marker residues of the nitrofuran drugs furazolidone, furaltadone, nitrofurantoin and nitrofurazone respectively
CCα / CCβ	Decision Limit / Detection Capability
CENAPA	*Centro Nacional de Servicios de Constatación de Salud Animal* - National Centre for Animal Health Certification Services
COFEPRIS	*Comisión Federal para la Protección contra Riesgos Sanitarios* - Federal Commission for the Protection against Sanitary Risks
DGIAAP	*Dirección General de Inocuidad Agroalimentaria, Acuícola y Pesquera* - Directorate General of Agricultural and Food Safety, Aquaculture and Fisheries
DGSA	*Dirección General de Salud Animal* - Directorate General of Animal Health
DG(SANCO)	Health and Consumers Directorate-General
EC	European Community
EEC	European Economic Community
ELISA	Enzyme-linked immuno-sorbent assay
EMA	*Entidad Mexicana de Acreditación* – Mexican National Accreditation body
EU	European Union
FVO	Food and Veterinary Office
GC	Gas chromatography
GC-MS/MS	Gas Chromatography-(Tandem) Mass Spectrometry
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC:
HMMNI	nitroimidazole metabolite
HPLC	High Performance Liquid Chromatography
ISO	International Organisation for Standardisation
LC-MS	Liquid Chromatography-Mass Spectrometry

LC-MS/MS	Liquid Chromatography-(Tandem) Mass Spectrometry
ML	Maximum Level
MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
NOM	*Norma Oficiale Mexicana* - Mexican Official Standard
PROTLCUEM	*Proyecto de Facilitación del Tratado de Libre Comercio entre México y la Unión Europea* - Co-financed project for the facilitation of free trade between Mexico and the EU
RASFF	Rapid Alert System for Food and Feed
RMP	Residue Monitoring Plan
SAGARPA	*Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación* - Agriculture, Livestock, Rural Development, Fisheries and Food Secretariat
SENASICA	*Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria* - National Service for Health, Food Safety and Food Quality
SINIIGA	*Sistema Nacional de Identificación Individual del Ganado* - National System for Individual Identification of Livestock
SOP	Standard Operating Procedure
TIF	*Tipo Inspección Federal* – Federal Inspection Type (of establishment)
US	United States of America
USDA	US Department of Agriculture

1 INTRODUCTION

The audit took place in Mexico from 8 to 17 November 2011. The audit team comprised two auditors 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 8 November 2011 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. The audit focussed on the roles of the competent authorities at central and regional levels, the legal and administrative measures in place to give effect to the relevant EU requirements, controls with regard to residues and veterinary medicinal products and their operation, and the performance of residue laboratories. Attention was paid to examining the implementation of corrective actions promised in response to recommendations made in the report of a previous FVO residues audit to Mexico (DG (SANCO)/2008-7772 – MR Final) in February 2008. The table below lists sites visited and meetings held in order to achieve that objective.

In addition, the team focused also on the implementation of the action plan provided by the competent authority in response to the European Commission letter of 17 April 2009 concerning imports of equine meat from third countries.

Meetings/Visits		N	Comments
Competent Authorities	Central	3	Opening, pre-closing and closing meetings at the National Service for Health, Food Safety and Food Quality (*Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria* – SENASICA) of the Agriculture, Livestock, Rural Development, Fisheries and Food Secretariat (*Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación* – SAGARPA)
	Regional	2	Meetings at the SAGARPA State Offices in Aguascalientes and Chihuahua
Laboratories		2	Two visits to the National Centre for Animal Health Certification Services (*Centro Nacional de Servicios de Constatación de Salud Animal* – CENAPA)

Meetings/Visits	N	Comments
Farms	1	Visit to the apiary
Establishments	3	Visits to two equine slaughterhouses and the honey collection centre
Other Sites	3	Visits to two collection centres for horses and the veterinary pharmacy

3 Legal Basis

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

– Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products, and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC;

– Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;

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 Mexico residue monitoring plan is approved in accordance with Council Directive 96/23/EC for equine, aquaculture, eggs and honey.

4.2 Summary of previous FVO audit reports

The residues sector was inspected by the FVO in 2005 (DG(SANCO)/7713/2005 - MR Final) and 2008 (DG(SANCO)/2008-7772 - MR Final). The reports of both missions (henceforth referred to as the 2005 and 2008 FVO missions, respectively) have been published on the website of the Directorate – General for Health and Consumers here: http://ec.europa.eu/food/fvo/ir_search_en.cfm.

Following the 2005 FVO mission, a safeguard measure was put in place (Commission Decision 2006/27/EC) requiring that all consignments of meat and meat products of *equidae* imported from Mexico should undergo official checks, in particular for hormones and beta-agonists used for growth promotion. To date, one RASFF notification has been reported for corticosteroid residues (see Section 5.1.5.).

The 2008 FVO mission report found that a number of shortcomings in the application of residues and veterinary medicines controls, originally identified in the 2005 mission, remained and had not been rectified in line with the competent authority's action plan provided in response to recommendations of the 2005 FVO mission. Hormones and beta-agonists continued to be

authorised for growth promotion in *inter alia* horses and in the absence of a "split system", Mexico did not comply with relevant EU requirements concerning the export of meat from potentially treated animals. There were no follow-up procedures in place to investigate the reasons for residues detected under the national residue monitoring plan (RMP) and no infringement procedures, meaning that no actions were taken to prevent recurrence of the violations. This was exacerbated by weak controls on the use of veterinary medicines and failure to implement the prescription system which has been legally required for several years. The laboratory capability was limited, which restricted the scope of substances included in the RMP to only a small fraction of veterinary medicines authorised for the relevant species. Overall, regarding the commodities for which Mexico was eligible to export to the EU, the competent authority's guarantees on the residue status of honey and eggs could be considered equivalent to the minimum EU requirements while for aquaculture shrimp and equine meat improvements were necessary.

4.3 Rapid Alert System for Food and Feed (RASFF) notification for products of animal origin from Mexico concerning residues

Since the 2008 FVO mission to date, there has been one RASFF notification for cadmium in equine meat (2008), four for streptomycin in honey (two in 2009 and two in 2010) and one for the corticosteroids dexamethasone and triamcinolone acetonide in equine meat (2010), the latter being related to sampling in accordance with Commission Decision 2006/27/EC (see also Section 4.2).

4.4 Production and Trade Information

Mexico exports honey, equine meat, aquaculture (shrimp) and egg products to the EU. Production data for 2010 were supplied by the National Service for Health, Food Safety and Food Quality (*Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria* – SENASICA) and are summarised in the table below.

Product	**National production in 2010** (*preliminary*) **(tonnes)**	**Volume of exports to the EU in 2010 (tonnes)**
Equine meat	15.911,43 *(91.372 heads)*	5.592,13
Aquaculture (shrimp)	114.709	393
Eggs	2.360.301	187 (egg products)
Honey	55.684	18.707

With regard to the number of slaughtering/processing establishments for *equidae*, aquaculture (shrimp), eggs an honey, SENASICA provided the following data:

Product	Total number of slaughtering/processing establishments in Mexico	Number of slaughtering/processing establishments approved for export to the EU
Equine meat	6	4
Aquaculture (shrimp)	55	17
Eggs	4	2
Honey	27	24

5 Findings And Conclusions

5.1 Residue monitoring

5.1.1 Planning of 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 2004/432/EC.

Findings

SENASICA within the Agriculture, Livestock, Rural Development, Fisheries and Food Secretariat (*Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación* – SAGARPA) is the competent authority with responsibility for drafting the RMP. More precisely, this responsibility lies primarily with the two bodies under the SENASICA´s Directorate General of Agricultural and Food Safety, Aquaculture and Fisheries (*Dirección General de Inocuidad Agroalimentaria, Acuícola y Pesquera* – DGIAAP):

- the Head Office of Agro-alimentary Safety, Organic Operation and Pesticides Intended for Agriculture Use - *Dirección de Inocuidad Agroalimentaria, Operación Orgánica y Plaguicidas de Uso Agrícola* (i.e. its Sub-directorate of Monitoring and Surveillance of Contaminants and Residues - *Subdirección de Monitoreo y Vigilancia de Contaminantes y Residuos*, where the national RMP co-ordinator is located) (hereafter referred to as the central RMP office);

- the Head Office of Federal Inspection Type (TIF) Establishments - *Dirección de Establecimientos Tipo Inspección Federal* (i.e. its Sub-directorate of Maintaining Certification of TIF Establishments ´ Facilities, Animals, Processes and Products - *Subdirección de Mantenimiento de la Certificación de Instalaciones, Animales, Procesos y Productos de Establecimientos*) (hereafter referred to as the central TIF office).

Planning of the RMP takes place mainly within the internal working group involving the central RMP and TIF offices and the national reference laboratory for residues, the National Centre for Animal Health Certification Services (*Centro Nacional de Servicios de Constatación de Salud Animal* – CENAPA). In addition to this working group, the Inter-Institutional Committee to Evaluate and Monitor National Programmes for Toxic Residues and Contaminants in Animal Products and By-Products (*Comité Interinstitucional de Evaluación y Seguimiento de los Programas Nacionales de Monitoreo para el Control de Residuos Tóxicos en Productos y Subproductos de Origen Animal*) is involved in the RMP planning process. As described in the 2008 FVO mission report, this committee comprises *inter alia* several experts from the relevant competent authorities (e.g. SENASICA´s Directorate General of Animal Health - *Dirección General de Salud Animal*, DGSA), responsible for *inter alia* the authorisation and control of veterinary medicinal products), and representatives of stakeholders. A representative from the Co-financed project for the facilitation of free trade between Mexico and the EU (*Proyecto de Facilitación del Tratado de Libre Comercio entre México y la Unión Europea* – PROTLCUEM) also participates in the RMP planning.

The RMP is finally adopted at the working group meeting, usually at end of the year (for the following year). The 2011 RMP was adopted in December 2010.

The Federal Law on Animal Health and the Mexican Official Standard (*Norma Oficiale Mexicana* - NOM) 004-ZOO-1994 form the main legal basis for the RMP in Mexico.

The audit team noted that:

- the RMP is, in terms of its layout and the substance groups tested for, generally in line with Council Directive 96/23/EC;

- as in 2005 and 2008, data on usage patterns of veterinary medicinal products are not taken into account, though some data in this respect is available to the competent authority;

- according to the central RMP office, the Inter-Institutional Committee which includes representatives of farmers´/food business operators´ associations and of pharmaceutical industry, is not informed about RMP details such as specific substances to be tested, methods used or regional distribution of sampling. This addresses recommendation no. 5 from the 2008 FVO mission report;

- there was no specific evidence that previous non-compliant results have been taken into account for RMP planning, though there was a general 10%-increase in sample numbers for *equidae*, aquaculture and eggs, and 20 additional honey samples from export establishments were planned in 2011 RMP. In addition, targeted sampling of horses from the supplier which was found responsible for the single RASFF notification (corticosteroids) in 2010 is foreseen (see Section 5.1.5.);

- the sample numbers for commodities intended for export to the EU are generally based on *Codex Alimentarius* guidelines i.e. 350 for *equidae*, 300 for honey and aquaculture respectively, the latter having been increased relative to 2008. In contrast, 30 samples are planned for eggs. Thus recommendation no. 4 from both the 2005 and 2008 FVO mission reports has not been fully addressed;

- some substances have been added to the scope of testing under the RMP since the 2008 FVO mission e.g. three fluoroquinolones and two amphenicols in *equidae* and in aquaculture, and dyes (malachite green and leucomalachite green) in aquaculture. Nevertheless, the overall scope of the RMP remains limited. Residues of a number of substances which are authorised for use in food producing animals are not tested for (several of them were seen also in the pharmacy visited) including the steroids boldenone, methandrostenolone, nandrolone and dexamethasone, the non-steroidal anti-inflammatory drug phenylbutazone, the antimicrobials gentamycin and trimethoprim, and acepromazine and coumaphos in *equidae*;

- three of four steroids included in the RMP for horses (nandrolone, ethynilestradiol and trenbolone) are tested by ELISA screening methods which are not validated and there are no confirmatory methods in place for these substances;

- with regard to the scope of RMP testing, the recommendations nos. 4 and 7 from 2008 FVO mission report have not been fully addressed yet, and the competent authority commitments from 2009 to broaden the scope of testing in *equidae* (in the 'horse action plan' - see Section 5.3.3.) have not been fulfilled;

- a number of discrepancies were noted between the RMP submitted to the Commission services and what was actually being tested. In relation to the substances specified, several of those listed are not currently being tested for e.g. boldenone and phenylbutazone in

equidae, monensin and salinomycin in eggs – which incidentally were reported to the Commission as having been tested for since 2008, when this was not actually the case. According to CENAPA, tests for some of these substances have been only recently been validated and the last few samples in 2011 RMP are either being tested for them (e.g. levamisole in *equidae*), or they are planned be included in the 2012 RMP (e.g. phenylbutazone in *equidae*) (see also Section 5.2.). In contrast, some substances which are not listed in the RMP are actually being tested for e.g. ciprofloxacin and sarafloxacin in *equidae* and in aquaculture, and thiamphenicol in *equidae*;

- in some cases the matrix tested (e.g. muscle) is not the most appropriate for the detection of substances in Groups A1, A3, A4 and A5;

- regarding methods used, some confirmatory methods specified in the RMP do not exist on-the-spot (e.g. "HPLC-MS" for a number of steroids);

- with regard to national MRLs, the NOM-004-ZOO-1994 (from August 1994 and modified in 1996 and 2001) is still in force. The adoption of its amendment was announced in the competent authority's responses to relevant recommendations from both the 2005 and 2008 FVO mission reports and, according to the competent authority, publication is now foreseen for sometime in 2011. Consequently the findings made in this respect in the 2005 and 2008 FVO mission reports are still current. For example, it is still the case that there are no MRLs for all commodities exported to the EU, the number of included substances is limited, there are national MRLs for substances for which no maximum limits have been set in the EU and several national MRLs are higher than those established in the EU;

- NOM-159-SSA1-1996 (published in December 1999) provides MRLs for eggs, however it covers only a limited number of substances (in total 14 antibacterial and antiparasitic substances and three heavy metals) and several of them have no EU MRLs for eggs (e.g. penicillin) or the national MRL is higher than in the EU (tetracycline);

- in the RMP, there are a number of tolerance limits indicated for some (but not all) of the substances which do not have national MRLs. The competent authority stated that these limits are sourced mainly from *Codex Alimentarius* and from legislation of the EU and other main trading partners of Mexico;

- according to the DGIAAP procedures in place (see also Section 5.1.2.), exporting TIF establishments must also comply with MRLs of countries for which they are authorised to export. If results are non-compliant (compared to an EU MRL), the sampled products would be redirected from EU destination or destroyed.

Conclusions on planning of the residue monitoring plan

The residues monitoring plan is generally designed in line with Council Directive 96/23/EC and some improvements in the scope of testing have been made relative to the last FVO mission in 2008. Nevertheless many of the issues identified in the previous mission report remain. The effectiveness of the plan is undermined by a limited scope of testing relative to the range of authorised/used products and an inadequate sampling frequency for eggs in comparison with EU requirements. The discrepancies in the information specified in the plan presented to the Commission services compared to what is actually being tested reduce confidence in the reliability of guarantees on residues provided by the competent authority.

5.1.2 Implementation of the residue monitoring plan

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. Article 4(2)(b) and (c) of Council Directive 96/23/EC lays down the requirements for central competent authorities in co-ordinating the activities of all bodies involved in residues controls. Articles 5 and 12 of Council Directive 96/23/EC deal with aspects pertaining to the implementation of the residue monitoring plan. Sampling requirements are specified in Annex IV to Council Directive 96/23/EC and Commission Decision 97/747/EC and Commission Decision 98/179/EC lays down the rules for official sampling under the residue monitoring plan. EU methods of sampling for the official control a wide range of residues in products of animal origin are laid down in several pieces of EU legislation: Commission Directive 2002/63/EC (pesticides); Commission Regulation (EC) No 1883/2006 (dioxins and dioxin-like PCBs); Commission Regulation (EC) No 333/2007 (certain chemical elements); Commission Regulation (EC) No 401/2006 (mycotoxins).

Findings

SENASICA (at central level) breaks down the RMP to sample numbers for each State, taking into account their production levels. For equine meat and eggs, calendars with sampling dates from January to November are prepared at the central level for each TIF establishment. These calendars are distributed in January to the State TIF supervisors in SAGARPA State Offices which in turn send (monthly) sampling requests to responsible official veterinarians in each establishment. For aquaculture (shrimp), the information on required sample numbers is sent in March/April to Aquaculture Health State Committees which have to submit sampling calendars to the central RMP office. These committees (or the authorised "third specialists") are requested to sample primarily farms supplying the EU-export approved processing establishments; committees receive a list of such farms, kept by the Federal Commission for the Protection against Sanitary Risks (*Comisión Federal para la Protección contra Riesgos Sanitarios* - COFEPRIS) of the Ministry of Health. For honey, the information on required sample numbers is sent in March to the State co-ordinators for the African Bee Control in SAGARPA State Offices, which decide on apiaries and dates for sampling. Selection of sampling sites for aquaculture and honey should take account some factors e.g. shrimp production levels and previously sampled apiaries (to avoid repeated sampling), while sampling dates follow the seasonal nature of these commodities. For honey, harvesting seasons vary between States in relation to geographical location and blooming whilst for aquaculture harvesting season is mainly in autumn and all samples are collected at the (pre-)harvest stage of farming.

All samples are collected by official staff and sent directly to CENAPA laboratory. Samples are analysed there in accordance with a colour-coded scheme (based on the sampling calendar) which attributes sets of parameters to be analysed in each sample, in accordance to the RMP. All laboratory analyses are financed by the SENASICA.

SENASICA (at central level) is responsible for the supervision of RMP implementation. Sampling of meat and eggs is supervised by the central TIF office whilst sampling of aquaculture and honey is supervised by the central RMP office. The Federal co-ordinator for the African Bee Control and the State TIF supervisors are also involved in supervision of sampling for relevant commodities.

According to the DGIAAP procedures in place (see below), residue sampling in TIF establishments should not be announced to food business operators.

The audit team noted that:

- there are DGIAAP manuals of procedures in place, including those for operation/co-ordination of the RMP for meat and eggs, aquaculture shrimp and honey. These procedures contain *inter alia* sampling instructions and forms. In addition, (summarised) instructions for residue sampling in TIF establishments and for honey were distributed by the central level to State officials together with the corresponding sampling calendars/requests. For residue sampling in TIF establishments, also more detailed instructions have been recently issued and according to the central TIF office, they are available to official staff on the intranet;

- evidence of several training events for official staff, organised in recent years specifically for residues sampling or covering *inter alia* this topic, was available to the audit team e.g. training courses on residues in aquaculture shrimp and training on EU requirements for honey (within the PROTLCUEM project). On-line training on national and international regulatory requirements for food safety is available to official staff;

- all sampling is carried out using standardised sampling forms and except for *equidae* (see Section 5.3.3.), samples can be traced to the farm of origin;

- samples are taken in duplicate in TIF establishments – the "primary" sample is sent to the laboratory whilst the "retention" sample is kept by official staff in the establishment as a counter-sample (for repeat/confirmatory analyses);

- insulated boxes are used for sample transport and aquaculture samples which arrived to the laboratory on the day of the audit team's visit were in an appropriate (frozen) condition, however, samples seen on-the-spot were not adequately sealed to prevent tampering. In the slaughterhouse visited this was the case also with transport packaging, and the storage of samples was not adequately safeguarded (samples were kept unlocked in the establishment's freezing facilities). The inadequate packaging of meat samples was noted also during the 2008 FVO mission;

- in the slaughterhouse visited, samples have been generally taken as planned and corresponding monthly reports were available. Officials in this establishment stated that these reports have been regularly sent directly to the central TIF office. Evidence of such reporting on RMP sampling from TIF establishments was available also at the central level;

- CENAPA informs the DGIAAP (central RMP and TIF offices) via e-mail about completed analyses and test reports are available in real time in the SENASICA web database, as well as sent to the DGIAAP by post;

- there was evidence of information exchange between the central RMP office and CENAPA regarding implementation of RMP sampling of honey. In the two States visited, honey samples had already been taken for 2011. However, according to data available at CENAPA, samples have not been received yet from approximately half of the States, accounting for around two thirds of the total number of honey samples planned in the 2011 RMP. The

Federal co-ordinator for the African Bee Control explained that in these States harvesting seasons are still on-going, but also that in one State there is a delay in sending of samples for analyses due to the lack of financial resources;

- the supervision of the RMP implementation for aquaculture is generally done at the end of year, however some e-mail tracking of sample deliveries from States to CENAPA would take place also during the year (one such example from 2011 was provided to the audit team). Aquaculture (shrimp) sampling is carried out in six States and according to data available at CENAPA, approximately 80% of the samples scheduled for 2011 have been received to date.

Conclusions on planning of the residue monitoring plan

There are tools in place for the supervision of RMP implementation and sampling has been generally carried out as planned, taking into account the seasonal nature of some commodities. Whilst instructions and training were in general provided to officials responsible for sampling and samples are kept/transported under appropriate temperature conditions, the inadequate sealing and safeguarding of samples has the potential to negate their legal validity.

5.1.3 Other residues monitoring programmes

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. Article 11 of Council Directive 96/23/EC gives the option of conducting other residues testing, particularly in relation to detection of illegal treatment of food producing animals. Article 9 of Council Directive 96/23/EC foresees the application of own-checks by food business operators.

5.1.3.1 Testing of honey intended for export to the EU

Findings

Residue testing of honey is a prerequisite for issuing of health certificates. The system has been described in the 2005 and 2008 FVO mission reports. Compliant residue results for chloramphenicol, streptomycin, fluvalinate, coumaphos, nitrofurans and sulphonamides were required for each lot before export. No detectable levels of these substances were accepted with the exception of sulphonamides (and coumaphos) where 0.1 mg/kg was tolerated (even though no residues of antimicrobials in honey are acceptable in the EU).

The audit team noted that:

- since May 2008, following RMP results and comments made in the 2008 FVO mission report, SENASICA has requested that for issuing of health certificates for export to the EU, exporters have to test honey for sulphonamides, tetracyclines, nitrofurans, streptomycin, chloramphenicol and coumaphos and results have to be compliant with Council Regulation (EEC) No 2377/90 (now superseded by Commission Regulation (EU) 37/2010). Since May 2010, these samples have to be taken in the exporter's establishment by (or under supervision of) officials from the SAGARPA Office in the State where establishment is located;

- official staff interviewed at the honey collection centre visited explained that according to procedures in place, samples are generally taken once per year from honey harvested in different regions (when there is a harvesting season) and the sample numbers depend on corresponding production levels. Samples from the same region/season are finally pooled and sent for analyses - if test results are compliant, this production from a given region/season is eligible for export;

- as for the RMP, samples seen on-the-spot were not adequately sealed (the absence of a seal was indicated also on test reports from the foreign laboratory);

- exporters - which pay for the analyses - decide whether they will send samples to either CENAPA or to the single foreign (EU) laboratory authorised to carry out the testing. Test reports were available in the honey collection centre visited and a test report selected by the audit team showed that the sample had been tested abroad for all of the required parameters with the exception of nitrofurans. Some additional parameters had been included (amitraz). The traceability system in place in the collection centre enabled tracing of this sample (batch) to the apiaries of origin;

- as seen from the test reports examined, all methods used by the foreign laboratory were accredited and except for chloramphenicol (ELISA), they were all instrumental – LC-MS or LC-MS/MS. In contrast, CENAPA a) did not test for tetracyclines, b) tested for chloramphenicol and streptomycin only by ELISA, c) had a significantly narrower scope for sulphonamides compared to the foreign laboratory and d) did not have all methods accredited (see Section 5.2.).

5.1.3.2 Establishment own-checks

Findings

As described in the 2008 FVO mission report, establishments may operate their own-checks for (*inter alia*) residues. Food business operators are not obliged to report on such programmes and/or test results to the competent authority, but the latter has access to this information on-the-spot.

Conclusions on other residues monitoring programmes

Despite some limitations and inconsistencies noted in testing of honey intended for export to the EU, this programme has the potential to provide additional guarantees on the residue status of this commodity.

5.1.4 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.

Findings

SENASICA (at central level) is overall responsible for the follow-up of non-compliant results. CENAPA informs the DGIAAP about completed analyses (see Section 5.1.3.). The DGIAAP written procedures/instructions for operation of the RMP for meat, eggs, aquaculture shrimp and honey (see Section 5.1.3.) were updated in 2011 to include requirements for follow-up actions.

According to the procedures in place for meat and eggs, the official veterinarian which is responsible for the establishment in question, has to trace back the origin of the non-compliant sample and to inform the food business operator on the non-compliant result, requesting that corrective actions are taken. The official veterinarian has to report the outcome to the central TIF office, which has to evaluate the corrective actions taken. In addition, it has to notify the official veterinarian and CENAPA that the incriminated owner/supplier has been placed under the vigilance programme according to which his/her animals have to be sampled and analysed for the same residue if and when they are presented for slaughter in that establishment.

The written procedures in place for honey foresee that the central RMP office informs the SAGARPA State Office on non-compliant results and on the actions to be carried out by the State officials (generally by the State co-ordinators for the African Bee Control). These actions include *inter alia* checking of records related to medical treatments at the apiary and determination of the cause of contamination. The State co-ordinator has to report to the central RMP office which monitors the actions taken and informs the Federal co-ordinator for the African Bee Control (at the General Livestock Department – *Coordinación General de Ganadería*).

The written procedures in place for aquaculture shrimp generally stipulate that in case of non-compliant results, the central RMP office establishes corrective actions and follows-up on them in co-ordination with two other sub-directorates within DGIAAP.

National legislation in force does not provide for sanctions or specific measures to be taken in case of non-compliant results obtained under the RMP. This is in contrast to information provided to the Commission services in the RMP where the application of administrative and judicial sanctions (when necessary) is foreseen in addition to corrective actions.

In commodities eligible for export to the EU, there were 30 non-compliant results found in the 2010 RMP (11 in horses: seven for beta-agonists, one for nitrofuran metabolite SEM, two for permethrin and one for mercury, and 19 in honey: 12 for nitrofuran metabolites (eight AHD and four SEM), two for streptomycin and five for coumaphos). In the 2011 RMP to date, there were 20 non-compliant results (ten in horses: five for beta-agonists, one for SEM and four for permethrins, and ten in honey: five for AHD, one for chloramphenicol, one for streptomycin, one for sulphathiazole and two for coumaphos).

The audit team noted that:

- the procedures/instructions for meat and eggs do not foresee on-farm investigations by the competent authority as part of the official follow-up in case of residue violations;

- follow-up files were available at the central and State offices visited and were generally complete;

- although national legislation in force does not include maximum limits for beta-agonists and nitrofurans in meat and there are no maximum limits for residues in honey (see Section 5.1.1.), findings of such substances have triggered response/follow-up from the competent

authority, though sanctions were not imposed;

- four follow-up cases for honey were examined by the audit team. Actions were generally carried out in line with the procedures/instructions, including on-farm visits and, in addition to these procedures, repeated samples were taken in two cases. In general, a possible cause of residue occurrence was reported and this had generally led to training of bee-keepers concerned on good production practices including the use of veterinary medicines and keeping of records;

- long overall turnaround times were noted in two of these cases i.e. more than seven months had elapsed between sampling and notifying the SAGARPA State Office concerned about the non-conformity, although the laboratory results were available in reasonable time;

- the 2011 RMP indicates a turnaround time of 20 days for laboratory analyses and an additional ten days (from the receipt of the "retention" sample) for repeated/confirmatory analyses. According to the competent authority, the CENAPA quality system allows ten days for issuing of results which is monitored through the National Laboratory System software. For samples taken in one slaughterhouse visited and for the non-compliant results in horse meat in 2010 and 2011, most of the turnaround times were 10-11 days, though there were exceptions to this (see below). However, there was no evidence that turnaround times for residue analyses have been systematically monitored;

- in one slaughterhouse visited, meat from sampled carcasses was detained for four weeks before being released, on the assumption that if no test results had been received within that period, the consignment would be compliant. Detention of meat is a common practice even though there is no legal obligation for the establishments to do so and the period of detection is at the discretion of the food business operator;

- out of 11 non-compliant results in horse meat samples in 2010, seven were from horses imported from United States of America (US), one was from a Mexican horse and in three cases the origin was not established. In 2011 to date, seven of ten non-compliant results were related to US horses. The remaining three non-compliant results (all Mexican horses) were for residues of the beta-agonists ractopamine or clenbuterol;

- in four follow-up cases for horse meat randomly selected by the audit team the actions taken were mainly in line with the procedures, except for the placing of incriminated owners/suppliers under the vigilance programme which was not done. In general, the actions taken by the food business operators were the confiscation/destruction of detained horse meat and stopping the sourcing of horses from the owners/suppliers concerned or requesting them to take corrective actions in order to provide only horses which are free from residues, as indicated in affidavits/statements on veterinary medical treatments (see Section 5.3.3.);

- similar to the situation noted during 2008 FVO mission, there were no official (on-farm) investigations to reveal the cause of residue violations and to prevent their recurrence (the "de-listed" owners/suppliers are free to supply horses to other establishments);

- in two of the cases (clenbuterol in 2011) the turnaround time for laboratory analysis was around 80 working days. The CENAPA staff explained that it was due to the breakdown of laboratory equipment;

- there are instructions in place for dealing with RASFF notifications related to TIF establishments, which is an improvement relative to observations made in 2008 and 2005 FVO missions. The audit team examined the follow-up file for the only 2010 RASFF notification in horse meat. Exports from the establishment concerned were immediately suspended pending the submission of its proposed corrective actions. Actions taken were generally as in follow-up procedures for non-compliant RMP results, including *inter alia* the (temporary) stopping of sourcing horses from the supplier concerned and announcement of recall of exported products. In addition official veterinarians in other EU-export approved equine slaughterhouses were requested to sample animals from the supplier in question if they were presented for slaughter, and to inform the central TIF office accordingly. CENAPA, which was immediately asked by the central TIF office about the availability of the analytical method for triamcinolone-acetonide, does not test for this substance under the RMP;

- one follow-up file for RASFF notification in honey was examined by the audit team. Information was promptly forwarded from the central level to relevant SAGARPA State Office, which informed the exporter in question accordingly. Exports were temporarily suspended pending the exporter's submission of requested documentation and information on corrective actions. An official visit to the exporter was carried out and shortcomings in good manufacturing practices were identified (however sanctions could not be applied as following of such practices is not compulsory);

- recommendation no. 6 from the 2008 FVO mission report required that official follow-up procedures provide guarantees at least equivalent to those provided in Council Directive 96/23/EC. In spite of the commitments given by the competent authority, this recommendation has not been adequately addressed.

Conclusions on follow-up investigations/actions

The procedures/instructions in place have been updated to include requirements for follow-up actions and these are triggered also in cases where substances without national permissible limits are found. However, the follow-up of non-compliant results differs significantly from the approach taken in the EU, including the delegation of responsibility for corrective actions to food business operators, no official on-farm investigations (except for honey) and no sanctions. Collectively these factors, combined with sometimes long turnaround times, undermine the effectiveness of follow-up investigations in revealing the causes for residue violations and preventing their recurrence. Therefore the current follow-up procedures do not provide guarantees at least equivalent to those provided in Council Directive 96/23/EC and relevant recommendations from previous FVO mission reports have not been adequately addressed.

5.2 LABORATORIES

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. Article 15 of Council Directive 96/23/EC requires that official samples are examined in approved laboratories. Requirements for accreditation of laboratories are laid down in Point 1.2. of the Annex to Commission Decision 98/179/EC. The rules for analytical methods to be used in the testing of official samples taken pursuant to Article 15(1) of Council Directive 96/23/EC are laid

down in Commission Decision 2002/657/EC – in particular Articles 3, 4, 5 and 6 which cover *inter alia*, validation requirements and quality control. More specific requirements for analytical methods for certain substances are laid down in the annexes to Commission Regulation (EC) No 1883/2006 (dioxins and dioxin-like PCBs in foodstuffs), Commission Regulation (EC) No 333/2007 (chemical elements in foodstuffs) and Commission Regulation (EC) No 401/2006 (mycotoxins).

5.2.1 General description

Findings

As was the case in 2008, all samples for the RMP are analysed at CENAPA. This laboratory is also designated by the SENASICA as the national reference laboratory for residues of veterinary medicinal products and contaminants in food from animal origin.

5.2.2 National Centre for Animal Health Certification Services (CENAPA)

Findings

RMP samples at CENAPA account for about 70% of the analyses carried out each year in this laboratory with the remaining 30% of analyses being carried out for private clients. CENAPA has to analyse approximately 2000 samples (bovine, equine, porcine, ovine, aquaculture, honey and eggs) under the 2011 RMP.

The laboratory has been accredited to ISO 17025 for residue assays on a fixed-term scope for ten years. The accreditation body (*Entidad Mexicana de Acreditación* – EMA) performs annual audits. The laboratory, through an internal Planning Committee, has established a new list of priorities for development/validation/accreditation/transfer of analytical methods to be implemented by the sub-directorate for the "transfer of analytical technology". This new sub-directorate is in charge of this reference activity since 2010 and tends to organise the validation and the transfer of the new analytical methods to the two routine control departments hosted by the sub-directorate for the "control of food products" and by the sub-directorate for the "quality of aquaculture and fishery products". These two sub-directorates are designed and organised mainly in order to enhance the efficiency in carrying out testing of the RMP samples. Over the past five years (2007-2011), CENAPA has sent staff for training in residue testing in several EU Member States and is also a participant in the PROTLCUEM project between Mexico and the EU which can facilitate the exchange of laboratory staff.

CENAPA is also accredited under the International Laboratory Accreditation Cooperation (ILAC) as a provider of Proficiency Testing Schemes and is in the process to apply for the new accreditation to ISO 17043.

The audit team noted that:

- the most recent audit by EMA occurred on a three-day visit in August 2011 and close-out actions have been proposed, implemented (September 2011) and accepted after a review on a two-day visit by EMA in October 2011. Out of 27 non-conformities in total, only one referred to residue controls i.e. to the amphenicols method for which four staff mentioned as trained had no/little knowledge of the theory and practice of this method. In addition to the 12 methods used for RMP analyses and accredited to ISO 17025 at the beginning of 2011 a

further eight methods passed the accreditation during this renewal audit;

- the Quality Assurance Officer, technically assisted by the sub-directorate for "transfer of analytical technology", has organised a number of proficiency tests for some relevant residue methods (this started in 2010 and has been organised once per year per method). The participants of these CENAPA-organised proficiency tests were CENAPA's own routine control departments and some external laboratories. CENAPA had a satisfactory Z-score in most of the analyses except in one for sulphonamides by HPLC. It has not participated in any external proficiency testing for residues of veterinary medicines over the past three years;

- the laboratory operates six LC-MS/MS systems and one GC-MS/MS along with a number of other suitable instruments for residue analyses such as HPLC and GC systems. Contracts for once-a-year maintenance are in place with the major instruments companies;

- the procedures for validation of residue analytical methods are in compliance with the principles of Commission Decision 2002/657/EC. A new procedure has been elaborated recently (2011) to consider the validation (still not in place) for the screening methods according to the European guidance document of January 2010 entitled: "Guidelines for the Validation of Screening Methods";

- progress has been made relative to the 2008 FVO mission in extending and completing the list of validated methods in line with recommendations no. 4 and 7 from that mission report;

- SOPs for the analysis of nitrofuran metabolites in meat tissues and in honey by LC-MS/MS were examined. The SOP did not contain any information on the specific procedure required for reliable confirmation of nitrofurazone abuse (i.e. the confirmation of protein-bound semicarbazide);

- validation was in accordance with the requirements of Commission Decision 2002/657/EC. However, the conditions for routine use of both methods differ from those used in the validation phase with an extended calibration range employed for routine use (0.3 to 4.0 µg/kg compared to the 0.5 to 1.5 µg/kg);

- the use of aqueous standard calibrants including a single matrix-spiked sample at the MRPL (instead of a set of matrix-spiked calibrants) is not best practice. Furthermore, when confirming results there is no confirmatory matrix-spiked calibration and no double-testing of the positively-screened samples. The test report sent to DGIAAP does not indicate any information regarding the analytical limit of the method (CC-alpha) and/or the uncertainty of measurement on the result;

- a method for nitroimidazoles in horse meat by LC-MS/MS was validated in May 2011 with the aim to be incorporated in the 2011 RMP but this has not occurred to date. It has been validated in line with the EU recommended level of 3 µg/kg and covers the 3 major banned nitroimidazoles including some of their metabolites but excludes the metabolite HMMNI. As for the nitrofuran method, the calibration range proposed for routine use is wider than that used in the validation phase;

- a method for testing clenbuterol, zilpaterol and ractopamine in horse meat by LC-MS/MS is

validated and the detection limits are in line with EU recommended levels. It was noted that some positive results were found with this method under the 2010 and 2011 RMPs. Muscle is not the most appropriate edible tissue to be tested for beta-agonists (liver is preferable as residues persist for longer in this tissue compared to muscle);

- a method for testing phenylbutazone in horse meat by LC-MS/MS is under development, however the main metabolite oxyphenylbutazone is not taken into consideration;

- three of four steroids included in the RMP (nandrolone, ethynilestradiol and trenbolone) are tested in horse meat by ELISA screening methods which are not validated and there are no confirmatory methods in place for these substances;

- antibiotics in meat are screened by the Swab Test and are confirmed by other microbial growth inhibition tests. Confirmation requirements as laid down in Commission Decision 2002/657/EC are not met (there are no HPLC or LC-MS/MS confirmatory methods in place for Group B1 substances);

- for honey streptomycin is analysed directly by LC-MS/MS and with a matrix-spiked calibration. (There is a screening ELISA method which is not yet validated). Quality controls in routine analysis are adequately performed. The tetracyclines are screened by an unvalidated ELISA and there is no confirmatory method for tetracyclines in honey.

Conclusions on laboratories

Notwithstanding the progress made in the performance of the laboratory relative to the 2008 FVO mission and the fact that there is an increased number of analytical methods included within the scope of accreditation, the fact remains that there are still shortcomings in the validation of analytical methods, which undermine the effectiveness of the residue monitoring plan.

5.3 VETERINARY MEDICINAL PRODUCTS AND MEDICATED FEEDINGSTUFFS

5.3.1 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 and meet the requirements of Article 11(2) of Directive 96/22/EC.

Article 7 of Council Directive 96/23/EC 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. Articles 4, 5 and 7 of Council Directive 96/22/EC establish conditions for the administration of substances, referred to in its Annex II, List B and Annex III, to farm and aquaculture animals.

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 the 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.

5.3.1.1 Authorisation of veterinary medicinal products

Findings

The system for authorisation of veterinary medicinal products has not changed since the 2008 FVO mission. SENASICA (through DGSA) is the competent authority for marketing authorisations for veterinary medicinal products for all animal species, although COFEPRIS is responsible for the authorisation of topical products for treatment against ectoparasites.

The audit team noted that:

- no MRLs have been laid down in national legislation for a number of authorised/used substances. Several national MRLs are higher than those applicable in the EU (see Section 5.1.1.);

- as in 2008, various veterinary medicinal products authorised and available for sale in Mexico contain active substances for which no MRL has been established in the EU or which have been explicitly forbidden for use in food producing animals in the EU;

- despite assurances from the competent authority in 2009 that anabolic steroids were not marketed for growth promoting purposes in horses (see Section 5.3.3.), the audit team found that this is not the case with several anabolic steroids authorised and available for sale for use in horses intended for human consumption. These include boldenone, methandrostenolone and nandrolone. This is contrary to the provisions of Article 11 of Council Directive 96/22/EC;

- nitrofurans (furazolidone and furaltadone) are marketed for use in poultry and horses. The

use of nitrofurans in food producing animals is forbidden in the EU;

- according to the competent authority, where no MRL has been laid down in Mexican legislation, withdrawal periods for veterinary medicinal products should be sufficiently long to ensure that the MRLs of major trading partners (e.g. the EU, the United States of America or Japan) or the *Codex Alimentarius* - whichever is proposed by the applicant - are complied with.

5.3.1.2 Distribution and use of veterinary medicinal products

Findings

A number of veterinary medicinal products are produced in Mexico whilst others are imported. Following production/import, products are distributed through wholesalers, veterinary pharmacies, agricultural outlet stores and veterinary clinics.

Veterinary medicinal products containing substances which may give rise to residues in food of animal origin are generally subject to the prescription system described in the 2008 FVO mission report. Group I products can be used by veterinarians only. Group II products can be sold on prescription only and Group III products are available over the counter. Pharmacies and prescribing veterinarians should retain respectively originals and copies of prescriptions for at least one year for Group I substances and for at least six months for Group II substances. Copies of prescriptions of Group II products should be provided to the product user, but there is no requirement that these should be retained for a given period of time.

The audit team noted that:

- the prescription system is generally in line with the rules applicable in the EU except in relation to the period for which prescriptions should be kept;

- the classification of anabolic implants (testosterone, estrogens, zeranol, progesterone) and beta-agonists (salbutamol and clenbuterol) in Group II (instead of the stricter controlled Group I) appears to be inconsistent with the classification rules of NOM-064-ZOO-2000 point 4.6.2;

- the system of veterinary prescriptions provides, if implemented as designed, for a paper trail of veterinary medicinal products used on farm. However, there is no legal requirement for keepers of horses, apiaries, laying hens, and aquaculture animals to keep records of medicinal treatment;

- vendor's declarations (being part of the horse 'passport' system for domestic horses), have been amended in order to reflect the (absence of) medicinal treatments during a six month period prior to sales. However, the passports are generally issued (and the horses identified) at a maximum of ten days prior to slaughter (see Section 5.3.3.);

- the manual for best practice for food safety in shrimp production provides templates for record keeping of medicinal treatments as well as guidance to producers on which substances should not be used and which contaminants should be avoided in shrimp intended for export to the EU. SENASICA indicated that COFEPRIS demands that shrimp

producers who wish to export to the EU must follow the manual i.e. to be certified for Good Aquaculture Practice;

- apiaries participating in a voluntary SENASICA certification scheme for good production (bee-keeping) practice also keep treatment records, and they are advised not to use any antibiotics;

- despite the commitments made by the competent authority in relation to the use of substances which have been forbidden in the EU, with regard to setting MRLs and concerning treatment records on farms, the recommendations nos. 1, 2, 3 and 8 of the 2008 FVO mission report have not been adequately addressed.

Conclusions on authorisation, distribution and use of veterinary medicinal products

The continued authorisation of *inter alia* nitrofurans and anabolic steroids for growth promotion purposes in horses, is not in line with the provisions of Council Directive 96/22/EC. Whilst the prescription system for veterinary medicinal products has been adequately designed to promote their correct use in accordance with label instructions, the absence of any legal requirement to keep medicines records has the potential to weaken guarantees on the residues status of food of animal origin exported to the EU. The continuing absence of national MRLs for many analyte-matrix combinations and the freedom to choose the MRL of an export market and set the product withdrawal period accordingly, may result in a situation where withdrawal periods may not sufficiently long to ensure that meat and offals do not contain residues in excess of EU MRLs.

5.3.2 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 stock 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 organisation of controls on the distribution chain has not changed since the 2008 FVO mission. The central level of SENASICA is responsible for manufacturers and importers, whilst the SAGARPA State Offices deal with wholesalers, veterinary pharmacies, veterinary clinics and feed

mills.

The audit team noted that:

- as in 2008, there are no regular official controls carried out on the use of veterinary medicinal products at apiaries, holdings with *equidae*, aquaculture farms and farms with layer hens;

- both SAGARPA State Offices visited had annual plans for controls on wholesalers, veterinary pharmacies, veterinary clinics and feed mills. Standardised check list are used for these official controls;

- in one of the two States (A+B) visited, the 2011 plan was not fulfilled (only one inspection had been carried prior to the FVO audit) because preference was given to clenbuterol controls on cattle farms following a case of clenbuterol findings in a doping control of the Mexican football team, which had been linked to the consumption of beef. In the second State all inspections had been carried out as planned (48 combined in 2010 and 2011). There were no non-conformances reported;

- the pharmacy in State B visited by the audit team had been inspected by a SAGARPA State Office inspector for the last time in 2009. The inspection covered *inter alia* the licence validity of the responsible veterinarians, general storage conditions and record keeping of Group I substances. Prescriptions and logbooks for Group I substances were present and duly maintained. The manager of the pharmacy indicated that 90% of the Group I products sold were handed over to the animal owners. According to the inspector, this practice was acceptable as long as the buyer produced a veterinary prescription. However, NOM-064-2000 stipulates in point 4.6 that Group I products are for exclusive use of the doctor of veterinary medicine with a professional license. There were no records of prescriptions of products scheduled in Group II, and the inspector did not consider this to be an issue which needs to be checked during inspections;

- the SAGARPA State Office inspector issued prescription books to authorised veterinarians. There was evidence that Group I sales records had been received and archived in the State Office. The records were traceable to veterinarians and prescription numbers, as long as these were located in the same State. The inspector had no tools to check prescriptions issued in other States as well as sales to entities outside the State. There was no exchange of information with neighbouring States on these matters;

- the official controls carried out at two of the six distributors in State A revealed several shortcomings: no records were kept of Group I substances by either distributor and one sold a large variety of Group II substances with labels that did not indicate the prescription status of the product. According to the documentation on the case, the distributor returned the products to the manufacturer as recommended by the SAGARPA State Office. However, the matter was not referred to the SAGARPA central office responsible for controlling the manufacturer and it was not investigated if the manufacturer had supplied the same wrongly labelled products to other distributors in the country. There was also no evidence that the situation with regard to not keeping records of Group I substances had been remedied;

- there was also a documented case of a distributor trading without licence. The distributor

received a 'courtesy visit' and was advised to apply for licence but was permitted to continue trading. When the site was re-visited after two weeks, it appeared that the business had closed or moved.

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

Inconsistencies in the application of official controls on the distribution of veterinary medicinal products and the absence of any such checks at the level of the primary producer (farm) undermine confidence in the effectiveness of the residue control system.

5.3.3 Identification of equidae and medicines records requirements

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 stock owners.

Equidae which are eligible for human consumption, when treated with pharmacologically active substances listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010, must have this treatment recorded in a medicines record kept on the farm as required by Article 10 of Council Directive 96/23/EC.

There is also more specific EU legislation governing the administration of veterinary products to such animals. Commission Regulation (EC) No 1950/2006 lists certain pharmacologically active substances which are deemed to be essential for the treatment of *equidae* and even though they are not listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 these substances may also be used to treat *equidae* intended for human consumption. Such treatment must also be recorded in Part 3 of Section IX of the equine passport and a period of six months from the date of last treatment to time of slaughter must be observed. The format of the passport (identification document) is laid down in Commission Regulation (EC) No 504/2008 which requires that all *equidae* must be accompanied by an identification document.

If *equidae* are treated with a substance which is neither listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 nor defined as an essential substance by Commission Regulation (EC) No 1950/2006, such a treatment permanently excludes the animal from the food chain. Exclusion from the food chain must be declared by the horse owner under Part 2 of Section IX of the equine passport.

Findings

On 17 April 2009, the European Commission wrote a letter to all countries exporting horse meat to the EU, explaining the Commission's position on such imports and requesting these countries to implement systems on equine identification, traceability and the keeping of medicines records which would give guarantees equivalent to those provided for by EU legislation and to provide an

action plan detailing these systems to the Commission services. Mexico gave a number of undertakings in this respect in a 'horse action plan'. In summary, these undertakings were:

- horses moving to collection centres or to slaughterhouses would be accompanied by identity document and vendor's declaration on medical treatments of animals (for the last six months) i.e. they would be identified on holdings,

- US horses would be micro-chipped at the border and horses of Mexican origin (domestic horses) would be micro-chipped no more than ten days prior to slaughter,

- US horses would be accompanied by the export certificate, issued by the US Department of Agriculture (USDA), including animals' identification, and by the owner's sworn statement on medical treatments of animals (for the last six months),

- the competent authority would audit (twice per year) authorised collection centres in Mexico and holdings from which these centres are sourcing the horses,

- anabolic steroids are not marketed (authorised) for growth promoting purposes in *equidae* and boldenone is not on the market,

- treatment records would be kept on horse identity document (passport) and DGIAAP would carry out (monthly) visits to EU-export approved establishments in order to verify whether only adequately identified animals, in which withdrawal periods were respected, are destined to slaughter for the EU market,

- official controls on the use of veterinary medicinal products would be carried out on holdings (according to risk-based programme),

- the scope of testing under the RMP was foreseen to be upgraded for a number of substances in 2010 (mainly steroids and phenylbutazone) (see also Section 5.1.1.).

The implementation of this 'horse action plan' was checked on-the-spot for the first time during the 2010 FVO mission (in November-December 2010). The report of that mission found that traceability of live horses was ensured only back to the last holding of origin (for Mexican horses) or to the collection centre (for US horses) and the competent authority did not verify the reliability/authenticity of the sworn statements made by owners on medical treatments, even in the presence of non-compliant results.

The audit team noted that:

- a new 'Inspection Manual for veterinary inspection of equine animals and meat products for export to the EU' has been issued June 2011. It includes a general requirement that *inter alia* food chain information has to be inspected by official veterinarians;

- staff from the central TIF office inspects twice per year EU-export approved slaughterhouses. Check lists are used for these inspections which mainly cover EU hygiene requirements, including food chain information. There are two questions related to the food chain information i.e. whether animals are received with relevant certificates and whether the sale declaration for horses is used (*declaración compra venta de équido*);

- in the slaughterhouse visited, the traceability check on origin of the animals, randomly selected by the audit team from a list of slaughtered horses, led to the exporter (collection centre) for US animals and to the last holding of origin (prior to collection centre) for a domestic animal; relevant documents were available.

With regard to US horses, in general there were no significant changes to the situation described in 2010 FVO mission report; an update to that description is provided below – the audit team noted that:

- US horses are identified (micro-chipped) in the US collection centres prior to their shipment to the exporters' facilities at the border. Their identification is included in the USDA export certificate, stating the green USDA label and microchip numbers;

- controls on imported *equidae* are carried out by border inspection offices (*Oficinas de Inspección de Sanidad Agropecuaria* - OISA). New guidelines for the official inspection of animals were issued in October 2011 (this was announced by the competent authority during the 2010 FVO mission);

- physical examination of imported horses takes place by OISA staff on the US territory. According to data presented by the competent authority, 9,057 live horses in 965 consignments were rejected out of 70,276 animals presented for import in 2010. In 2011 to date, 19,203 live horses in 2,154 consignments out of 58,300 animals were rejected. Rejections were due to various reasons e.g. illness, injuries, inadequate identification and documentation etc.;

- following the border check, an import certificate is issued by OISA. As noted during the 2010 FVO mission, this certificate indicates only the total number of animals and not their individual identification, which makes it difficult to identify which animals are at that moment present in the consignment and which were rejected at the border (e.g. 30 and 32 animals were indicated in the import certificates examined by the audit team, whilst in the corresponding USDA export certificates individual identification was listed for 34 and 42 horses, respectively). During the 2010 FVO mission, the competent authority announced an amendment to the import certificate in 2011, in order to address this shortcoming;

- horses imported for slaughter are directed to the slaughterhouse indicated in the import certificate. Trucks are sealed by OISA staff and the seal can only be broken by official staff at arrival to the slaughterhouse, where horses are usually slaughtered within ten days after arrival;

- imported animals are accompanied by an affidavit (sworn statement) on veterinary medical treatments, signed by the owner (exporter). This statement is aligned with the arrangements agreed in the 'horse action plan' i.e. it covers 180 days period in which animals are declared as not being treated with the listed EU-banned substances. The SENASICA document on import requirements (*Requisitos Zoosanitarios para Importación*) defines *inter alia* the content of this sworn statement which has to be annexed to the USDA export certificate;

- since May 2011, identification and other documents related to the imported consignments of live horses have been sent (also) by e-mail from OISA to slaughterhouses of destination, in order they can be checked by official staff in these slaughterhouses before the arrival of the

animals;

- as noted also during the 2010 FVO mission, there was no evidence in the USDA documents seen or from the statements/descriptions received from different parties on-the-spot, that the USDA takes any responsibility with regard to the origin of the animals (expect that they originate from US), controls over US assembly centres or to the reliability of the sworn statements on medical treatments of animals. The latter, as noted in the follow-up files examined by the audit team (see Section 5.1.5.), is also not verified by the Mexican competent authority (all those horses were covered by a sworn statement).

With regard to Mexican horses, some changes to the situation described in the 2010 FVO mission report were noted e.g. with regard to availability of anabolic steroids (see Section 5.3.1.1.). An update to that description is provided below. The audit team noted that:

- holdings keeping *inter alia* horses comprise farms (e.g. ranches) and large community farmlands assigned to villages (*ejidos*). The process of registering animals and holdings i.e. primary production units with bovines, ovines, caprines, pigs and bees by the National System for Individual Identification of Livestock (*Sistema Nacional de Identificación Individual del Ganado* – SINIIGA) is ongoing but a lot of these have not been registered yet, in particular backyard and other small farms. From those holdings which have been registered to date (in total around 850,000), approximately 200,000 also keep horses in addition to other animals. SINIIGA also registers separately the livestock service providers, including horse collection centres. All registered entities are kept in the SINIIGA database. The competent authority stated that SINIIGA registration will become compulsory when the Federal Law dealing with animal identification/traceability comes into force (expected in 2012);

- according to the competent authority, there are no dedicated horse farms in Mexico and horses are mainly kept at smaller holdings as working animals which are unlikely to receive medical treatments (due to economical reasons). Nevertheless, non-compliant residue results have been found in Mexican horses under the RMP (see Section 5.1.5);

- currently there are 14 SENASICA-approved collection centres for domestic horses intended for production of meat for export to the EU (though three are not in operation). Collection centres can only be approved if they have been previously registered by SINIIGA;

- updated procedures for approval of collection centres were issued by SENASICA in January 2011, to address *inter alia* some of the observations made in the 2010 FVO mission report e.g. collection centres are now requested to keep records of treatments administered there and to report them to slaughterhouses, and a passport can be used to identify one animal only;

- identification of horses is done in collection centres where passports are issued and the animals are micro-chipped, generally within ten days prior to slaughter;

- according to the current practice, only the last holding of origin (prior to the collection centre) needs to be indicated in the passport. In one collection centre visited, the responsible person stated that they try to indicate the last two holdings in the passport and examples of that were available;

- as noted during the 2010 FVO mission, there is currently no legal framework for the identification of horses, except the general traceability requirements included in the Federal Law on Animal Health and specific requirements of the importing party. The competent authority stated that identification of domestic horses by SINIIGA is foreseen to take place at the holding of origin (birth) from next year onwards i.e. when new legislation comes into force and SINIIGA registration becomes compulsory (see above);

- horses can be identified by freeze brands but this is not regulated by federal legislation i.e. it is up to individual States to decide upon this requirement. If animals are moved between States they should be accompanied with the federal movement certificate, otherwise States´ transport certificates are sufficient;

- in line with the 'horse action plan', passports include treatment records and an owner's/vendor's declaration (statement) on the non-usage of EU-banned substances for at least six months before horses were sold to the collection centre. The pharmacologically active substances and not the veterinary medicinal product used are to be recorded, and the indication of (product-specific) withdrawal periods is not foreseen which makes it difficult to establish whether these have been respected;

- the micro-chipping is done by SINIIGA through authorised staff (a training manual for staff was available). According to the SENASICA procedures in place, only horses from SINIIGA-registered holdings are allowed to enter approved collection centres (and may receive micro-chips). In one collection centre visited, all domestic animals had been supplied by one horse gatherer whose assembly centre was registered by SINIIGA as a holding (production unit). In the other collection centre animals from holdings not registered by SINIIGA have been accepted (approximately 60% according to the responsible person in the collection centre), but were not micro-chipped and therefore excluded from slaughter for the EU market;

- to date, in total 14,293 horses have been micro-chipped by SINIIGA, of which 7,932 are registered as being slaughtered and 6,361 as being still alive. In the three slaughterhouses currently exporting horse meat to the EU, 30,179 Mexican horses have been slaughtered in 2011 to date – this accounts for approximately 30% of the total number of horses slaughtered in 2010;

- the official staff in slaughterhouses visited stated that microchips need to be removed from the carcasses and destroyed. Slaughter of domestic horses has to be reported to the SINIIGA State office in the State where the slaughterhouse is located, in order that database can be updated. If horses were micro-chipped in another State, data on slaughter are forwarded to the SINIIGA office in that State. However, in one State visited it was noted that this has not always been done promptly e.g. horses micro-chipped in April 2010 were still indicated as alive in SINIIGA database (although they had been sent to the slaughterhouse shortly after micro-chipping). A similar situation was also seen in the 2010 FVO mission report;

- the holdings register kept in one collection centre visited was based on the logbook template for incoming and outgoing animals, annexed to SENASICA procedures for approval of collection centres. Movement dates for each animal were duly recorded, along with other required data (the absence of movement dates in registers was noted during the 2010 FVO mission). The other collection centre visited was attached to the slaughterhouse; it only had one supplier of domestic horses and a holding register (logbook) was not kept;

- according to the 'horse action plan', the competent authority stated that it would carry out controls at holdings (selected from the registers kept at collection centres) at least twice per year. However, such controls have not been put in place (see also Section 5.3.2.). A similar observation was made in the 2010 FVO mission report;

- according to the updated procedures for approval of collection centres, the competent authority should visit them at least once per year (half the frequency indicated in the 'horse action plan'). Documented evidence of controls carried out was seen in both collection centres visited, however in one of them no records were available for 2011 - the competent authority stated that these visits had been delegated to the SAGARPA State Office which had not yet submitted the records;

- in several aspects the situation on-the-spot is not in line with the 'horse action plan' according to which, animals would need to be identified before their movement to collection centres and accompanied by vendors' declarations accordingly (only micro-chipping was foreseen to be carried out at collection centres). Currently horses are not identified for six months prior to slaughter but generally only for the last ten days at the most. The reliability of the vendor's declaration and treatment records (both included in the passport) covering this period can not be, and is not verified. Indeed, non-compliant results for *inter-alia* beta-agonists were found in both the 2010 and 2011 RMPs. Furthermore, two other components of the horse action plan are not in place – there are no treatment records on farms and holdings are not controlled by the competent authority.

Conclusions on requirements for the identification of *equidae* and maintenance of medicines records

Some improvements have been noted relative to the situation described in the 2010 FVO mission report e.g. in terms of updated documents/instructions and enhanced flow of information, but overall, there have been no significant changes regarding the identification of equine animals. The components of the 'horse action plan' have not all been implemented and, as a result, the guarantees given on horse meat exports to the EU are insufficient to guarantee that equivalent standards to those provided for by EU legislation are applied.

6 Overall Conclusions

The residues monitoring plan (RMP) is generally designed in line with Council Directive 96/23/EC and some improvements have been made since the last FVO mission in 2008, however its effectiveness is undermined by an overall limited scope of testing and an inadequate sampling frequency for eggs. Sampling under the RMP has been generally carried out as planned, however the inadequate sealing and safeguarding of samples has the potential to negate their legal validity. Whilst follow-up actions in case of detection of residues are triggered, also in cases where substances without national permissible limits are found, the procedures differ significantly from the approach taken in the EU and are in general not effective in revealing the causes for residue violations and in preventing their recurrence.

Notwithstanding the progress made in the performance of the laboratory relative to the 2008 FVO mission, the shortcomings in the validation of analytical methods undermine the effectiveness of the residue monitoring plan.

Whilst an adequately designed prescription system for veterinary medicinal products has been put

in place, the shortcomings concerning treatment records, MRLs and setting of withdrawal periods have the potential to weaken guarantees on the residues status of food of animal origin exported to the EU. Furthermore, weak official controls on the distribution and use of veterinary medicinal products undermine confidence in the effectiveness of the residue control system.

With regard to the competent authority assurances, given in 2009 under the 'horse action plan' on identification, traceability and keeping of treatment records for equine animals, some improvements have been noted relative to the situation described in the report of 2010 FVO mission on horse meat production, but overall there have been no significant changes to this situation. The key components of the 'horse action plan' have not all been implemented and, as a result, the guarantees given on horse meat exports to the EU are insufficient to guarantee that equivalent standards to those provided for by EU legislation are applied.

Overall, in respect to commodities currently exported to the EU, the audit identified several shortcomings in the application of residues and veterinary medicines controls. Several of them were present also at the time of previous FVO residue missions in 2008 and 2005, and most of the recommendations from the report of the 2008 FVO residue mission have not been adequately addressed - despite the commitments made by the competent authority in the action plan provided in response to these recommendations. In particular, hormones are still authorised for growth promotion in horses.

7 Closing Meeting

A closing meeting was held on 17 November 2011 with representatives of the central competent authority. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities did not express disagreement and stated that they would take actions where necessary in order to address the shortcomings identified.

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.

N°.	Recommendation
1.	Ensure that information included in the RMP provided to the Commission services is accurate, that the scope of testing carried out under RMP is broadened and includes all relevant substances in line with the range of veterinary medicinal products on the market, and that the RMP includes sufficient number of samples for all commodities, taking into account the requirements as laid down in Article 7 of Council Directive 96/23/EC.
2.	Ensure that sampling for residues is carried out in such a way as to guarantee their legal validity, in order to provide guarantees at least equivalent to the requirements laid

N°.	Recommendation
	down in point 2.6 in the Annex to Commission Decision 98/179/EC.
3.	Ensure that the follow-up of non-compliant results is always carried out by the competent authority and is effective in order to provide guarantees at least equivalent to the relevant requirements of Council Directive 96/23/EC (Articles 12, 13, 16-18, 23, 24, 27 and 28), including turnaround times from sampling to investigation which should be short enough to allow (when necessary) this effective follow-up, and that adequate measures are taken to prevent re-occurrence of residue violations.
4.	Ensure that all analytical methods used for the RMP are validated to a standard equivalent to Article 3 of Commission Decision 2002/657/EC, and that confirmatory methods are used to confirm screening-positive or questionable results in order to decide on non-compliance, providing guarantees at least equivalent to the requirements of Article 6(1) of Commission Decision 2002/657/EC.
5.	Ensure that commodities exported to the EU are not derived from animals treated with hormones or beta-agonists for growth promotion in order to fulfil the requirements of Article 29 of Council Directive 96/23/EC and Article 11 of 96/22/EC.
6.	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.
7.	In respect of commodities exported to the EU, ensure that national MRLs are established in line with the provisions of the fourth indent of Article 7 of Council Directive 96/23/EC, with a view to ensuring that food of animal origin exported to the EU will comply with MRLs/MLs laid down in Table 1 of Annex to Commission Regulation 37/2010 and other applicable EU legislation.
8.	Ensure that controls on the distribution and use of veterinary medicinal products are carried out throughout the distribution chain – including farms, and that they are effective, 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.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2011-8906

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Audits by the Commission Services		
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Food Law		
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Monitoring and sampling of residues in food of animal origin		
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
Dec. 97/747/EC	OJ L 303, 6.11.1997, p. 12-15	97/747/EC: Commission Decision of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products
Dec. 98/179/EC	OJ L 65, 5.3.1998, p. 31-34	98/179/EC: Commission Decision of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products
Approval of residue monitoring plans submitted by third countries		

Legal Reference	Official Journal	Title
Dec. 2011/163/EU	OJ L 70, 17.3.2011, p. 40-46	2011/163/EU: Commission Decision of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC
Validation of analytical methods for residues and Minimum Required Performance Limits		
Dec. 2002/657/EC	OJ L 221, 17.8.2002, p. 8-36	2002/657/EC: Commission Decision of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results
Bans on the use of hormones and beta-agonists for growth promotion in food producing animals		
Dir. 96/22/EC	OJ L 125, 23.5.1996, p. 3-9	Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
Maximum Residue Limits for veterinary medicinal products in food of animal origin		
Reg. 470/2009	OJ L 152, 16.6.2009, p. 11-22	Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council
Reg. 37/2010	OJ L 15, 20.1.2010, p. 1-72	Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin
Maximum Residue Levels for pesticide residues in food of animal origin		

Legal Reference	Official Journal	Title
Reg. 396/2005	OJ L 70, 16.3.2005, p. 1-16	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
Maximum Levels for contaminants in food		
Reg. 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Authorisation of veterinary medicinal products		
Dir. 2001/82/EC	OJ L 311, 28.11.2001, p. 1-66	Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products
Dir. 2006/130/EC	OJ L 349, 12.12.2006, p. 15-16	Commission Directive 2006/130/EC of 11 December 2006 implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription
Reg. 726/2004	OJ L 136, 30.4.2004, p. 1-33	Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
Medicated feedingstuffs and additives		
Dir. 90/167/EEC	OJ L 92, 7.4.1990, p. 42-48	Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community

Legal Reference	Official Journal	Title
Reg. 183/2005	OJ L 35, 8.2.2005, p. 1-22	Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene
Sampling methods and methods of analysis for contaminants in foodstuffs		
Reg. 333/2007	OJ L 88, 29.3.2007, p. 29-38	Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs
Reg. 401/2006	OJ L 70, 9.3.2006, p. 12-34	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs
Reg. 1883/2006	OJ L 364, 20.12.2006, p. 32-43	Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs
Sampling methods for pesticides in foodstuffs		
Dir. 2002/63/EC	OJ L 187, 16.7.2002, p. 30-43	Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC
Horse identification (passport)		
Reg. 504/2008	OJ L 149, 7.6.2008, p. 3-32	Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae
Medicines essential for the treatment of equidae		

Legal Reference	Official Journal	Title
Reg. 1950/2006	OJ L 367, 22.12.2006, p. 33-45	Commission Regulation (EC) No 1950/2006 of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae