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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

CANADA

FROM 13 TO 23 SEPTEMBER 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 Canada, carried out between 13 to 23 September 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.

Canada is listed in Commission Decision 2011/163/EU as having an approved residue monitoring plan (RMP) for all commodities (bovine, ovine/caprine, swine, equine, poultry, aquaculture, milk, eggs, rabbit, wild game, farmed game and honey).

The national chemical residue monitoring programme (NCRMP) is comprehensive in scope and, with the exception of poultry and aquaculture products, for which certain important substance groups are not included in the respective plans in spite of previous commitments from the competent authority to include these, the NCRMP can be judged to provide guarantees with an effect equivalent to that foreseen by Council Directive 96/23/EC. Its implementation has generally been satisfactory for the meat commodities and eggs. However, for milk and honey, the planned sample numbers have not been realised and there was no evidence that corrective action had been undertaken to address this shortcoming, an issue already identified in the previous FVO mission. Implementation of the NCRMP is further compromised by the fact that the private laboratories, which are responsible for the majority of testing, effectively decide on the basis of the release of monies for testing, which tests to do and report in any given call-up period, adding to problems in realising the NCRMP. The follow-up of non-compliant results – an essential component of any system to control residues – is also compromised by weaknesses in the legislative framework, long storage times between sampling and dispatch to the laboratories, ill-defined turnaround times from sampling to analysis, delays in freezing samples and inadequate sealing of samples. Several of these factors also militate against the detection of residues in the first place.

Regarding the programme for certifying freedom from hormonal growth promotants and/or beta-agonists having an anabolic effect in cattle, this was well structured and implemented and could deliver the requisite guarantees. The same can largely be said for the ractopamine-free pork certification programme though, there are some shortcomings in relation to verifying that ractopamine-free feed produced in those feed mills also manufacturing ractopamine-containing feed, is not contaminated.

The residue laboratories visited were in general functioning in a manner consistent with that expected of accredited facilities. Some shortcomings notwithstanding (e.g. methods not always validated for all species from which tissues are analysed), regular participation of the laboratories in proficiency testing with generally satisfactory results and the fact that all methods used in the NCRMP are included within the scope of accreditation give the Canadian Food Inspection Agency (CFIA) confidence in the reliability of the results generated.

With regard to veterinary medicinal products, their classification differs from the EU approach with the majority of veterinary medicines being available over-the counter. The legal but unregulated importation of non-authorised veterinary medicinal products for "own use" remains a concern. There are also many substances authorised for use in food producing animals which are either non-authorised in the EU or are expressly prohibited. The authorisation of the beta-agonist ractopamine as a growth promotant for turkey means that, in the absence of a 'split system' for poultry, the requirements of Article 11(2) of Council Directive 96/22/EC are not currently met for poultry.

Official controls on the use of veterinary medicinal products are split between the federal and Provincial levels. Notwithstanding the audit team's findings that medicines records were properly maintained on the farms visited, the lack of official on-farm controls on the use of veterinary medicinal products has the potential to weaken the effectiveness of the residue control system, particularly in light of the unregulated personal imports. Whilst the CFIA's controls on feed mills are comprehensive and provide assurances that feed mills are satisfying national requirements, those requirements however have not addressed the possibility of cross-contamination of un-medicated feed with certain hormonal growth promotants (HGPs) and beta-agonists which could be an issue for those EU-eligible HGP-free beef and ractopamine-free pig farms sourcing their feedingstuffs from these establishments.

With regard to horse meat, the national requirements implemented for the slaughter of domestic horses or imported horses kept under an approved horse feed lot programme, give guarantees which are at least equivalent to those provided for equine identification (Commission Regulation (EC) No 504/2008) and treatment records (Article 10 of Council Directive 96/23/EC). The reliability of information in these documents can be and has been verified by means of on-farm/feed lot controls. In contrast, for those horses imported from the United States of America for direct slaughter, the equine identification documents received were not reliable, with verification only being possible by means of residue testing.

The report makes a number of recommendations to the Canadian 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
CCalpha / CCbeta	Decision Limit / Detection Capability
CCIA	Canadian Cattle Identifiction Agency
CFIA	Canadian Food Inspection Agency
CMIB	Compendium of Medicated Ingredient Brochures
DFO	Dairy Farmers of Ontario
DG(SANCO)	Health and Consumers Directorate-General
EC	European Community
EID	Equine identification document
ELISA	Enzyme-linked immuno-sorbent assay
EU	European Union
EU RL	European Union Reference Laboratory
FVO	Food and Veterinary Office
GC-MS/MS	Gas Chromatography-(Tandem) Mass Spectrometry
gFARAD	Canadian global food animal residue avoidance databank programme
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC:
HACCP	Hazard Analysis and Critical Control Points
HPG free cattle programme	Canadian programme for certifying freedom from hormonal growth promotants (HPG's) and/or beta-agonists having an anabolic effect
HPLC –DAD/Fluor	High Performance Liquid Chromatography with Diode Array Detector / Fluorescence Detector
HPTLC	High performance thin layer chromatography
ISO	International Organisation for Standardisation
LC-MS/MS	Liquid Chromatography-(Tandem) Mass Spectrometry
LIMS	Laboratory Information Management System
LSTS	Laboratory Sample Tracking System
ML	Maximum Level
MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
NCRMP	National chemical residue monitoring programme
NRL	National Reference Laboratory
QA	Quality assurance
RAMS	Residues, Antimicrobials, Microorganisms Infraction Tracking Database
RASFF	Rapid Alert System for Food and Feed

SD	Standard Deviation
SOP	Standard Operating Procedure
US	United States of America
VDD	Veterinary Drugs Directorate

1 Introduction

The audit took place in Canada from 13 to 23 September 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 planned audit programme, evaluating control systems and operational standards in this 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 13 September 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 Canada (DG (SANCO)/2007/7317 MR Final) in May/June 2007. The table below lists sites visited and meetings held in order to achieve that objective.

Meetings/Visits		**No**	**Comments**
Competent Authorities	Central	2	Opening and closing meetings with the representatives of the central competent authorities, Health Canada, and the Canadian Food Inspection Agency (CFIA)
	Regional	2	Meetings with the State (CFIA) Offices, Western Area and Ontario Area
Laboratories		2	Governmental CFIA laboratory in Calgary and a private laboratory
Farms		4	Dairy, cattle (beef), horse and pig farms
Establishments		3	Cattle, pig and horse slaughterhouses
Other Sites		3	A feed mill producing medicated feedingstuffs; a wholesaler and a retailer of veterinary medicinal products

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;

Whilst there is an Agreement between the European Union and the Government of Canada on Sanitary measures to protect public and animal health in respect of trade in live animals and animal products, residues are not included within the scope of the agreement.

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 Canada's residues monitoring plan is approved in accordance with Council Directive 96/23/EC for all commodities (bovine, ovine/caprine, swine, equine, poultry, aquaculture, milk, eggs, rabbit, wild game, farmed game and honey).

4.2 Summary of previous FVO audit reports

The residues sector was last inspected by the FVO in 2007. The report of that mission, DG(SANCO)/2007/7317 MR Final (henceforth referred to as the 2007 FVO mission) has been published on the website of the Directorate – General for Health and Consumers here: http://ec.europa.eu/food/fvo/ir_search_en.cfm.

The report concluded that the residues control system provided guarantees which were largely equivalent to those provided for by EU legislation. However, it was hampered by a number of shortcomings including a substantial shortfall in the number of samples taken versus the number planned, the length of time from sampling to analysis and several loopholes in the federal legislative framework governing residues and veterinary medicines controls, which restricted the ability of the competent authorities in executing follow-up and enforcement actions. The Canadian competent authorities undertook to address the deficiencies noted.

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

From 1 January 2008 to 1 July 2011, there had been no RASFF alerts or notifications for food of animal origin exported to the EU from Canada with respect to residues of veterinary medicinal products.

4.4 Production and Trade Information

Canada is a major exporter of horse meat to the EU, accounting for 24 % (more than 10,100 tonnes) of all horse meat imports into the EU. Eggs are another important export commodity, accounting for 5 % of total EU imports (755 tonnes). In addition, porcine meat (301 tonnes), dairy products (3500 tonnes) and honey (775 tonnes) are exported, each accounting for approximately 1 % of total EU imports for each commodity respectively. There are also limited exports of bovine and farmed game meat to the EU. With regard to poultry, there is only one establishment listed for export to the EU, slaughtering ducks, and with regard to aquaculture, approximately 237 tonnes (0.2%) of Canadian annual aquaculture fish production are exported to the EU.

5 Findings And Conclusions

5.1 Residue monitoring

5.1.1 Competent authorities involved

Health Canada is the central competent authority responsible for policy and legislation in the area of residue controls and for authorisation of marketing of veterinary medicinal products. Health Canada is also responsible to assess the effectiveness of the work of the CFIA, – an agency of the federal government – which is responsible for the implementation and enforcement of residues control legislation. Within CFIA, the Food Safety Division is responsible for planning and reporting of the Canadian national chemical residue monitoring programme (NCRMP), which covers meat, dairy products, eggs and honey; its Fish, Seafood and Production Division is responsible for drafting a separate residue monitoring programme (RMP) for aquaculture products.

Implementation of the residue monitoring programmes is established via four CFIA Area Offices, their respective regional offices, districts' and sub-districts' staff.

5.1.2 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 2011/163/EU.

Findings

There are two RMPs in place, the NCRMP which is composed of plans for meat (all species), dairy, eggs and honey, and a separate RMP for aquaculture products. The legal basis for the planning and implementation of the NCRMP and the RMP for aquaculture products is laid out in several federal Acts and Regulations made thereunder.

The NCRMP is designed annually by the Chemical Evaluation Section of the Food Safety Division at central level according to guidelines laid down by the Codex Alimentarius Commission (CAC/GL 16-1993 "Codex guidelines for the establishment of a regulatory programme for control of veterinary drug residues in foods"). It is principally based on unbiased statistical sampling. In addition, biased or directed sampling is possible if residue concentrations in excess of acceptable standards are suspected, e.g. during ante- or post-mortem meat inspection activities. The CFIA did not provide information, if there had been any amendments made to the NCRMP based on the new Codex Guidelines 71/2009, "Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals".

The process for planning the NCRMP is described in detail in the report of 2007 FVO mission (DG SANCO)/2007/7317 MR Final.

The number of samples planned in the NCRMP is approximately 10% higher than the budget available for analysis, to cover shortfalls in operational delivery either due to seasonality of products or reduction in establishments.

The audit team noted that:

- the NCRMP plus the RMP for aquaculture products of 2010/2011 and 2011/2012 covered all commodities for which Canada is listed in the Annex to Commission Decision 2011/163/EU;
- with regard to meat, milk, eggs and honey, all relevant substance groups (relative to the list in Annex I to Council Directive 96/23/EC) were included in the 2010/2011 NCRMP and in general, many substances were included for testing within each of the substance groups;
- with regard to raw milk, the NCRMP did not require sampling of raw milk of sheep and goat;

- regarding analysis of milk for phenylbutazone, the required limit of detection (LOD) is 50 µg/kg. In the EU, 5 µg/kg is the level recommended by the EU Reference Laboratory;
- in response to the 2007 FVO mission, since October 2010, the NCRMP has included testing of honey for both oxytetracycline and fumagillin, both of which are authorised for use in honey bees in Canada;
- in response to 2007 FVO mission, the NCRMP 2010/2011 for poultry had been improved with the addition of testing for substance groups A2, A3 and A5, but not A1 and A4. For 2007/2008, CFIA had undertaken to test for these substances in poultry which were slaughtered in the only EU-approved poultry slaughterhouse. Testing was to be carried out as a stand-alone programme outside the NRCMP. CFIA headquarters was not aware of any industry group availing themselves of this stand alone program;
- in response to 2007 FVO mission, the RMP for aquaculture products from 2008/2009 onwards was modified to include groups A6 and B3e for aquaculture fish. Furthermore the range of substances tested for within B1 was extended. However, groups A1 (stilbenes) and A3 (steroids) and A6 (specifically nitroimidazoles - although indicated in the RMP of 2010/2011 for finfish – have not yet been tested for. The CFIA informed the audit team, that its multi-year work on validating a method for nitroimidazoles in aquaculture fish and crustaceans was finalised and that a validated method was now available[1]. The work for validating a method for stilbenes was ongoing and was anticipated to be completed by April 2012. CFIA planned to start testing for both substance groups at the same time - one year *after* validation of the stilbene method (i.e. by April 2013). With regard to steroids, the work to validate a method had not yet started and the method was expected to be available after a three years project;
- the number of samples of domestic aquaculture product taken under the RMP (50) falls short of the number required under Codex Alimentarius Guidelines (upon which the plan is based) to detect a 1% violation prevalence rate for any given residue in the population with 95% confidence.

Conclusions on planning of the residue monitoring plan

Relative to the findings in the 2007 FVO report, the NCRMP – with the exception of poultry and aquaculture products - is comprehensive in scope and can be judged to provide guarantees with an effect equivalent to that foreseen by Council Directive 96/23/EC.

With regards to the plans for poultry and aquaculture products, certain important substance groups are not included in the respective plans in spite of previous commitments to do so, and therefore these plans are not fully equivalent to the requirements of Council Directive 96/23/EC.

5.1.3 Implementation of the residue monitoring plan

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans

1 *In their response to the draft report the Competent Authority stated that in 2008, CFIA identified the need to develop a method for 'nitroimidazoles' (EU Group A6). Preliminary investigations were undertaken with a review of available literature methods in order to define the work needed to complete the project. The proposal identified that a 2-year timeline, involving full method development, would be needed due to a lack of available literature methods in fish. This project was submitted and approved to begin in 2009. A fully validated method was made available, as per the project timeline, in March of 2011.*

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

CFIA has four Operational Areas and in each of them, Area Network Programme Specialists are responsible for the residue controls in all commodities. Operational Areas are divided into between four and six regions with districts and sub-districts, the latter representing federally-registered establishments. The residue monitoring plans are disseminated from CFIA headquarters to the Area Network Programme Specialists.

The NCRMP for **meat** is provided as a sampling plan spreadsheet comprising the samples for all Operational Areas. The sampling plan specifies each individual sample to be taken (unique sample number), indicating date of sampling (day and time), the slaughterhouse, species, matrix and quantities to be sampled and which laboratory the sample should be sent to. No information is given as to the substances to be analysed in order to avoid bias by the sampler.

The Area Network Programme Specialist forwards the sampling plan to the official veterinarians in the slaughterhouses, adding any reminders about the sampling and submission procedures deemed necessary in the area. Each sample has its own electronic sampling form with space for the sampling officer to note down the actual date of sampling, submission date to the laboratory and information about the farm of origin for the sampled animal.

Additionally the NCRMP 2010/2011 for meat provides for 76 targeted samples from cattle slaughtered under the Canadian programme for certifying freedom from the use of hormonal growth promotants (HGPs) and/or beta-agonists having an anabolic effect (**HGP-free cattle programme)**. These samples are to be tested for HGPs (i.e. substance groups A1, A3, A4), thyrostats (A2) and beta-agonists (A5).

The NCRMP for **eggs** and **honey** indicated the Operational Area, sampling month and laboratory responsible for the analysis for each uniquely numbered sample. Each Area Network Programme Specialist forwards the sampling plans to the relevant CFIA Operational Regional Offices whose staff will choose the individual egg grading stations and apiaries for sampling, carry out said sampling and submit the samples to the relevant laboratories.

The NCRMP plan for **raw milk** is implemented by the Governments of nine of the 10 provinces: Ontario; Québec; British Columbia; Alberta, Saskatchewan, Manitoba; New Brunswick; Nova Scotia; Prince Edward Island and Newfoundland. The majority (75%) of the samples are to be taken in Ontario and Quebec. The plan indicates for each uniquely numbered sample the province and the month of sampling. The sampling of raw milk is carried out at farm level by staff nominated by the provincial governments, who receive the sampling plans and sampling equipment (bottles) from the CFIA. Each sample comprises two or three sub-samples, depending on the

number of analyses. The samplers select which farms to sample. Samples are delivered to the Area Network Programme Specialists who enter the samples in the Laboratory Sample Tracking System (LSTS) and submit the samples to the analysing laboratories.

The RMP for **aquaculture** products is sent from the Fish and Seafood Production Unit in CFIA Headquarters to the Fish and Seafood Production Specialists in the relevant Operational Areas. All samples are taken in federally-registered establishments by CFIA personnel [2].

As described in the report of 2007 FVO mission, contracted private laboratories start to analyse samples after CFIA authorises the release of the respective share of budget for testing (the so-called 'call-up') twice a month. The contract of private laboratories requires a target turnaround time of 20 working days for most of the pharmacologically active substances. It is calculated afresh after every call-up and therefore does not define a time-frame between receiving a sample until reporting the result of analysis [3]. In order to achieve shorter turn-around times, the laboratory has implemented testing of the most recently received samples. If the laboratory has received more samples in the last half month than the allocated budget allows for analysis, the samples are stored. Those stored more than three months are no longer eligible for analysis and this is recorded.

Reporting of results by the private laboratories is linked with invoicing and is done batch-wise twice a month. Results for residues of pharmacologically active substances are to be provided in mg/kg. In the event of results exceeding MRLs, reporting to CFIA within 24 hours is required (see also point 5.2.2.2).

Results from the CFIA laboratories are uploaded into the LSTS, which is accessible *inter alia* to the Area Operational Offices and local CFIA staff taking the samples.

The audit team noted that:

- CFIA headquarters had sent the NCRMP for 2011/2012 to the Operational Areas by the end of March 2011;
- in the three slaughterhouses visited, local CFIA staff sampled cattle, pigs, horses, farmed bison and farmed elk in accordance with the NCRMP. Each sample could be traced back to the farm of origin. Samples were routinely frozen in the slaughterhouse and submitted batch-wise to the laboratories within a period of 1-2 weeks from the sampling date;
- all of the samples specifically allocated to HGP-free cattle (for group A substances) are taken in the two slaughterhouses currently exporting beef to the EU;
- the sample information for the routine NCRMP samples of pigs or cattle did not indicate if the sampled animal was part of the HGP-free cattle programme or ractopamine-free pork programme respectively. The Area Operational Office had to request background information regarding the origin of the animal from the local CFIA staff in the slaughterhouse, before it could be established if detection of residues for HGPs or beta-agonists in a sample, taken in a slaughterhouse approved for export to the EU, was non-compliant;
- for honey, 72% of the planned samples of the NCRMP for 2009/2010 and 59% of the NCRMP for 2010/2011 had been taken/analysed. 22% of the honey samples planned for the first five months of the NCRMP for 2011/2012 had arrived at the laboratories;

2 *In their response to the draft report the Competent Authority stated that all samples are analysed in the CFIA Laboratory with sample documentation generated by the computerised Laboratory Sample Tracking System (LSTS). The LSTS allows inspectors and CFIA management to retrieve testing results.*

3 *In their response to the draft report the Competent Authority stated that this turnaround time is a contractual benchmark established for commercial and legal/performance reasons. Dates of sampling, receipt of samples are tracked as part of the ISO certification programme.*

- sampling of raw cow's milk had not been implemented as planned:
  - during the first five months of the NCRMP for 2011/2012, 64 samples of raw milk were planned for Québec and 42 for Ontario. However, by 8 September 2011, Québec has submitted 46 samples (71%) to the CFIA Calgary laboratory and no samples had been submitted from Ontario. The CFIA Ontario Operational Area office (visited by the audit team) was not aware of any samples of raw milk having been taken to date under the NCRMP for 2011/2012;
  - the CFIA sampling instructions for milk state that samples should be collected throughout the year and submitted to the laboratories by the CFIA at the beginning of each month or quarter. This instruction foresees storage of samples for up to three months before dispatch to the laboratories;
  - under the NCRMP for 2010/2011, 106 samples of raw milk from Ontario had been submitted to the CFIA Calgary laboratory in one batch in October 2010 and in six batches between 15 February and 5 April 2011. On the sample submission forms provided to the laboratory, CFIA staff had indicated the sampling dates for 93 of the 106 samples as one (89 samples) or two (four samples) days before arrival in the laboratory. These data were neither in accordance with the sampling plan nor the sample handling procedures described by the sampler (the Dairy Farmers of Ontario - DFO) and the CFIA staff (see below);
  - under the NCRMP for 2010/2011, 142 samples of raw milk from Québec had been submitted to the CFIA Calgary laboratory. The samples had arrived in the laboratory in batches in August, October, January and March. According to data in the laboratory the time from sampling until delivery to the laboratory had been between two and 154 days, with an average of 52 days and a median of 47.5 days;
- the Ontario (provincial) Ministry of Agriculture, Food and Rural Affairs has provided the legal authority to enforce the provincial Milk Act (Ontario Regulation 121/98) to specific members of the Dairy Farmers of Ontario organisation (DFO), a marketing group owned by the Ontario dairy farmers. All sampling of raw milk under the NCRMP is carried out by DFO staff. The milk samples are collected on-farm, are refrigerated in unsealed containers in the local DFO office and sent after one to three days to a university laboratory near the CFIA Operational Area Office. In this laboratory the samples are frozen and stored, unsealed, until submitted to the analysing laboratories following re-packing in sealed boxes by the CFIA;
- in response to 2007 FVO mission, CFIA sent an email on 7 September 2011, to remind CFIA staff, that samples under the NCRMP have to be sealed in a tamper-evident manner with a CFIA yellow tape (Form No 4561) if they cannot be maintained under official control during storage and/or transport. However, it was not a requirement in the current contracts of the private laboratories, to refuse or report samples which were received unsealed and the laboratories visited still accepted sample boxes without the specified tape. In addition, it was noted that CFIA yellow tape was not always used in a tamper-proof manner;
- the RMP 2010/2011 for aquaculture products was implemented as planned and results were available for the requested analysis of the samples taken, except for the samples indicated for groups A1, A3 and A6 (see also point 5.1.2) but not yet analysed for.

Conclusions on implementation of the residue monitoring plan

Implementation of the NCRMP has been satisfactory for meat commodities and eggs. However, for

milk and honey (as previously described in the report of 2007 FVO mission), the planned sample numbers were not met and there was no evidence that corrective action had been undertaken to address this shortcoming despite the tools being in place to allow a regular assessment of the progress being made in testing, indicating problems with regard to supervision of implementation [4].

The effectiveness of the NCRMP is further compromised by the fact that the private laboratories, which are responsible for the majority of testing, effectively decide on the basis of the release of monies for testing, which tests to do/report in any given half-month call-up period, adding to problems in realising the NCRMP.

Frequently observed long storage times between sampling and dispatch to the laboratories in conjunction with ill-defined turnaround times from sampling to analysis, delays in freezing samples and issues with inadequate sealing of samples are factors which militate against the detection of residues (due to time-dependent analyte instability) and have the potential to weaken the effectiveness of follow-up investigations.

5.1.4 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.

5.1.4.1 Canadian programme for certifying freedom from hormonal growth promotants (HGP's) and/or beta-agonists having an anabolic effect

Findings

At time of the visit, there were approximately 10,000 cattle from 86 farms and four feed lots enrolled in the HGP-free cattle programme. One of the four slaughterhouses listed for export of beef to the EU was operational.

Annex R of Chapter 11 (Export-European Union) of the Meat Hygiene Manual of Procedures contains the updated Canadian programme for certifying freedom from HGP's. The Annex provides for various templates of certificates and records required under the HGP-free cattle programme. The programme consists of an enrolment system for cow/calf farms and feed lots, segregation of implanted and non-implanted cattle, special identification of HGP-free animals, certification of implant-free status by CFIA-accredited private veterinarians before transport to the finishing farm, during their residence and prior to slaughter and keeping of records at specified stages in the production process on farm. On feed lots, the taking of one urine sample per 250 animals is required either by CFIA staff or by a CFIA-accredited veterinarian. These samples are tested in the CFIA Saskatoon laboratory and results forwarded to the CFIA.

CFIA animal health staff are responsible to verify if the requirements of the programme are being correctly implemented on the feed lots. The audit team visited a cattle feed lot on which both HGP-treated and HGP-free cattle were kept and noted that:

4 *In their response to the draft report the Competent Authority stated that the Calgary Laboratories track delivery per month and that they share the data with the Dairy Program staff. The Dairy Program regularly discuss the need to improve delivery (and have regular, monthly shipments) with the Area Specialists. They have taken corrective actions, yet further improvement is being sought to ensure an integrated coordinated effort is employed.*

- of the12,650 cattle on site, approximately 50 % were under the HGP-free programme. The other cattle received HGPs as implants and also feed medicated with authorised beta-agonists for growth promotion;
- the feed lot had to renew on an annual basis its enrolment in the programme. The CFIA-accredited veterinarian of the feed lot visited the feed lot and confirmed, that it was still applying the programme's requirements correctly;
- cattle/calves had been received from different cow/calf farms enrolled in the programme. These farms indicated in their enrolment, if they also treated animals with growth promotants. If so, the measures in place to ensure separation of the different animals must be described and approved by the CFIA. CFIA staff informed the audit team, that none of the farms delivering calves to the feed lot visited had indicated the use of growth promotants;
- consignments of calves received at the feed lot, were accompanied by the Annex R 12 (report of veterinary on-farm visit) and a transfer certificate in which *inter alia* the CFIA-accredited veterinarian of the farm stated the number of animals which had been tested for implants;
- cattle under the HGP-free programme could only enter the feed lot if they had been ear tagged with a Canadian Cattle Identification Agency's (CCIA) tag (a unique cattle number, obligatory for all Canadian cattle) and with a HF ear tag (unique ear tag for cattle under the HGP-free programme). In the electronic database of the feed lot, both ear tag numbers were linked to each other and to the number of pen, in which the animal was kept. Each enrolled farm or feed lot ordered its establishment-specific HF ear tag at the one company contracted for this task by CFIA. At the feed lot, HF ear tags had been used to replace lost HF ear tags of the farms of origin. The CFIA-approved veterinarian recorded such replacements in a register and the new HF ear tag number was linked to the CCIA number;
- the feed lot purchased feed supplements (including medicated feed) from different feed mills. With regard to feed for cattle under the HGP-free programme, an affidavit was received from the feed mill confirming that the supplements purchased did not contain either hormones or beta-agonists. A procedure was implemented to clean and flush the truck after the delivery of feed supplements containing growth promotants, in order to minimise the possibility of cross-contamination. However, in those feed mills manufacturing both HGP/beta-agonist-containing and HGP/beta-agonist-free feed for cattle, there is no obligation to have flushing procedures in place to minimise cross-contamination (see section 5.3.2.2.);
- the CFIA-approved veterinarian recorded treatments of all animals (under the HGP-free programme and other cattle) linked to their CCIA number in the electronic database of the feed lot. These records contained the veterinary medicinal product used, date of application, dosage and withdrawal period;
- the CFIA-approved veterinarian took urine samples during the second half of the feeding period, always ten samples from ten different pens, and sent them together with the completed laboratory sample submission forms (Annex R 11) to the CFIA Saskatoon laboratory by courier. These samples were not sealed. The laboratory forwarded the results to CFIA (Animal Health) of the Area, which informed District CFIA staff who informed the CFIA-approved veterinarian;
- for transport to the slaughterhouse the CFIA-approved veterinarian issued a transport certificate according to Annex R7 (which required a list of all individual HF ear tag

numbers), the report of veterinary on feed lot visit (Annex R 12) (which required the number of implant tests carried out) and the relevant laboratory results of the urine sample testing;

- District CFIA staff carried out a yearly inspection of the feed lot to verify that the requirements of HGP-free cattle programme were met. There was no specific checklist developed for inspection of feed lots under the HGP-free cattle programme. A standard report template provided by CFIA at central level was used. The summary report of the last inspection carried out on 23 June 2010 covered the main requirements of the HGP-free programme. One minor non-compliance was recorded and followed up. Inspections were announced to the feed lot a couple of days in advance. Cow/cattle farms under the HGP-free cattle programme are not inspected by CFIA.

The audit team visited a slaughterhouse for cattle listed for export of beef to the EU and it was noted that:

- routines for acceptance, slaughter and processing of cattle under the HGP-free cattle programme (as well as for other types animals slaughtered) were clearly laid out in an up-to-date Standard Operating Procedure (SOP) under the Hazard Analysis and Critical Control Points (HACCP) system of the slaughterhouse as required under the HGP-free programme. Revisions of the HACCP (and the SOP) since 10 August 2007 were clearly documented in a log book by the company;
- the documents accompanying the animals to the slaughterhouse were in line with the requirements in the HGP-free cattle programme: Annex R7 (transfer certificate from feed lot to slaughterhouse confirming palpation of 10 % of the animals for implants and that feed and urine samples have been taken) with endorsement by the CFIA or an CFIA-accredited veterinarian; Annex R12 as verification of the veterinary on-farm visit and where relevant, a further Annex R7 (transfer documents for cow/calf transferred to the feed lot);
- staff of the establishment carried out checks on ear tags and documents prior to slaughter and checks for implants during slaughter;
- HGP-free cattle were slaughtered as the first lot on a shift on each of the slaughter days randomly selected by the audit team for evaluation;
- local CFIA staff had carried out checks on the HACCP/SOP revisions and adherence to the SOP as part of their monthly checks of the slaughterhouse and had documented these checks in their worksheets;
- in the HGP-free programme it was stated that priority would be given to sampling tissues from HF-tagged animals when NCRMP samples were taken at slaughter. However this requirement had not been implemented as the (few) NCRMP samples had been taken at random and in accordance with the day and hour stipulated in the NCRMP.

With regard to sampling and analysis of samples taken under the HGP-free programme the audit team noted that:

- due to a communication error between the CFIA headquarters and the CFIA Operational Area Offices, no targeted sampling of cattle slaughtered under the HGP-free cattle programme had been carried out during the first three quarters of the NCRMP for 2010/2011. Once this error had been noted, ten (13%) of the 76 planned samples had been taken, all in the last quarter of the sampling year. However, samples which had been planned to be tested for zeranol and stilbenes, had not been analysed due to the suspension of the testing programme at this time. Sampling under the NCRMP for 2011/2012 had

started as planned in April 2011 [5];

- in the slaughterhouse visited, one targeted sample had been taken from each lot of cattle slaughtered under the HGP-free cattle programme. Thirteen samples out of the 38 samples allocated to this slaughterhouse had been collected to date;
- 59 on-farm samples of bovine urine in feed lots had been taken under the HGP-free programme in 2010/2011 and 21 samples had been taken in 2011/2012 to date.

5.1.4.2 Ractopamine-free pork certification programme

Findings

Annex E of Chapter 11 (Export-European Union) of the Meat Hygiene Manual of Procedures described the Canadian programme for certifying freedom from ractopamine. The main elements of the ractopamine-free pork certification programme are the production of pork meat under a documented control system (established by the operator) including pig farms, slaughterhouses and so-called 'Type 1' (ractopamine-free) and 'Type 2' (ractopamine-using and ractopamine-free) feed mills. Laboratory results for samples of feedingstuffs and pork as well as internal (twice per year) and external (once per year) third party audits are required in order to confirm the effectiveness of the operator's programme. The audit team was informed by CFIA, that the CFIA could function as a third party for audits of an operator's programme.

Annex E provides for participation of Type 2 feed mills in the ractopamine-free pork certification programme, and in this case, the programme requires an SOP to be established, which specifies the measures in place to prevent cross-contamination of drug-free feed with ractopamine. Requirements for sequencing of feed production, flushing or clean-out procedures are not specified however.

At time of the audit, export activities were taking place in one of the five pig slaughterhouses listed for export to the EU. The audit team evaluated the ractopamine-free pork certification programme of one operator, which had already been accepted by CFIA. Under this operator's programme, about 150 pig farms, eight feed mills and one slaughterhouse were enrolled. The operator had not yet exported to the EU, but was "exercising" his programme. The audit team visited one of the pig farms and the slaughterhouse and noted that:

- the operator's programme accepted only Type 1 feed mills. Each **feed mill** had been audited by a third party, before its enrollment was accepted by the operator. These audits started in 2009 and the last one was in July 2011. An accreditation certificate (valid for one year) had been issued by the third party. There had been no further internal audits in addition to the eight external audits recorded;
- the **pig farmer** visited, could demonstrate the required documentation for his enrollment for breeding of piglets and hog finishing. The farm had been audited twice per year by the operator's internal auditor and the last audit was on 12 July 2011. Reports had been drawn up and in the most recent audit, an adverse finding on record keeping requirements for feedingstuffs, had been rectified. Feed samples were available from May 2011 onwards together with the label of the feed/supplements to demonstrate that the feed delivery had the required information with regard to ractopamine ("produced in Type 1 for EU");
- to date the CFIA (CFIA food hygiene - CFIA animal health was not involved) had not requested copies of the internal audit reports of this farm for review;

5 *In their response to the draft report the Competent Authority stated that there was one shipment in 2009 and 26 shipments in 2010 (from two establishments) to the EU.*

- the **pig slaughterhouse** visited, had been listed since December 2009 for export to the EU. In addition to other pigs slaughtered, about 250 pigs per week (13,000 per year) were slaughtered under the ractopamine-free pork certification programme. The operator's own monitoring sampling programme had started prior to its approval for export in July 2010. The programme was based on Annex IV to Council Directive 96/23/EC and required one sample of 150 g pig tissue for every 5000 pigs to be taken (0.02 % of 13000 animals = three samples). So far, seven samples had been sent to a private laboratory which was also contracted by CFIA for analysing samples under the NCRMP. The reporting limit of the laboratory for ractopamine was 1 µg/kg. This figure is in line with the EU-RL recommended performance level. The slaughterhouse had received the results promptly - within two weeks. Residues of ractopamine were not detected in any of the samples. The operator's procedure requires that the laboratory would inform CFIA staff of the slaughterhouse and the auditor of the operator immediately of any non-compliant results;
- there was a procedure in place to ensure separation between pigs under the ractopamine-free pork certification programme and other pigs. This was seen to function properly. Pigs were identified (by tattoo) and an affidavit from the pig producer (Annex B according the the operator's procedure) accompanied the pigs to the slaughterhouse. Data on this form included the producer number, identification of the pigs (tattoo-number), number of animals and a statement attesting that the animals had never been fed ractopamine. CFIA staff verified if the producer number recorded in the affidavit was on the operator's list of enrolled pig farms. This activity however, was not documented;
- the identification of each pig was verified at the scale by writing the tattoo-number into the electronic system of the slaughterhouse. Carcasses without a tattoo were not eligible for export. Weekly internal audits of the operator verified the proper separation of pigs and their proper identification (ten carcasses were cross-checked with regard to the tattoos);
- in the CFIA's tasks list, one (no 3.201) of the about 60 tasks listed, required a yearly verification of the implementation of all programmes relevant for EU export, which included at eligible pig slaughterhouses, the ractopamine-free pork certification programme. The last verification had been carried out 12 May 2011 and was documented.

5.1.4.3 Establishment own-checks

Findings

At slaughterhouses, CFIA staff were carrying out screening tests for residues of antibiotics in carcasses which were used in suspect carcases identified during ante- or post-mortem inspection.

Conclusions on other residues monitoring programmes

As concluded in the report to 2007 FVO mission, the "Canadian programme for certifying freedom from hormonal growth promotants (HPG's) and/or beta-agonists having an anabolic effect" was well structured and implemented and could deliver the requisite guarantees.

The ractopamine-free pork certification programme is also well implemented and can provide the expected guarantees on freedom from ractopamine in pork produced in systems where Type 1 (totally ractopamine-free) feed mills were used. However, where Type 2 feed mills are used (which can produce both ractopamine-containing and ractopamine-free feedingstuffs), current national requirements for avoidance of cross-contamination do not include ractopamine and there is no verification (under the National Feed Inspection Programme) that the measures in place are

effective in that regard.

5.1.5 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

The audit team noted that:

- in general, the laboratories reported residues detected for pharmacologically active substances at their level of detection (LOD);
- CFIA laboratories report their results by means of the LSTS to the CFIA staff who have taken the sample and to the relevant Area Network Programme Specialist who decides whether results are non-compliant. He/she will then transfer the data into the Residues, Antimicrobials and Microorganisms Infraction Tracking (RAMS) database in order to trigger a trace-back investigation;
- for samples tested by the private laboratories, which do not use LSTS, results are reported to the Chemical Evaluation Section of the CFIA where they are assessed for compliance. For honey, dairy and eggs, all non-compliant results are referred to the appropriate program for follow up including contacting the Area Network Programme Specialists. Non-compliant results in meat commodities are entered in to RAMS for follow up;
- if there is no MRL or administrative MRL (AMRL) established for the substance, all values below their level of quantification (LOQ) are classified by CFIA to be non-violative. For residues detected above the LOQ, an individual assessment is carried out by CFIA at central level, taking into consideration the advice from the Veterinary Drugs Directorate (VDD), in order to establish the health risk and, if the results have to be classified as violative, which follow-up activities this would require [6];
- as described in the report to 2007 FVO mission, the Health of Animals Act gives CFIA inspectors the right to enter farms if 'toxic substances' (e.g. such as residues of veterinary medicines and pesticides) have been detected at slaughter. However, the list of these substances has not yet been drafted and consequently this right of entry can not yet be invoked by the CFIA. In its action plan to address the recommendations of the 2007 FVO mission report, the CFIA aimed to have this list published by autumn 2007 for public consultation prior to adoption in law in 2008. However, due to the time consuming legislative procedure required, the list has not yet been published and CFIA could not provide a date when the legislative procedure might be completed;

6 *In their response to the draft report the Competent Authority stated that all values below the least sensitive LOQ are classified by CFIA to be non-violative unless there are additional considerations (example, banned drugs). For residues detected above this level, in addition to follow-up through RAMS (for meat products), an individual assessment is carried out by CFIA at central level, to establish, if a risk is present, additional action to be taken by the CFIA including, but not limited to, product recall.*

- under all of the various residue monitoring programmes in place, follow-up activities in the event of non-compliant results had been performed. In the meat programme, in addition, follow-up activities of non-compliant results had been recorded in detail in RAMS (e.g. the CFIA personnel involved, dates and summary reports of actions taken). In response to the report of 2007 FVO mission, CFIA informed the audit team, that it is not intended to extend the application of the RAMS to the commodities other than meat.

5.1.5.1 Non-compliant results in the 2010/2011 residue monitoring plan

Findings

In the results submitted to the Commission services for the sampling period April 2009 until October 2010, there were non-compliant results for the following analyte/matrix combinations: 1 benzimidazole in eggs, 1 clopidol and 40 ionophores, in raw milk; 1 penicillin and 2 phenicols, in honey 1 nitrofurans and 1 macrolides in addition to 96 benzaldehydes and 47 butyric anhydride, in meat: 13 beta-agonists (4 chicken, 6 game birds, 2 horses and 1 turkey), 8 benzimidazoles (6 muttons, 2 pigs), 1 carbadox in mutton, 1 ceftifur in veal, 7 chlorinated phenols in horses, 2 clopidol in rabbit, 24 endectocides (5 bisons, 4 game, 9 horses, 1 mutton and 5 veal), 6 fluoroquinolones (1 chicken and 5 veal), 4 glycosides (1 horse and 3 veal), 7 macrolides (6 rabbit and 1 veal), 1 nitrofuran in a piglet, 3 NSAIDs in cattle, 3 penicillins (1 beef, 1 horse and 1 rabbit), 2 sulphonamides in duck, 18 tetracyclines (1 goat, 2 horses and 15 veal), 11 thyrostats (8 in pigs and 3 in rabbit), 2 tranquilisers in horses and 1 trenbolone acetate in bison. In addition, about 230 non-compliant results for ionophores were reported in most of the animal species tested. The more than 200 findings for thyrostats in ruminants were considered to be related to (natural) feed components and not to the administration of a drug. Since 2008, there have been no non-compliant results for aquaculture products.

The audit team noted that:

- for the follow up files evaluated by the audit team, between six and 12 months had elapsed from sampling until the investigation of the potential source of the residue had commenced. In some cases the investigations had not yet been completed (e.g. detection of a banned substance). This was caused by several factors including storage of samples before delivery to the laboratory, storage in the laboratory before analyses, the time needed to trigger a trace-back activity, the time needed to establish the farm of origin, the time needed to request follow-up activity by another unit of CFIA (animal health or feed) or by the Provincial authorities and the time needed to carry out the investigation on-farm and report accordingly;
- follow-up investigations undertaken were not always successful in establishing the source of the residue. Common issues identified included cross-contamination between medicated and non-medicated feed and off-label use of veterinary medicinal products under an inadequately short veterinary practitioner-recommended withdrawal period;
- of particular interest was the finding in March 2011 of residues of dienestrol (a banned substance for all food producing animals in Canada and in the EU) in a veal calf. The follow-up investigation was not completed at the time of the audit.

5.1.5.2 Non-compliant results in the 'other' residue monitoring programmes

Findings

Under the other residue monitoring programmes (HGP-free programme and ractopamine-free pork certification programme), no non-compliant results were reported.

5.1.5.3 Non-compliant results reported under the RASFF

Findings

No RASFF alerts or notifications for food of animal origin exported to the EU from Canada with respect to residues of veterinary medicinal products (see also 4.3) had been notified since 2008.

Conclusions on follow-up investigations/actions

Since 2007, the central competent authority had taken steps to address loopholes in the federal legislative framework, which currently restricts certain follow-up activities of the competent authority. Nevertheless the frequently observed delays in the follow-up of non-compliant results, compromises the effectiveness of the residue control programme.

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

CFIA retains the services of three governmental laboratories and five 3rd party (private) contract laboratories for testing of samples under the various residue testing programmes. The 3rd party laboratories in general, are awarded contracts on an annual basis, which may be renewed on a further two occasions for a period of one year each. The audit team noted that:

- accreditation is a pre-requisite for all laboratories involved in the NCRMP;
- the contracts with 3rd party laboratories stipulate the reserved capacity available for testing, for which substances, the preference method to be used, the detection/ quantification/reporting limits that must be achieved and the turnaround time of samples.

5.2.2 On the spot visits in the laboratories

The audit team visited two laboratories, one governmental laboratory and one private laboratory. The audit team noted that:

- both laboratories were accredited to ISO 17025:2005 by the Standards Council of Canada with a fixed scope of accreditation and a validity of two years. The current schedule for each laboratory included all of the tests requested by the CFIA. The test methods for residues of pharmacologically active substances included in their respective scopes of accreditation are listed on the Standards Council of Canada website at: http://palcan.scc.ca/specs/pdf/132_e.pdf. The laboratories hold annual ISO 17025 Management Reviews, which were comprehensively minuted, and which were attended by senior staff in the organisation;
- the laboratories were well equipped with state-of-the-art equipment (including GC-MS and tandem LC-MS systems). Staff were sufficiently qualified and experienced to satisfactorily perform their designated tasks;
- the laboratories had SOPs for validation which were based on Commission Decision 2002/657/EC;
- both laboratories received and accepted NCRMP samples in boxes taped either with sellotape or with the CFIA yellow tape (form no. 4561), which according to the CFIA headquarters' email of 7 September 2011 was the only legally approved tape available;
- on receipt of samples, label(s) bearing a unique identification number were printed by the respective laboratory information management system. Subsequently the samples were thawed, two sub-samples were taken, labelled with the laboratory number and then re-frozen. Each of these sub-samples were thawed on further occasions (e.g. eggs two, or milk three times) when the scheduled tests were due to be performed.

5.2.2.1 CFIA Calgary Laboratory

Findings

Under the NCRMP, this laboratory carries out analyses for antimicrobials, amphenicols, endectocides, flunixin and phenylbutazone in raw milk and for fluoroquinolones, nicarbazin and ionophores in eggs. The audit team noted that:

- turnaround times were monitored in the laboratory on a monthly and annual basis and assessed against the stipulated maximum turnaround times for NCRMP samples (60 days for raw milk, 40 days for eggs). Since April 2010 test results for residues of veterinary drugs had been provided within those deadlines for the vast majority of samples;
- with regard to validation of methods:
  - all validation files examined were peer-reviewed by an analyst in another section of the same laboratory;
  - one negative and two spike recovery samples are included in every batch. Internal Quality Assurance (QA) data are logged onto a database and used to generate control charts, with automated trend analysis and flagging of runs outside warning and control limits (mean ±2 Standard Deviation (SD) and ±3 SD, respectively). Sufficient data on the pipettes used, reagent lot numbers, etc. were recorded to ensure full traceability. A low level recovery was also included to check instrument sensitivity;

- the LC-MS/MS method for nicarbazin and ionophores in eggs (five analytes) was developed to replace a previous method that had been audited in the 2007 FVO mission. The test employed method-matched extracted standard curves and had a reporting limit for all compounds (0.2 µg/kg) which met the limits set within the EU. The method had been validated at concentrations ranging from 0.3 to 10 µg/kg for each compound over six days. Data for method optimisation and validation were presented in a comprehensive file. Ion ratios were used for establishment of the identity of the analytes in accordance with the requirements of Commission Decision 2002/657/EC;
- the LC-MS/MS method for fluoroquinolones in eggs employed method-matched extracted standard curves and had reporting limits of between 1 and 10 µg/kg. The method had been validated at concentrations ranging from 1 to 60 µg/kg for each compound over six days. Data for method optimisation and validation were presented in a comprehensive file. Ion ratios were used for establishment of the identity of the analytes in accordance with the requirements of Commission Decision 2002/657/EC;
- an older GC-MS method was used for phenylbutazone in milk. On the accreditation schedule its scope was shown as "dairy products". It had been validated in butter and cheese, but not in raw milk – the commodity for which it was used in the NCRMP. For this method only the molecular ion was monitored – increasing the risk of false positive results. The sensitivity of the method (detection limit of 18 µg/kg), while better than the CFIA's required reporting limit of 50 µg/kg was well short of the EU-RL recommended level of 5 µg/kg (there is no MRL established for this drug in the EU);
- an older HPLC method with ultra-violet detection for flunixin in milk was not fit for purpose as it measured only the parent drug and not the marker residue (5-hydroxy flunixin) which is specified both in national and EU legislation;

- the laboratory has participated in a range of proficiency tests covering several of the analyte matrix combinations for which they were responsible in the NCRMP. Performance had generally been good. In the case of minor (z-score below or above the value 2) and major (z-score below or above the value 3) non-conformances, corrective and preventive measures had been carried out and documented;
- some discrepancies in document control (an out of date SOP version number on the worksheet of the nicarbazin/ionophores method) and use of out of date standard solutions (for selamectin) were observed;
- balances were calibrated annually and on each day of use. Pipettes were calibrated annually. However, two pipettes that had not been calibrated for five years were present in a rack alongside other pipettes that were currently calibrated. The laboratory staff stated that the non-calibrated pipettes were not in routine use;
- the maximum temperature recorded in two successive weekly measurements in a freezer (acceptable range -10 to -30 °C), used for the storage of samples, was in excess of +4°C. No explanatory comments were noted by the laboratory staff on the recording sheet.

5.2.2.2 Private Laboratory

Findings

The audit team visited one 3rd party laboratory carrying out analyses of meat tissues, eggs, honey and dairy products under the NCRMP and noted that:

- each individual sample was subjected to a large number of separate analyses;
- on receipt, sample submission documentation was scanned into the laboratory information management system (LIMS), assigned a unique number and an appropriate number of bar code labels were generated. The submitted samples were homogenised and sub-divided into three portions, each of which were frozen. In a separate area, test requests for individual samples were accessed, via the database, and individual test portions for all of the analyses were weighed out and frozen in separate racks, according to the test method. Each sample was analysed singly with one sample in 20 being analysed in duplicate;
- with regard to validation of methods:
  - multi-day, multi-level validation of analytical methods (frequently five replicates at five levels were used) was performed at concentration levels relevant to Canadian MRLs or at low concentration levels for unauthorised substances and for licensed substances without an MRL;
  - validation of analytical methods did not cover all of the matrices that were required by the CFIA contract. This was not clear from the schedule of accreditation which often described the matrices covered by the methods in more general terms such as "animal tissue and animal derived food";
  - the LC-MS/MS method for beta-agonists had been validated for porcine muscle, porcine liver, egg and cheese. The detection limit (signal-to-noise ratio of 3:1) was 0.2 µg/kg. In 2010, the scope of the method was increased to include three further analytes, including zilpaterol, and some validation data were available to support this extension to the scope. However, the method had not been validated for any of the other species for which it was used (e.g. cattle/sheep, poultry, horse) and results (including non-compliant results) had been reported for these species;
  - the SOP for the LC-MS/MS method for beta-agonists claimed that matrix-matched calibration standards were used for construction of the calibration curve. However, the matrix chosen was usually porcine liver, even when non-compliant results for other species were being reported. The SOP stated that the r^2 value of the calibration curve had to exceed 0.99, but this was not respected – even for calibration curves which were used to quantify/report non-compliant samples;
  - the LC-MS/MS method for aminoglycosides had been validated in porcine muscle, egg and cheese, but not in any other matrix. No validation data were available for poultry tissues, a species for which spectinomycin is authorised and a national MRL (100 µg/kg) has been established;
  - the GC-MS/MS method for zeranol and stilbenes had been validated in bovine liver and cheese but not in the wide range of other species/matrix combinations for which the method was used. In 2010/2011, a sample of muscle from a veal calf had been reported to the CFIA as non-compliant for dienestrol (0.43 µg/kg);
- the laboratory did not use data generated during routine long-term use of the method, to measure the within-laboratory reproducibility of the method, although the laboratory's data recording system would permit it;
- following a comment from the Standards Council of Canada (in their 2009 re-assessment inspection) that the use of ion ratios to confirm analyte identity did not conform to the EU (or any other) guidelines, the SOPs of all methods had been altered to include implementation of the EU guidelines on the use of ion ratios. However, in the three methods

examined (above), there was no written documentation to demonstrate that ion ratios had been calculated or checked for agreement with EU identification guidelines for the results reported [7];

- in all methods a negative control and a number of positive control samples (spiked at a relevant concentration) were included with every batch. The laboratory had set acceptability limits (mean ± 3 SD) for analytical recovery, and had an electronic flagging system to alert the QA Manager of trends/failures. There was a policy in place to plot three analytes in larger multi-residue tests. The analytes chosen were not always those which were the most relevant for the NCRMP;
- blind check samples were utilised periodically, particularly for those methods where it had not been possible to benchmark performance through the use of proficiency testing. These samples had to satisfy the same recovery criteria as non-blind recovery samples;
- a computerised system for traceability of analytical standards was available. Where standard stability data were available from the method developer (e.g. CFIA) these were used. Where data were not available, the laboratory used a default expiry date and adjusted this, if necessary, on the basis of standards comparison data (where a tolerance of ± 15% had been set);
- the laboratory has participated regularly and frequently in proficiency tests, some organised by CFIA and others organised by commercial suppliers. Performance in the proficiency tests had been satisfactory – although the number of participants in the CFIA tests tended to be low. Where minor and major non-conformances were found, corrective and preventive measures were carried out and were documented.

Conclusions on laboratories

The laboratories visited were in general functioning in a manner consistent with that expected of accredited facilities. Their regular participation in proficiency testing with generally satisfactory results and the fact that all methods used in the NCRMP are included within the scope of accreditation give the CFIA confidence in the reliability of the results generated. However, some shortcomings in method validation, calibration and performance were observed and the policy of repeated freezing and thawing of homogenised samples (which increases the risk of *in vitro* drug metabolism) collectively reduce the reliability of some analyses.

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

7 *In their response to the draft report the Competent Authority stated that the laboratory has implemented procedures and a spreadsheet to calculate the ion ratios calculations as per EU Guidelines.*

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 17-beta 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.

Findings

The Food and Drugs Regulations govern manufacture, distribution, use and control of veterinary medicinal products in Canada. VDD within Health Canada is responsible for the authorisation of veterinary medicinal products and determines the conditions of their sale and label requirements. For all new veterinary medicinal products, VDD establishes MRLs. The most recent list, dated 2 August 2011, contains 278 MRLs/AMRLs for 87 different pharmacologically active substances. For already authorised veterinary medicinal products, VDD has tried to establish withdrawal periods based on EU MRLs for the respective pharmacologically active substance(s).

Part C.01.046 of the Food and Drug Regulations permit the selling of drugs for "veterinary use only" and are listed in Part II of Schedule F to the Regulations, without prescription. Only veterinary drugs that contain a substance(s) listed on Part I of Schedule F are required to be sold pursuant to a prescription by a licensed veterinarian.

Part C.01.610.1 of the Food and Drug Regulations prohibit selling a drug for administration to food producing animals if that drug contains chloramphenicol or its salts or derivatives, a 5-nitrofuran compound, clenbuterol or its salts or derivatives, a 5-nitroimidazole compound or diethylstilbestrol or other stilbene compounds. In addition, any substance having oestrogenic activity for poultry is banned. Thyrostats, carbadox, olaquindox and dyes malachite green and crystal violet are not

authorised for use in food producing animals.

There are six HGPs (progesterone, testosterone, oestradiol-17 beta, trenbolone acetate, zeranol and melengestrol acetate) and two beta-agonists (ractopamine and zilpaterol) approved in Canada for use in beef cattle as growth promoters, al of which are authorised as over-the-counter drugs.

Veterinary medicinal products authorised by VDD as drug premixes for use in animal feedingstuffs, are listed in the Compendium of Medicated Ingredient Brochures (CMIB) and can be added to animal feedingstuffs without a veterinary prescription.

In contrast to Article 11 of Directive 2001/82/EC which lays down rules for the use of drugs for food producing animals under the 'cascade' principle and establishes default withdrawal periods for such use, there is no equivalent in Canada. Health Canada has published a policy with respect to the practice of extra-label use of veterinary medicinal products in food producing animals as a response to the respective recommendation in the report of 2007 FVO mission. The main aspects of this policy were: (a) extra-label use by persons other than licensed veterinarians is not recommended except when such use is conducted under the supervision of a veterinarian within the context of a valid "Veterinarian-Client-Patient Relationship"; (b) it should not be used for antimicrobials with a high importance for human health and (c) it should only be undertaken in compliance with the requirements of the Food and Drugs Act and its Regulations with regard to banned substances (C.01.610.1), medicated feed (C.08.012) and violative residues.

For the decision on an appropriate drug withdrawal period following extra-label use some guidance is available for registered veterinarians from the Canadian global food animal residue avoidance databank programme (gFARAD) based at the Western College of Veterinary Medicine in Saskatoon and the Faculty of Veterinary Medicine at St Hyacinthe, Québec.

Current legislation allows veterinarians or producers to import veterinary drugs for "personal use" i.e. to treat their own animals or use in their own practice. VDD stated that they intend to close this loophole by implementing an import license requirement.

The audit team noted that:

- the competent authorities have no information about either the quantities of or the range of pharmacologically active substances in those veterinary medicinal products which have been imported by veterinarians and farmers for "own use";
- the CMIB list of drugs which can be used for feed production without veterinary prescription include melengestrol actetate, ractopamine and zilpaterol for growth promotion;
- as noted in the 2007 FVO mission report there are a number of substances which are either not authorised or have been expressly prohibited for use as feed additives for food producing animals in the EU, e.g. arsanilic acid, bacitracin zinc, flavomycin and virginiamycin;
- since 5 May 2010, a feed premix containing ractopamine has been authorised for growth promotion in turkeys for the last one/two weeks before slaughter. There is no withdrawal period and AMRLs of 30 µg/kg in turkey muscle and 200 µg/kg in turkey liver have been established. In contrast to the situation for pigs, there is no split system (ractopamine-free poultry programme) to ensure that poultry meat exported to the EU has been derived from poultry which have not been treated with ractopamine for growth promotion. Eight non-compliant results for ractopamine in poultry liver (seven in chicken one in turkey) have been reported under the NCRMP up to Sept 2010;
- one veterinary medicinal product containing 17-beta estradiol is authorised for therapeutic use in heifers and cows. The use of this substance is also expressly prohibited food producing animals in the EU under Council Directive 96/22/EC;

- oxytetracycline is authorised for use in honey bees up to four weeks "prior to the main honey flow" and VDD has established an MRL of 300 µg/kg for the drug in honey. The results of tetracycline testing of 307 domestically produced honey samples revealed 104 findings of tetracycline residues between 1 April 2009 and 30 September 2010. None of these was considered to be violative as the Canadian MRL had not been exceeded. As there are no EU MRLs for antibiotics in honey Canadian exporters must provide a declaration to CFIA, that their honey meets EU requirements with regard to residues of antibiotics, before the CFIA will sign an export certificate;
- until Health Canada suspended the sale of the (EU-banned) feed additive roxarsone in August 2011, it had been authorised as an antiparasitic agent for chickens, turkeys and pigs. Feed mills have been permitted to use their remaining stocks of roxarsone;
- as described in the report of 2007 FVO mission there are significant differences between EU and Canadian MRLs /AMRLs for *inter alia* chlortetracycline, fenbendazole and levamisole.

Conclusions on authorisation, distribution and use of veterinary medicinal products

In Canada the classification of veterinary medicinal products for use in food-producing animals differs from the EU approach with the majority of veterinary medicines being available over-the counter and, additionally, the fact that there are many substances authorised for use in food producing animals which are either non-authorised in the EU or are expressly prohibited.

The centralised procedure for the authorisation of veterinary medicinal products in Canada has, relative to the situation observed in the 2007 FVO mission, improved with regard to setting MRLs and establishing withdrawal periods. Nevertheless the legal loophole allowing the unregulated importation of non-authorised veterinary medicinal products for "own use" remains a concern. The authorisation of the beta-agonist ractopamine as a growth promotant for turkey means that, in the absence of a 'split system' for poultry, the requirements of Article 11(2) of Council Directive 96/22/EC are not currently met for this species.

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 stockowners.

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 Inspectorate of Health Canada is responsible for Good Manufacturing Practice inspections on sites conducting licensable activities as defined by the Food and Drug Regulations. Such activities include *inter alia* manufacturing, import, distribution and wholesale of veterinary medicinal products.

Retail sales of veterinary medicinal products are regulated and controlled by each Province. There is no federal legislation in this field. According to the Livestock Medicines Newsletter (July 2010) from the Ontario Ministry of Agriculture, Food and Rural Affairs, licensing is required for over-the-counter sale of veterinary medicinal products in the provinces of Ontario, Alberta and British Colombia. In Québec veterinary medicinal products for livestock can only be sold by veterinarians, whilst in Manitoba, Saskatchewan and several Atlantic provinces there are no licenses required for the retail sale of over-the-counter veterinary medicinal products.

The activities of veterinary practitioners, including their distribution and use of veterinary medicinal products, is regulated and controlled by the professional bodies in each Province.

5.3.2.1 Controls at wholesale and retail level

Findings

In 2010, the Inspectorate of Health Canada carried out pre-announced inspections in five of the 15 wholesalers of veterinary medicinal products - in accordance with the requirement to inspect wholesalers every three years - using a standardised protocol.

Wholesalers are required to record batch numbers of incoming and outgoing products and to keep records which allow for recall of a product. They are not required to provide regular information about the sale of veterinary medicinal products to the competent authorities. The audit team visited one major wholesaler of veterinary medicinal products and noted that:

- the last two inspections were in 2006 and 2009, and the Inspectorate of Health Canada had sent the reports of both inspections to the wholesaler. Non-compliances including, *inter alia* a lack of self-audits and deficiencies in the management of SOPs, had been noted in both inspection reports;
- after each inspection, the wholesaler had provided an action plan, addressing the non-compliances listed in the inspection report. In 2010, the Inspectorate of Health Canada carried out a follow-up inspection (re-assessment). The follow-up inspection report did not contain any (cross) reference between the findings made and the recommendations given in the previous inspection report, making it difficult to assess whether those recommendations had been followed up.

The audit team visited a retailer of over-the-counter veterinary medicinal products in the Province of Ontario. Under provincial legislation (Ontario Livestock Medicines Act) shops for over-the-counter sale of veterinary medicinal products must be licensed and inspected by the provincial authorities. In addition, provincial legislation (R.R.O. 1990, Regulation 730) specifies those pharmacologically active substances in veterinary medicinal products which are permitted to be sold in licensed shops. The audit team noted that:

- in Ontario the Provincial Inspectorate carried out inspections of retailers of veterinary medicinal products once per year and inspection records on a standardised form were provided to the retailer. Depending on the severity of any non-compliances observed (which are graded in a points system) follow-up inspections or (temporary) cancellations of sales

licences may take place;

- the veterinary medicinal products available for sale in the shop visited were all labelled in accordance with federal legislation and included, *inter alia* the target species, dosage, and withdrawal periods which were printed in both official languages (English and French);
- in line with provincial requirements, the retailer included the name and address of the buyer of veterinary medicinal products in its sales records. For vaccines, the lot number and the expiry date were also included with records being maintained for two years.

5.3.2.2 Controls on feed mills (medicated pre-mixes and medicated feedingstuffs)

Findings

According to information provided by the competent authority there are 510 commercial feed mills producing approximately 50 % of total amount of animal feedingstuffs. There are more than 25,000 on-farm feed mills. Registration of feed mills for the purpose of production of medicated feedingstuffs is not a legal requirement.

Veterinary medicinal products which can be used in animal feedingstuffs are listed in the CMIB, which is maintained by the CFIA. This list includes premixes containing *inter alia,* melengestrol acetate, ractopamine, zilpaterol, virginiamycin, zinc bacitracin, all of which are either not licensed or are expressly prohibited from use in food producing animals in the EU.

A veterinary prescription for inclusion of veterinary drugs in animal feedingstuffs is not needed as long as the products are used as described in the CMIB. However, any change e.g. in the dosage rate, would require a veterinary prescription. An example of this was seen on the dairy farm visited where the veterinarian had issued a veterinary prescription for a particular type of medicated feed. The prescription was valid for one year and could be used for successive batches of that feed type.

Feed mills are also permitted to buy and store any authorised veterinary medicinal products (not just restricted to the CMIB list). Such products however, may only be used for production of medicated feed pursuant to a veterinary prescription (Food and Drug Regulations C.08.012). The veterinary prescription and the labelling of the medicated feed must indicate *inter alia* a warning statement respecting the withdrawal period to be observed following the use of the medicated feed.

According to the information provided on-the-spot, CFIA has provided guidance on how to avoid cross-contamination between medicated and non-medicated feed. After the production of medicated feed using a CMIB-listed drug for which there is a pre-harvest/slaughter withdrawal period for animal products, flushing is required or – instead of flushing – the medicated feed had to be followed by a non-medicated feed (other than a finishing fattening feed) for a species for which the pharmacologically active substance used is also authorised. For pharmacologically active substances listed in the CMIB, for which there is no withdrawal period e.g. ractopamine, zilpaterol and melengestrol acetate, no flushing is required. Therefore non-medicated finishing fattening feed could be produced directly after feed containing the above substances (for the same species).

CFIA is also responsible to monitor feed for food-producing animals for the presence of residues of veterinary medicinal products in the framework of the National Feed Inspection Programme (Programme 42) and to inspect feed mills producing medicated feed regularly (one to three times per year) based on their risk category. The feed samples analysed for residues under programme 42 (140 samples in 2011 - of feed produced after flushing) were analysed for the pharmacologically active substances considered to be high risk (i.e. for which a pre-harvest withdrawal period had to be respected). Therefore, ractopamine, zilpaterol and melengestrol acetate have not been tested in this programme.

Additional information regarding data on ractopamine in feed was provided at the closing meeting. In Canada, the LOQ for ractopamine in feed is 1 mg/kg, about 20% of the of the lowest recommended inclusion rate (5 mg/kg). A typical limit of quantification for EU laboratories testing feedingstuffs for ractopamine would be in the order of 10 µg/kg – about 100-fold less.

At the feed mill visited, the audit team noted that:

- the feed mill was a member of the Feed Assurance Programme and had a hazard based quality system implemented. About 50 % of the produced feed (for swine and poultry) was medicated feed, either containing veterinary medicinal products listed in the CMIB or prescribed by a veterinarian;
- flushing procedures were in place (300 kg 'forward flushed' and added to the three tonne batch (capacity of mixer). In addition to CFIA guidance on avoiding cross-contamination, the mill had strengthened its procedures followed each flush with the production of a non-finishing feed;
- the feed mill collected samples to verify the effectiveness of its flushing procedures with testing being carried out in the laboratories of the companies producing the feed additives or veterinary medicinal products in question. Results were available;
- the operator kept detailed records about the production of medicated feed, veterinary prescriptions and names of farmers. The required labelling of medicated feed was done by providing either the CMIB instruction or attaching a copy of the veterinary prescription to the shipping bill;
- CFIA inspectors had inspected the feed mill in line with the national requirements, based on a comprehensive checklist and had provided reports of the inspections to the feed mill. The CFIA inspector had followed up non-compliances observed in a timely fashion and records were available. Inspections were announced four weeks in advance together with a questionnaire to be filled in and the checklist used for the inspection.

5.3.2.3 Controls on farms

Findings

Federal legislation requires that poultry farms maintain treatment records ("flock sheets") which are to accompany the birds to the slaughterhouse. In addition, farmers who have enrolled in the ractopamine-free pork certification programme or in HGP-free cattle programme, operators of horse feed lots enrolled in the equine lot programme and CFIA-registered honey establishments have to keep treatment records. Certain voluntary industry operated quality programmes (e.g. The Canadian Quality Milk Programme) include rules for and inspections of *inter alia,* treatment records on farm. The audit team noted that:

- in response to 2007 FVO mission, the CFIA had implemented a procedure for farmed bison whereby the owner provides the slaughterhouse with a written declaration that withdrawal periods have been respected and that the animals have not been treated with hormones for growth promotion (in order to exclude the extra-label use of HGPs in these animals);
- CFIA stated that the legal procedure initiated in response to 2007 FVO mission, to include into the regulated Canadian HACCP the requirement for the operator to obtain a livestock information sheet (as already in use for poultry) has not been finalised.

During the course of the audit one dairy farm, one HGP-free cattle feed lot (see point 5.1.4.1), one pig farm (see point 5.1.4.2) and one horse feed lot (see point 5.3.3) were visited. The audit team

noted that:

- as described in the report of 2007 FVO mission it remains the case that neither the CFIA nor Health Canada are responsible for on-farm controls on the storage and use of veterinary medicinal products;
- on the two feed lots visited (for horses and HGP-free cattle), treatment records were maintained in accordance with the requirements of each programme. In the horse feed lot two of the three veterinary medicinal products regularly used were extra-label;
- in contrast to the situation for cattle, horses and farmed bison the affidavits accompanying pigs and farmed elk to the slaughterhouses approved for export to the EU, did not contain any declarations regarding withdrawal periods;
- on the dairy farm visited, treatment records were maintained and veterinary prescriptions (including those for medicated feed) were retained – a requirement of the Canadian Quality Milk programme which was operated and controlled by the DFO. In Ontario there are no legal provisions for official controls on the use of veterinary medicinal products on-farm. None had been carried out on the farm in question.

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

Official controls by Health Canada on wholesalers of veterinary medicinal products were comprehensive, with consistency in approach across the country ensured by the use of a standardised procedure. In contrast the rules governing the distribution of veterinary medicinal products in retail outlets and the obligation to carry out official controls of this activity vary considerably between the Provinces.

Notwithstanding the audit team's findings that medicines records were properly maintained on the farms visited, the lack of official on-farm controls on the use of veterinary medicinal products, has the potential to weaken the effectiveness of the residue control system, particularly in light of the fact that un-licensed (in Canada) veterinary medicinal products can be legally imported and used by farmers.

With regard to controls on feed mills, the CFIA controls are comprehensive and provide assurances that feed mills are satisfying national requirements. Those requirements however have not addressed the possibility of cross-contamination of un-medicated feed with certain HGPs and beta-agonists which are of importance for those EU-eligible HGP-free beef and ractopamine-free pig farms sourcing their feedingstuffs from these establishments.

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 stockowners.

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

The CFIA has given undertakings to the Commission services that it would implement EU-equivalent requirements regarding horse identification and treatment records, including on-farm verification.

National requirements regarding identification of horses and use of pharmacologically active substances in slaughter horses (food chain information) are described in Annex E to Chapter 17 of the Meat Hygiene Manual of Procedures, in force since August 2010. Annex E includes three lists of pharmacologically active substances, the first of which lists those not permitted for use in horses intended for slaughter, the second of which lists those considered to be essential for use in horses with a six month withdrawal period and the third of which lists those which are safe for use in slaughter horses, and their respective drug withdrawal periods. The audit team noted that:

- the requirements of Annex E to Chapter 17 of the Meat Hygiene Manual of Procedures are also applicable for horses imported for direct slaughter from other countries, e.g. the United States of America (US);
- identification and treatment records are implemented by means of an *individual* equine identification document (EID) for direct slaughter horses, or a *lot* identification document which may be used, provided that the horses have been enrolled in a CFIA accepted lot programme.

The audit team visited a horse feed lot enrolled in a lot programme accepted by CFIA and noted that:

- CFIA (Animal Health, Area level) had approved the lot programme in place and the method used to identify the lot;
- at time of the visit, 11,936 horses were resident in the feed lot. They are kept there for between 26 weeks and two years. The horses originate from Canada and the US;
- on arrival, horses are branded on the right shoulder with a three digit number (which

identifies the lot, week and year of arrival) and are allocated to pens. All of the animals examined by the audit team were clearly identified;

- the owner kept a list of the drugs routinely used. Two of the three veterinary medicinal products (penicillin and ivermectin for pour on and injection) were extra-label use (as they are not licensed for horses). The licensed veterinarian had requested gFARAD to recommend respective withdrawal periods and a documented response was available (60 days). For each lot, treatments were recorded with date of application, dosage and withdrawal period to be respected and the longest withdrawal period of any of the treated horse was applied to the entire lot;
- for transport to the slaughterhouse, the owner issued an equine lot information document containing the number of animals, their lot numbers and, for each lot, the treatment history over the previous six months (drug used, dosage, last treatment, withdrawal period);
- the licensed veterinarian had carried out two inspections in the last 12 months, records of which had been given to the owner and the CFIA District staff. One minor deficiency had been recorded and followed up;
- the required yearly CFIA audits had also taken place and records were available.

The audit team visited a horse slaughterhouse listed for export of horse meat to the EU and noted that:

- of the 30,000 horses slaughtered per year, around 15 % originated from Canada and 85% from the US, all imported for direct slaughter. 90% of the production was exported (50 % to the EU);
- only horses which arrived with the required EID document were eligible for slaughter and four staff of the operator were authorised to check if each EID had been completely filled in. These checks were recorded;
- two slaughterhouse staff were responsible for verifying the identity of each horse, based on the description provided in the EID. One horse from the USA, for which the identity could not be confirmed, had been detained until a correct document was received. The identity of 30 % of the horses was checked a second time, according to the operator's HACCP procedure in place. The EIDs received on the date of the visit were evaluated by the audit team and none were found which were not completely filled in;
- examples were seen for an EID which included a second EID of a previous owner in order to cover the required 180 day period. On another EID seen, treatment was recorded. but the route of administration and the withdrawal period was not specified (penicillin and ivermectin had been used). CFIA staff explained, that for verification if the withdrawal period had been respected, the relevant list (E 7) of the Annex E would be consulted, which for both substances recommended a 28 days withdrawal period – shorter than the 60 days recommended by gFARAD for off-label ivermectin use;
- CFIA staff checked the identity of 10-15 % of the horses during their ante-mortem inspection and all EIDs were checked for completeness and regards treatment/withdrawal periods. In the last three months, ten horses had been found to be ineligible for slaughter (on the basis of an incorrectly completed EID) and in all cases, outstanding information had been obtained or mistakes corrected by the operator;
- several EIDs, on which the owner's information was filled out in different writing and/or colour than the owner's signature, or on which the name of the indicated owner differed from name on the owner's signature were seen. CFIA staff had also detected such discrepancies

and had requested an explanation from the operator. It was stated that buyers of the horses know that only complete EIDs are accepted at the slaughterhouse and, if incomplete, they request the missing information from the owner and fill in the information themselves;

- the last two inspection reports of CFIA recorded findings with regard to insufficient checks of EIDs by the operator (e.g. no signature of the owner). In response to the first report of 18 March 2011, the operator had provided additional training to the staff responsible for the checks. The same findings were recorded in the next report of 16 September 2011.

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

National requirements implemented for the slaughter of domestic horses or imported horses kept under an approved horse feed lot programme, give guarantees which are at least equivalent to those provided for equine identification (Commission Regulation (EC) No 504/2008) and treatment records (Article 10 of Council Directive 96/23/EC). The reliability of information in these documents can be and has been verified by means of on-farm/feed lot controls.

However, for those horses imported from the US for direct slaughter, the EIDs received were not reliable, with verification only being possible by means of residue testing.

6 Overall Conclusions

The NCRMP is comprehensive in scope and, with the exception of poultry and aquaculture products, for which certain important substance groups are not included in the respective plans in spite of previous commitments from the competent authority to include these, the NCRMP can be judged to provide guarantees with an effect equivalent to that foreseen by Council Directive 96/23/EC. Its implementation has generally been satisfactory for the meat commodities and eggs. However, for milk and honey, the planned sample numbers have not been realised and there was no evidence that corrective action had been undertaken to address this shortcoming, an issue already identified in the previous FVO mission. Implementation of the NCRMP is further compromised by the fact that the private laboratories, which are responsible for the majority of testing, effectively decide on the basis of the release of monies for testing, which tests to do and report in any given call-up period, adding to problems in realising the NCRMP. The follow-up of non-compliant results – an essential component of any system to control residues – is also compromised by weaknesses in the legislative framework, long storage times between sampling and dispatch to the laboratories, ill-defined turnaround times from sampling to analysis, delays in freezing samples and inadequate sealing of samples. Several of these factors also militate against the detection of residues in the first place.

Regarding the programme for certifying freedom from hormonal growth promotants and/or beta-agonists having an anabolic effect in cattle, this was well structured and implemented and could deliver the requisite guarantees. The same can largely be said for the ractopamine-free pork certification programme though, there are some shortcomings in relation to verifying that ractopamine-free feed produced in those feed mills also manufacturing ractopamine-containing feed, is not contaminated.

The residue laboratories visited were in general functioning in a manner consistent with that expected of accredited facilities. Some shortcomings notwithstanding (e.g. methods not always validated for all species from which tissues are analysed), regular participation of the laboratories in proficiency testing with generally satisfactory results and the fact that all methods used in the NCRMP are included within the scope of accreditation give the CFIA confidence in the reliability

of the results generated.

With regard to veterinary medicinal products, their classification differs from the EU approach with the majority of veterinary medicines being available over-the counter. The legal but unregulated importation of non-authorised veterinary medicinal products for "own use" remains a concern. There are also many substances authorised for use in food producing animals which are either non-authorised in the EU or are expressly prohibited. The authorisation of the beta-agonist ractopamine as a growth promotant for turkey means that, in the absence of a 'split system' for poultry, the requirements of Article 11(2) of Council Directive 96/22/EC are not currently met for poultry.

Official controls on the use of veterinary medicinal products are split between the federal and Provincial levels. Notwithstanding the audit team's findings that medicines records were properly maintained on the farms visited, the lack of official on-farm controls on the use of veterinary medicinal products, has the potential to weaken the effectiveness of the residue control system, particularly in light of the unregulated personal imports. Whilst the CFIA controls on feed mills are comprehensive and provide assurances that feed mills are satisfying national requirements, those requirements however have not addressed the possibility of cross-contamination of un-medicated feed with certain HGPs and beta-agonists which could be an issue for those EU-eligible HGP-free beef and ractopamine-free pig farms sourcing their feedingstuffs from these establishments.

With regard to horse meat, the national requirements implemented for the slaughter of domestic horses or imported horses kept under an approved horse feed lot programme, and the official controls performed give guarantees which are at least equivalent to those provided for in EU legislation. In contrast, for those horses imported from the US for direct slaughter, the documentation received was not reliable, with verification of the data contained therein only being possible by means of residue testing.

7 Closing Meeting

A closing meeting was held on 23 September 2011 with representatives of the central competent authority. At this meeting, the audit team presented the main findings and preliminary conclusions of the mission. The authorities did not express disagreement and stated that they would look into the issues mentioned in particular with regard to the authorisation of ractopamine for use as a growth promotant in poultry (turkey).

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.	Address the identified shortcomings in planning and implementation of the NCRMP with regard to poultry and of the RMP for aquaculture products in order to ensure that the plans will offer guarantees on the residue status of exported food commodities which are at least equivalent to the standards set out in Article 29 of Council Directive 96/23/EC.

N°.	Recommendation
2.	Address shortcomings identified for implementation or supervision of implementation of the NCRMP with regard to milk and honey in order to ensure that it will offer guarantees on the residue status of exported food commodities which are at least equivalent to the standards set out in Community legislation (Article 29 of Council Directive 96/23/EC).
3.	Improve the procedure in place for storage and dispatch of samples to the laboratories in order to be at least equivalent to the Annex to Commission Decision 98/179/EC.
4.	Provide further detailed instructions on the prevention of cross-contamination in Annex E of Chapter 11 of the Meat Hygiene Manual of Procedures with regard to the participation of Type 2 feed mills in the ractopamine-free pork certification programme, with the aim to ensure that pigs slaughtered for export to the EU are not inadvertently exposed to these compounds during the rearing period, in accordance with the provisions of Article 11 of Council Directive 96/22/EC.
5.	Extend official controls with regard to the prevention of cross-contamination of un-medicated feedingstuffs with the feed additives melengestrol, zilpaterol and ractopamine in feed mills producing feed for cattle under the HGP-free cattle programme in order to ensure that cattle slaughtered for export to the EU are not inadvertently exposed to these compounds during the rearing period, in accordance with the provisions of Article 11 of Council Directive 96/22/EC.
6.	Ensure that, when non-compliant results are detected, the legal and/or administrative framework in place is strengthened in order to permit the application of follow-up procedures, which are at least equivalent to those described in Articles 16-19, 22 and 23 of Council Directive 96/23/EC, to be carried out in a timely fashion.
7.	Ensure that all analytical methods are validated for the species and matrices they are used for, that calibration standards used are suitable for the species and matrices analysed and that handling of the samples does not have an adverse effect on the reliability of the results obtained in order to guarantee that analytical testing meets standards which are at least equivalent to those required by Council Directive 96/23/EC and Commission Decision 2002/657/EC.
8.	Implement a 'split system' for poultry, if further export of poultry meat is intended, in order to meet the provisions of Article 11 (2) of Council Directive 96/22/EC.
9.	Improve further the regulation of extra-label drug use and the importation of veterinary medicinal products for 'own use' in food producing animals to ensure that if such use is continued, appropriate withdrawal periods are observed in order to guarantee that residue concentrations present in the tissues derived from animals so treated and intended for export to the EU do not exceed EU MRLs as laid down in Commission

N°.	Recommendation
	Regulation (EU) No 37/2010.

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=2011-8913

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
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
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

Legal Reference	Official Journal	Title
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		
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		

Legal Reference	Official Journal	Title
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		
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

Legal Reference	Official Journal	Title
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
Reg. 1831/2003	OJ L 268, 18.10.2003, p. 29-43	Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition
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

Legal Reference	Official Journal	Title
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		
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