FINAL REPORT OF A MISSION
CARRIED OUT IN CANADA
FROM 28 MAY TO 7 JUNE 2007
CONCERNING THE EVALUATION OF THE CONTROL OF RESIDUES AND
CONTAMINANTS IN LIVE ANIMALS AND ANIMAL PRODUCTS,
INCLUDING CONTROLS ON VETERINARY MEDICINAL PRODUCTS

Please note that factual errors in the draft report have been corrected. Clarifications provided by the
Canadian Competent Authorities are given as footnotes, in bold, italic, type, to the relevant part of the report.
EXECUTIVE SUMMARY

This report describes the outcome of a mission carried out by the Food and Veterinary Office (FVO) in Canada, from 28 May to 7 June 2007. The mission was part of a series of FVO missions on residue controls in third countries.

The objective of the mission was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, including the controls on the distribution and use of veterinary medicinal products (VMPs) and feed additives, the use of which may give rise to residues in such products. The evaluation was based on the standards set out in Council Directive 96/23/EC, and other relevant Community legislation in this field, including legislation on the control and distribution of veterinary medicinal products. The mission 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 Community requirements with regard to import of food of animal origin into the EU.

It is concluded that the residue control system in Canada is comprehensive and well structured. Many improvements in the system have been implemented since the last residues mission in 2000. Strengths include the scope of analytical testing in the national chemical residue monitoring programme, the analytical capabilities of the network of fully accredited residues laboratories, implementation of a comprehensive proficiency testing programme to assure laboratory performance, the establishment of a residues committee to discuss problem cases on a regular basis, the use of a computerised infraction tracking system for violations in meat and objective evidence indicating a low prevalence of violative residues in all domestic food commodities.

However, the effectiveness of the system in practice is weakened by several factors. Firstly, for several analyte-matrix combinations, there were substantial shortfalls in the number of samples taken versus the number planned and the number tested, thereby questioning the supervision of implementation of the programme in terms of monitoring both sampling and analysis. Secondly, in many cases the length of time from sampling to analysis was extremely long, which would reduce the ability of the competent authority to launch prompt follow up investigations. Thirdly, the current federal legislative framework governing residues and veterinary medicines controls has several loopholes – recognised by the competent authority - which restrict the ability of the competent authorities to take certain actions in respect of follow-up and enforcement. Fourthly, in some cases where residues of hormonal growth promotants were detected in species for which their use is not authorised, investigations had not been carried out.

With regard to controls on the authorisation, distribution and use of veterinary drugs, the systems in place appear to be generally effective. Medicines records, whilst not compulsory by law, were maintained in each of the farms visited and official checks had been performed. In particular the hormonal growth promotant-free beef programme for the EU has been well structured and provides sound guarantees on the residue status of this commodity. However, the fact that extra-label drug use with hormonal growth promotants is legal for bison, the fact that such substances appear to have been used in bison production (albeit with a low incidence), much of which is destined for the EU market, the absence of investigations as to the cause of these violations, and the apparent absence of a coherent policy when such findings are made in this species, indicate that controls in this sector require to be enhanced in order to meet Community requirements. Aside from the concerns relating to the extra-label use of hormonal growth promotants in bison, on the whole it can be concluded that the residues control system in Canada provides guarantees which are largely equivalent to those provided for by Community legislation.

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 & SPECIAL TERMS USED IN THE REPORT

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>AOZ and AMOZ</td>
<td>Marker residues of the nitrofuran drugs furazolidone and furaltadone respectively</td>
</tr>
<tr>
<td>gFARAD</td>
<td>global Food Animal Residue Avoidance Databank</td>
</tr>
<tr>
<td>(C)CA</td>
<td>(Central) Competent Authority</td>
</tr>
<tr>
<td>HACCP</td>
<td>Hazard Analysis Critical Control Point</td>
</tr>
<tr>
<td>HGP</td>
<td>Hormonal Growth Promotant</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organisation for Standardisation</td>
</tr>
<tr>
<td>DG(SANCO)</td>
<td>Health and Consumer Protection Directorate General</td>
</tr>
<tr>
<td>LC-MS-MS</td>
<td>Liquid Chromatography-(Tandem) Mass Spectrometry</td>
</tr>
<tr>
<td>LoD</td>
<td>Limit of Detection</td>
</tr>
<tr>
<td>LoQ</td>
<td>Limit of Quantification</td>
</tr>
<tr>
<td>LSTS</td>
<td>Laboratory Sample Tracking System</td>
</tr>
<tr>
<td>(A)MRL</td>
<td>(Administrative) Maximum Residue Limit</td>
</tr>
<tr>
<td>NCRMP</td>
<td>National Chemical Residue Monitoring Plan</td>
</tr>
<tr>
<td>QCA</td>
<td>Quinoxaline carboxylic acid – marker residue of carbadox</td>
</tr>
<tr>
<td>RAMS</td>
<td>Residues, Antimicrobials, Micro-organisms Infraction Tracking Database</td>
</tr>
<tr>
<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
</tr>
<tr>
<td>SCC</td>
<td>Standards Council of Canada</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
</tr>
<tr>
<td>VDD</td>
<td>Veterinary Drugs Directorate (in Health Canada)</td>
</tr>
<tr>
<td>VMP</td>
<td>Veterinary Medicinal Product</td>
</tr>
<tr>
<td>WRL</td>
<td>Working Residue Limit</td>
</tr>
</tbody>
</table>

CONVENTIONS USED IN THE REPORT

Bullet points marked thus ➤ indicate findings made by the mission team on the basis of observations on the spot or assessment of information received.
1. **INTRODUCTION**

The mission took place in Canada from 28 May to 7 June 2007. The mission team comprised two inspectors from the Food and Veterinary Office (FVO). The mission was undertaken as part of the FVO’s planned mission programme, evaluating control systems and operational standards in this sector.

Representatives from the central competent authority (CCA), the Canadian Food Inspection Agency (CFIA) – an agency of the federal government - accompanied the inspection team during the whole mission. An opening meeting was held on 28 May 2007 with the CFIA and representatives of the CCA responsible for the authorisation of veterinary medicinal products – Health Canada. At this meeting, the objectives of, and itinerary for, the mission were confirmed by the inspection team and the control systems were described by the Canadian authorities.

2. **OBJECTIVES AND SCOPE OF THE MISSION**

The objective of the mission was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, including the controls on the distribution and use of veterinary medicinal products (VMPs) and feed additives, the use of which may give rise to residues in such products. The mission was based on the evaluation of the equivalence of Canada’s standards to Council Directive 96/23/EC and other relevant Community legislation in this field, including legislation on the control and distribution of VMPs. The mission focussed on the roles of the CFIA and Health Canada at central and provincial levels (federal representations in the provinces), the legal and administrative measures in place to give effect to the relevant EU requirements with regard to import of food of animal origin into the European Union (EU), controls with regard to residues and VMPs and their operation, and the performance of residue laboratories. Attention was paid to examining the implementation of corrective actions promised by CFIA and Health Canada in response to recommendations made in the report of the previous FVO residues mission to Canada (DG(SANCO)/1188/2000). The following sites were visited and meetings were held with:

<table>
<thead>
<tr>
<th><strong>COMPETENT AUTHORITIES</strong></th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competent Authorities</td>
<td></td>
</tr>
<tr>
<td>Central</td>
<td>2</td>
</tr>
<tr>
<td>Regional</td>
<td>3</td>
</tr>
</tbody>
</table>

| **LABORATORIES** | 4 | 2 governmental laboratories – CFIA Saskatoon and CFIA Calgary - and 2 private laboratories involved in residues controls. |
|                 |   |  |
| ** FARMS**      | 3 | 1 horse feedlot exporting horsemeat to the EU in Alberta; 1 veal calf unit in Québec with private veterinarian in attendance; 1 Hormonal Growth Promotant – Free (HGP-free) beef feedlot in Alberta (with the HGP-free programme CFIA-accredited veterinarian in attendance). |

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1 EU legal acts quoted in this report and included in the Annex refer, where applicable, to the last amended version.
3. LEGAL BASIS FOR THE MISSION

The mission was carried out under the general provisions of Community legislation, and in particular:

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

Whilst there is an Agreement between the European Community 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 report is provided in the Annex.

4. BACKGROUND

4.1. COUNTRY STATUS IN RELATION TO SUBMISSION OF RESIDUES CONTROL PLANS


4.2. SUMMARY OF PREVIOUS MISSION RESULTS

A previous residues mission to Canada was undertaken from 16 to 26 September 2000 (DG(SANCO)/1188/2000), the report of which has been published on the Health and Consumer Protection Directorate General web site at:


The report identified a number of deficiencies in several key areas of the Canadian system for residues control, including shortcomings in the performance of laboratories, a lack of control on the availability of veterinary medicinal products, the existence of Maximum Residue Limits for a relatively small number of pharmacologically active substances, and problems with the implementation of Hormonal Growth Promotant (HGP)-free beef system. In response the Canadian authorities undertook to rectify these issues by means of an action plan which
addressed four main areas: (1) Planning to ensure that there was a national approach for the effective control of extra-label use of drugs; (2) Broadening the ban on the use of diethylstilbestrol in food producing animals; (3) Establishing legal limits for all veterinary drug residues under the authority of the Canadian Food and Drugs Act and (4) implementing a mutually agreed residues sampling and testing programme.

4.3. **RAPID ALERT SYSTEM FOR FOOD AND FEED (RASFF) NOTIFICATIONS FOR CONSIGNMENTS FROM CANADA CONCERNING RESIDUES**

Regarding residues of veterinary medicinal products, there have been no RASFF alerts or notifications for food of animal origin exported to the EU from Canada over the last three years.

4.4. **PRODUCTION AND TRADE INFORMATION**

Detailed information on the quantities of food commodities of animal origin exported from Canada to the EU in 2006 (listed in the table below) was supplied by the CFIA. (Source: Statistics Canada).

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Total amount (tonnes)</th>
<th>Live animals</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bovine meat</td>
<td>-</td>
<td>Bison</td>
<td>2</td>
</tr>
<tr>
<td>Ovine meat</td>
<td>-</td>
<td>Chicken</td>
<td>1</td>
</tr>
<tr>
<td>Swine (sausage meat)</td>
<td>69.3</td>
<td>Chicken Eggs</td>
<td>329400</td>
</tr>
<tr>
<td>Equine (horse meat)</td>
<td>813.4</td>
<td>Day Old Chicks</td>
<td>102671</td>
</tr>
<tr>
<td>Aquaculture</td>
<td>Data being compiled*</td>
<td>Day Old Turkeys</td>
<td>180863</td>
</tr>
<tr>
<td>Bison Meat</td>
<td>186.4</td>
<td>Donkey</td>
<td>7</td>
</tr>
<tr>
<td>Bison, Elk and Horse Meat</td>
<td>3621.6 (all to France)</td>
<td>Duck</td>
<td>500</td>
</tr>
<tr>
<td>Wild game</td>
<td>-</td>
<td>Duck Eggs</td>
<td>600</td>
</tr>
<tr>
<td>Honey</td>
<td>1202</td>
<td>Horses</td>
<td>243</td>
</tr>
<tr>
<td>Dairy products</td>
<td>9231</td>
<td>Moose</td>
<td>1</td>
</tr>
<tr>
<td>Processed egg</td>
<td>908.3</td>
<td>Musk Ox</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other Hatching Eggs</td>
<td>55800</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Swine</td>
<td>649</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Turkey</td>
<td>2994772</td>
</tr>
</tbody>
</table>

* In 2005, the total national production of aquaculture product in Canada was 155,000 tonnes, including both finfish and bivalve molluscs. Approximately 1% of the national production was exported to the EU.

5. **MAIN FINDINGS**

5.1. **NATIONAL CHEMICAL RESIDUE MONITORING PLAN**

5.1.1. **Planning**

The legal basis for the planning and implementation of the annual national chemical residue monitoring plan (NCRMP) is laid out in several federal Acts and Regulations made there under.

The NCRMP is designed 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") and is principally based on unbiased statistical sampling. There is also provision for biased or directed sampling where samples are obtained from food products/animals which are suspected of containing residue concentrations in excess of acceptable standards.
In Canada for all commodities and slaughter animal groups the content of the monitoring programme is developed following a statistical analysis of the previous 1 or 2 years monitoring data. This analysis is based on a statistical model that estimates worst case contamination levels and in turn potential risk associated with such levels. The calculation is at the level of the specific contaminant or residue and the specific food group or animal species. It includes consideration of the toxicity of the residue, the consumption volumes of the commodity and the background worst case contamination of the commodity by the residue. Based on these calculations a risk estimate is produced for each commodity/residue combination. In turn the numbers of samples required in the following year’s monitoring programme are determined on the basis of the risk grouping which has been assigned to the commodity/residue. The assignment is such that monitoring resources are focused on those commodity/residue combinations which represent the greatest potential risk to the consumer. CFIA is of the opinion that this process leads to an approach similar to the targeted approach of the EU in that those commodity/residue combinations posing the greatest potential risk are tested in the greatest annual test volumes.

Directed sampling programmes may be initiated if the monitoring data reveals that a specific issue of non-compliance needs to be addressed over and above what is carried out under the monitoring programme. This might result in a programme focused on a particular geographic region, a particular residue or a commodity group.

The NCRMP is essentially composed of separate plans for meat (all species), dairy, eggs and honey, all of which are designed (taking account of the above risk evaluation process) by the National Manager, Chemical Hazards in CFIA at central level. For aquaculture products, a separate plan is elaborated by that part of CFIA responsible for this sector. The same rationale as that used for the other commodities is used for elaboration of the aquaculture plan.

The mission team noted that:

- all relevant bodies within CFIA are involved in the planning process – laboratories and network programme specialists for each of the commodities;
- for the meat plan, at central level, samples are assigned to locations (federally registered slaughterhouses) in proportion to slaughter volumes. The meat plan focuses solely on domestic production. Imported meat products could be sampled if this was warranted, however there is no specific sampling plan for this. For other commodities (particularly honey and aquaculture), imported products are included along with domestic product in the plan. For the aquaculture plan, imported products account for the majority of testing;
- for dairy, eggs and honey, the production patterns in a given region are used as a criterion for the distribution of samples. In contrast to the meat programme, where sampling is decided at central level, for the other commodities decisions on which establishments to sample are taken at regional level. For honey registered establishments non-registered establishments and individual producers are liable to be sampled. Eggs are sampled at (registered) grading stations;
- the sampling year follows the fiscal year i.e. starts in April and runs through to March of the following year. The 2007-2008 plan was delayed by a month due to an increase in the time taken to award contracts for testing to the commercial laboratories involved in delivering some of the programme;
for the majority of commodities (honey, milk, egg, swine, equine, rabbit and wild game), all of the requisite substance groups required by Council Directive 96/23/EC are included in the plan however for bovine and ovine/caprine, substance group B3d (mycotoxins) is not covered;

- the plan for honey does not include fumagillin, one of two antibiotics authorised for use in honey bees in Canada. The other substance, oxytetracycline, is included;

- for aquaculture, in contrast to the situation in 2000, the plan is administered by CFIA and not the industry;

- in the aquaculture plan covering domestic production there is no testing for substance groups A1, A3, A6. (A6 – chloramphenicol and nitrofurans are included in testing of imports). Testing for Group B1 is restricted to sulphonamides and tetracyclines and the number of samples taken of domestically produced fish is much less than the number required under Codex guidelines to detect a 1% violation prevalence rate in the population with 95% confidence;

- the mission team was informed that steroids (e.g. methyl testosterone) had not been used for the purposes of sex inversion in farmed finfish in Canada for many years and there is no authorised VMP containing this steroid. The CFIA therefore took the view that testing for steroids in finfish is not necessary;

- for poultry substance groups A1, A2, A3, A4 and A5 not covered. (For 2007-2008, CFIA undertook to rectify this difference in respect of those poultry which are slaughtered in the only EU approved poultry slaughterhouse as a standalone testing programme outside the NRCMP).

5.1.2. Implementation

After being elaborated, the meat plan is disseminated from central level to so-called ‘Area Network Programme Specialists’. These specialists are located in each of the four Operational Areas into which Canada has been divided for the purposes of residues control (‘West’, ‘Ontario’, ‘Québec’ and ‘Atlantic’). Each of the four Operational Areas is comprised of at least four regions (six in ‘West’) making eighteen regions in all. In collaboration with his/her contact from CFIA Operations Division also located in each of the Operational Areas, the assigned Network Programme Specialist reviews the sample allocation in the plan and verifies that each of the identified slaughterhouses is still in operation and slaughters the species or classes indicated in the plan. The Area Network Programme Specialist then forwards the sampling plan to the specific slaughterhouses, adding any reminders about the sampling and submission procedures deemed necessary in his/her area.

For eggs products and honey, the NCRMP is disseminated from the central level to the relevant Area Network Programme Specialists dealing with these commodities in each of the four Operational Areas. These individuals forward the sampling plans to the relevant CFIA Operations Division, whose staff will carry out the sampling. For dairy, eggs and honey, samples are allocated to a region, not to a specific establishment. Inspectors are instructed to conduct broad sampling across the region, following the sampling schedule provided.

For the dairy plan, the numbers of samples for raw milk sampling are sent directly to the relevant provincial government inspectors from the Area Network Programme Specialists since sampling of raw milk is not carried out by CFIA staff but is coordinated with the provincial governments which are responsible for collecting
samples at the farm level. The provincial officials collect the allocated samples and provide these to CFIA field staff for their completion of the requisite Laboratory Sample Tracking System (LSTS) documentation and shipment to two different CFIA laboratories for analysis.

The aquaculture plan operates as a standalone programme to the rest of the NCRMP. All samples are taken in federally registered establishments by CFIA personnel.

The mission team noted that:

- all sampling in the NCRMP is carried out by officials. With the exception of raw milk sampling, CFIA inspectors take residues samples in federally registered establishments. Samples are randomly allocated and sampling is unforeseen by the owner;
- detailed instructions for taking samples (meat from all species) are contained in the Meat Hygiene Manual of Procedures. The Dairy Programme has a sampling chapter in the Dairy Products Inspection Manual and the Egg Programme has a sampling chapter in the shell egg Inspection Manual. For honey, directions for taking honey samples are provided for inspection staff when the NCRMP is distributed. In the aquaculture plan, guidance on sampling is given in the actual plan itself;
- in the beef slaughterhouse visited, the entire plan was available (in an Excel spreadsheet) though sampling under the 2007-2008 plan had yet to start from this establishment. The CFIA veterinarian in charge of the establishment knew when samples were to be taken, the matrices to be sampled and the laboratories to which the samples should be sent. Sampling materials were available;
- in the CFIA laboratory in Calgary it was stated that for the 2006-2007 plan, all of the raw milk samples had been delivered in the period January to March 2007. It was not known when these samples had been taken by the provincial authorities or whether some or all had been stored pending dispatch to Calgary. In the Annex to Commission Decision 98/179/EC it is specified that sampling should be carried out at variable intervals spread out over the entire year;
- notwithstanding the uncertainty over the sampling dates of the raw milk samples, in a selection of individual cases chosen at random by the mission team it could be seen that in general the submission of samples to the laboratories had occurred promptly following sampling;
- there is uniform sample submission documentation which accompanies those samples being submitted to CFIA laboratories. Although CFIA at central level stated that these are not used for samples sent to private laboratories which only receive the NCRMP identifier number, this was not actually the case on the spot – hand written ‘LSTS’ forms had been submitted with the samples to the private laboratories;
- sampling for the 2007-2008 NCRMP had commenced in May 2007 and samples had been delivered to all of the laboratories visited. A commercial courier was used to deliver the samples. Samples were appropriately packaged and identified but not officially sealed on arrival at the laboratory in order to

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2 In their response to the draft report the Canadian Competent Authority stated that the samples taken in the Province of Alberta had been taken during the period June to December 2006. Sampling is more spread throughout the year in some Provinces compared to others.
guarantee security of the sample. In the Annex to Commission Decision 98/179/EC it is specified that official samples should be sent in officially sealed containers;

- in both of the private laboratories visited, analysis did not commence (even though samples had been received) until CFIA authorised the release of money for testing, usually on a monthly basis. Both laboratories decided what testing was to be carried out in order to ensure that the monthly budget allocation from CFIA was spent and would continue testing outstanding samples taken in the previous sampling year (to make up the numbers for a given month) unless otherwise instructed by the National Manager, Chemical Hazards;

- the target turnaround time of 40 working days from sample receipt to reporting of a result in each of the CFIA laboratories was rarely met for monitoring samples. There were often delays of several months for a variety of reasons. In the Saskatoon laboratory it took 6 months from sample receipt to the reporting of AMOZ in a pork sample. However, the turnaround times for suspect or directed samples were generally quite short;

- reporting of results by the private laboratories was batch-wise on a monthly basis. When putative non-compliant results were detected, these were highlighted to the National Manager, Chemical Hazards in CFIA in advance of the monthly reporting cycle. It was stated that there was regular communication between the National Manager and the private laboratories;

- in some cases of putative non-compliant results selected at random by the mission team in both of the private laboratories, the time taken from receipt of a sample to reporting of a result was sometimes very long. For example in two cases of carbadox in pig liver and trenbolone in bison liver tested in private laboratory ‘A’, ten and nine months respectively had elapsed between sampling and reporting the result to CFIA (in both cases 9 months from laboratory receipt of the sample to reporting). For a case of trenbolone in bison liver tested in private laboratory ‘B’, 7 months elapsed between receipt of sample (on the same day as when it was sampled) and reporting the result.

5.1.3. Supervision of implementation

The responsibility for ensuring that sampling is carried out according to the plan rests with the Area Network Programme Specialists in each of the four Operational Areas and, in respect of the meat programme alone, Regional Veterinary Officers (in the Operations Division, whose inspection personnel actually take the samples). Regional Veterinary Officers are obliged to check that (meat programme) sampling is being performed according to the schedule. With regard to the meat plans, in cases where an impact on the NCRMP is anticipated (e.g. closure of slaughterhouse, substantial changes in the numbers or classes of animals being slaughtered or other work constraints), the relevant Area Network Programme Specialist is informed who in turn communicates this to the National Manager, Chemical Hazards in CFIA at central level. On the basis of this information, the National Manager may decide to reallocate samples to other facilities. Changes to the plan are then cascaded back down the line from the central level to the Operational Areas.

The mission team was informed that because of the possibility of slaughterhouse closures etc, approximately 10% more samples are included in the plan than are needed.
Concerning the aquaculture plan, supervision of implementation is managed on an ongoing basis at operational area level and quarterly at central level.

With regard to supervision of implementation of the plan, the communication channels established for dissemination of information within CFIA gives the possibility of a real time overview of how sampling and testing is progressing. Those samples destined for analysis in CFIA Laboratories are submitted with sample documentation generated by the computerised Laboratory Sample Tracking System (LSTS). LSTS allows inspectors and CFIA management to retrieve testing results and there is a provision for automatic updates of results by e-mail to officials subscribing this service.

With regard to those samples submitted to the private contract laboratories (accounting for approximately 95% of the testing carried out), these laboratories do not use LSTS. The National Manager, Chemical Hazards receives monthly reports from the contract laboratories and is thus in a position to track whether scheduled samples have been received.

The mission team noted that:

- in contrast to the situation in 2000 where it was not possible using LSTS to extract performance data to determine the number of samples received versus tested etc, this is now possible. With regard to the delivery of the 2006-2007 NCRMP, the number of samples planned was compared with the number received and the number analysed in each of the four laboratories visited. For the samples allocated to the CFIA laboratory in Saskatoon, in the main, sampling had proceeded as planned. For the CFIA laboratory in Calgary, there was a shortfall of around 30% in number of domestic honey samples submitted for analysis versus the number planned to be sampled;

- in both of the private laboratories visited, for some commodities there were significant shortfalls in the number of tests scheduled in the plan versus the number of samples received. For example in the case of dairy products (cheese, butter etc), in the first private laboratory visited, 169 samples were scheduled to be tested for chloramphenicol, 29 were received and testing was completed on 18. The corresponding figures for gestagens were 292, 0 and 0. In the second private laboratory whilst the bulk of domestic meat samples had been taken (1890 planned, 1652 received), 56% (925) of the number received had been reported;

- whilst the information management tools are in place to facilitate supervision of implementation, the shortfalls in sampling suggest that supervision of implementation has not been fully effective.

5.1.4. Other residues control programmes

5.1.4.1. HGP-free beef programme

In respect of the export of HGP-free beef to the EU, the CFIA has instituted a standalone HGP-free beef control programme in 2001 which consists of a registration system for farms, 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, keeping of records at specified stages in the production process on farm. This is augmented by on-farm urine sampling of cattle carried out by the CFIA-accredited private veterinarian and the cost of this sampling
is borne by the farmer. These samples are all submitted to the CFIA Saskatoon laboratory for analysis.

For the slaughterhouses, there is also a clearly described system of controls which are designed to ensure that there is no possibility of co-mingling of hormone treated and HGP-free cattle. These include compulsory physical checks of 10% of the consignment for evidence of hormone implants, identity checks, segregation of animals at all stages of the meat production process and maintenance of appropriate documentary records. In addition, urine samples are taken at slaughter and analysed for residues of HGPs. These measures are supervised by the CFIA veterinarian in the slaughterhouse.

The mission team visited a cattle feedlot on which both HGP-treated and HGP-free cattle were kept and the EU-approved slaughterhouse in which the HGP-free cattle are due to be slaughtered later this year. The mission team noted that:

- there has been no export of HGP-free beef to the EU for several years. The system has recently been reactivated and the first shipments of HGP-free beef to the EU are planned for later this year. Even though the system has been dormant for several years, in 2006-2007, five samples were submitted under this programme to CFIA Saskatoon for analysis. All results were compliant;
- on the feedlot visited where both HGP-implanted and HGP-free cattle were being held, the HGP-free programme was being implemented properly with all of the specified requirements having been satisfied. HGP-free cattle were appropriately identified with the Canadian Cattle Identification Agency (CCIA) radio frequency identifier (RFID) tags and separate barcoded tags and ‘hormone-free’ tags and were kept in a secure segregated pen;
- in the slaughterhouse, whilst there has been no production of HGP-free meat, there were systems in place to ensure that the programme would function as specified and both of the CFIA veterinarians in the establishment operator had full knowledge of the requirements of the HGP-free programme;
- there is no separate HGP-free system established for veal calves since HGPs are not authorised for use in this production sector. The industry is mainly located in the province of Québec and to a lesser extent in Ontario. In Québec HGPs are available only on prescription. Health Canada issued a recommendation in spring 2004 that HGP implants should not be used in veal calves, with the use being phased out by January 2005. Since November 2005, CFIA policy as laid down in the Meat Inspection Manual of Procedures is that any finding of a HGP implant in veal calves would result in the destruction of the carcase;
- as a result of finding residues of testosterone at injection sites (not implants) in veal calves detected in an intensive suspect testing programme in early 2005, a CFIA policy to deal with such injection sites was published in Summer 2005. There have been no non-compliant results for hormone residues at injection sites from mid 2005 to date;
- there is no separate HGP-free system established for bison since HGPs are not authorised for use in this species. The mission team was told that (a) it would be difficult to implant bison as they are semi-wild animals and difficult to handle, (b) male bison are not castrated and therefore do not benefit from HGP implants and (c) due to the meat grading system the implantation of female bison would be counterproductive since it would result in maturation earlier than expected and a consequent downgrading in carcase quality. However, it is not illegal to use HGPs in this species under extra-label drug use and, in the majority of provinces in Canada, HGPs are available over the counter. In 2004-2005 and
also in the 2006-2007 NCRMP, residues of trenbolone acetate (authorised as a HGP implant for cattle in Canada) were detected in bison liver. In the most recent year, 4% of the randomly sampled bison livers contained residues of trenbolone. (See Section 5.1.5. on Follow-up).

5.1.4.2. Ractopamine-free pork programme

The use of the beta-agonist ractopamine is authorised in Canada for use as a growth promoter in pigs. In 2006 CFIA indicated to the Commission services that they wished to export ractopamine-free pork to the EU and as a pre-requisite would implement a ‘split’ system, using the principles of the HGP-free beef programme. As yet, there are no producers enrolled in this programme and it has not yet started. Consequently it was therefore not possible to evaluate its implementation. The mission team noted that:

- monitoring of ractopamine is routinely carried out under the NCRMP in all meat producing species. Whilst ractopamine residues have been detected in pigs, no residues have been detected in any of the other species tested.

5.1.4.3. Establishment antibiotic testing programmes

A number of other residue monitoring programmes for antimicrobial residues are running (at provincial level and also by the establishments/companies themselves) and the results of these programmes were submitted to the Commission services along with the 2006 NRCMP. CFIA has stated that due to different provincial jurisdiction, there can be different agreements with each province. The province of Ontario has an informal agreement with the CFIA under which violative results from the provincial Chemical Residue Monitoring Programme in domestic establishments are provided to CFIA, and followed up in the same manner as CFIA NRCMP results would be. In Québec, violative results found through the ‘Sulfa On Site’ programme in the slaughterhouses are shared with the provincial authorities under a special agreement for their own regulatory actions.

Testing done by companies to meet Quality Control requirements of clients is common but the results are not routinely known to the CFIA, though CFIA could have access to this information on request.

5.1.5. Follow-up of non-compliant results

CFIA is responsible for the follow-up of non-compliant residues results generated under the NCRMP. CFIA have dictated that results should be issued from the laboratories with a numerical value – i.e. the laboratories should not indicate on their results report whether the result is non-compliant. It is up to the CFIA to decide whether a result is non-compliant and if follow-up investigations are to be carried out, on a case by case basis.

For those samples tested in the CFIA laboratories, the results are reported back to the inspectors in the Operations Division (who took the samples) and the Area Network Programme Specialists via LSTS. The results of those samples submitted to the private contract laboratories are not reported using LSTS. Instead, information on non-compliant results for these samples is transmitted from the National Manager, Chemical Hazards to the Area Network Programme Specialists. In the case of raw milk samples, results are sent to the Area Network Programme
Specialists who in turn inform their Provincial Dairy counterparts. In cases where there are violations there is a follow-up by CFIA and the provinces.

The mission team noted that:

- whilst the CFIA laboratory in Saskatoon reported results as per CFIA requirements, the Calgary laboratory did not as results were classified as either satisfactory or unsatisfactory. Similarly in one of the two private laboratories visited, results were reported as non-compliant;

- a monthly meeting is held with the CFIA officials at central and area levels to discuss *inter alia*, residues issues, progress being made in investigations etc. Minutes are kept of these meetings and the mission team had evidence that this was the case however, precise details of the discussions held were not released to the mission team because of national laws on confidentiality;

- whilst 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, the list of these substances has not yet been drafted and consequently this right of entry can not currently be invoked by CFIA. CFIA aims to have the list published by Autumn 2007 for public consultation prior to (planned) adoption in law in 2008;

- under the Food and Drugs Act and Regulations made under that Act it is possible for CFIA to inspect on-farm for banned substances when residues of these have been detected at slaughter. When feedingstuffs are implicated as a source of residues, CFIA may also enter a farm and take samples (of feedingstuffs) under the Federal Feed Act and Regulations. Consequently at present if a residue of an authorised veterinary medicine is detected at slaughter in excess of either a Maximum Residue Limit (MRL) or, where these have not yet been promulgated in the Food and Drugs Regulations, an Administrative MRL (AMRL), CFIA inspectors have no legal basis to enter a farm and take samples for follow-up investigation. In spite of this issue CFIA stated that this lack of legal basis has not prevented on-farm investigations from being carried out and there are ‘enforcement and investigations units’ in each of the Operational Areas who work with the Area Network Programme Specialists;

- in contrast to the provisions of Council Directive 96/23/EC, CFIA has no legal basis under either the Meat Inspection Act, Health of Animals Act or Food and Drugs Act to ‘block a farm’ and prevent a farmer from placing potentially contaminated animals on the market when residue violations have been detected.

The mission team was informed that in the meat programme, on farm investigations in the event of non compliant results detected are performed on a priority basis and are tracked in the Residues, Antimicrobials, Micro-organisms Infraction Tracking Database (RAMS). RAMS has been operational since January 2005. With the exception of the Québec operational area, in the remaining three operational areas, the Area Network Programme Specialists function as the RAMS co-ordinators for follow up in the commodities for which they are responsible. In Québec there is a separate RAMS co-ordinator who reports to the Area Network Programme Specialist. The role of the RAMS coordinator is to assess whether the result is violative and if so, launch the trace-back procedure to identify the farm of origin and initiate the on-farm investigation which will be conducted by CFIA Operations Division inspection staff. If the non-compliant residue is as a result of a feed contamination problem, a CFIA Feeds inspector will perform the on-farm inspection.
When non-compliant results are found in the dairy, egg, honey and aquaculture programmes, investigations are initiated which includes trace-back activities to the farm and feed mill (depending on programme), follow-up (targeted) sampling, monitoring and procedural review. Compliance/enforcement activities can include food recall, product detention, seizure, and destruction.

The mission team noted that:

- RAMS is not currently applied to commodities other than meat, though according to CFIA, the system could be extended to the other commodities;
- entry of residues data into RAMS differs depending on where the sample was tested. For the CFIA laboratories, results are reported by means of the LSTS system and the relevant Area Network Programme Specialist will decide whether the result is non-compliant and should trigger a trace-back investigation. For those samples tested by the private laboratories, the National Manager, Chemical Residues makes this decision;
- the RAMS system facilitates the collation of follow-up activities carried out on a specific case, identifies which CFIA personnel have been involved, the dates and nature of actions taken, and allows an overview of the actions taken by both CFIA at central and area levels. Both of the Area Network Programme Specialists questioned were familiar with the programme and could demonstrate the documented actions taken in respect of residue violations in the meat programme;
- as in 2000, the hard copy of the residues follow up files is kept in the Operational Area in which it is performed, however, RAMS stores an electronic record (including scanned copies of original reports and investigation sheets) which is accessible at all levels of CFIA.

In the results submitted to the Commission services for the 2004-2005 sampling period, there were 11 AOZ in suspect domestic honey, 4 trenbolone acetate positives in bison and 2 in veal calves (HGP implants are not authorised for use in either category of animal), 10 thyrostats in veal calf liver, 5 testosterone injection sites in veal calves, 3 zeranol positives in veal calf liver and 1 ivermectin in horse liver.

In respect of the AOZ findings in honey, the mission team was informed that in 2004, following the discovery of nitrofurantoin residues in imported honey, CFIA carried out directed sampling and testing of honey to determine the extent of contamination in the Canadian marketplace. Analysis was performed on domestic, imported and blended honey (import and domestic honey). The 11 AOZ non-compliant samples were found in blended honey all of which contained AOZ honey from the same foreign country. None of the unblended domestic honey samples contained any AOZ residues, though some of the samples of unblended honey from the country in question did contain AOZ residues. CFIA concluded that the contamination in the blended honey samples was due to the imported honey.

In respect of the thyrostat non-compliant results, residues of thiouracil were detected. The concentrations were very low (~ 10 µg/kg) and similar to those reported in the scientific literature as being due to ingestion of brassica plants. No evidence of illegal use of thyrostats was found on these farms but evidence of a link with the use of canola or feeding of cruciferous plants was found on some farms. Consequently these results were attributed to natural causes and not illegal use.

In respect of the findings of trenbolone acetate in livers from 2 veal calves and 4 bison, trace-backs were not available in RAMS as they occurred before the system
was operational. CFIA stated that these investigations became obsolete once Health Canada issued a recommendation in January 2005 that HGP implants should not be used extra-label in the veal sector and when an MRL for trenbolone was established for bovine as the concentrations found in the bison liver did not exceed this MRL. The mission team noted that:

- there is no legal basis preventing the use of HGP implants (which are freely available without veterinary prescription in all provinces with the exception of Québec) in either veal calves or bison. As bison are not cattle and there is neither the authorisation to use trenbolone in this species nor an MRL for this species, the finding of trenbolone in bison liver should have been treated as an adulteration of food under the Food and Drugs Act.

Non compliant results for the 2006-2007 NRCMP were furnished to the mission team during the opening meeting. The mission team noted that:

- in bison, approximately 4% of the random monitoring samples of liver contained residues of alpha-trenbolone (7/188) at concentrations ranging from 2 - 4 µg/kg. There is an administrative MRL of 10 µg/kg in cattle liver. These non-compliant samples were reported in February and March 2007 but had not been entered into the RAMS system and consequently no follow-up investigations had been initiated to date (See section 7 – Closing Meeting);

- in the case of a finding of AMOZ (the marker residue of furaltadone which is banned from use in food producing animals in Canada as in the EU) in veal calf liver, there were very long delays in reporting the result from the laboratory (five months – largely because (a) this was the first detection of this residue, (b) the concentration was quantitatively less than the Limit of Quantification of the method but was unequivocally confirmed and (c) there was no established policy as to what to do in such cases). To date, follow up samples from this farm have not been furnished to the laboratory for analysis. A detailed file showing the measures and investigations that had been taken was available for inspection. The farm had been visited and no evidence of the use of furaltadone could be found. No samples of feed or urine had been taken because of the absence of an analytical method for these matrices. It is planned that the next batch of calves slaughtered on this farm will be sampled. This case is ongoing;

- in samples chosen at random on the RAMS system in the CFIA area office in Alberta, it could be seen that investigations had been carried out but the timescale from initial sampling through to the generation of an analytical result and the completion of an investigation was sometimes very long. In one case of carbadox in pork (carbadox is not authorised in Canada), the sample report was issued eight months after sampling and more than one year after the initial sample was taken. The RAMS file was still not complete though the Network Programme Specialist had been active in pursuing the case. Other investigations though had been dealt with much more promptly (e.g. two months from sampling to completion of the follow up investigation of a horse containing residues of tilmicosin – in this case the animal had originated in the USA).

5.2. LABORATORIES

5.2.1. General description

Under the NCRMP, CFIA contracts out approximately 95% of the testing to private laboratories. In the 2006-2007 NCRMP, six laboratories were involved (3 CFIA
facilities and 3 private laboratories). For the 2007-2008 NRCMP there are now eight laboratories – the same three CFIA laboratories (Saskatoon for meat and live animal – urine samples, Calgary for eggs, raw milk and honey and Dartmouth for raw milk and fish) and five private laboratories. The current contracts for the private laboratories run from 1 April 2007 to 31 March 2009.

All of the laboratories are accredited by the national Accreditation body, the Standards Council of Canada (SCC), to ISO 17025. All of the methods used within the NRCMP are included within the scope of accreditation – indeed this is a prerequisite for the private laboratories to bid for the work.

The mission team noted that:

- CFIA laboratories are not permitted to undertake commercial work. The Canadian government is the sole customer. All directed sampling (i.e. suspect sampling and compliance testing) is carried out in the CFIA laboratories;
- senior CFIA laboratory staff participate in ISO 17025 audits of the private laboratories in their role as SCC auditors;
- in addition to a limited volume of testing under the NCRMP, the CFIA laboratories are responsible for analytical method development. These methods are made available to the private laboratories which are free to use the methods or alternative methods which, as a minimum, must meet the same performance criteria as the CFIA methods. Many of the methods being used for veterinary drug residues in both private laboratories visited had been adapted from CFIA methods developed in both of the laboratories in Saskatoon and Calgary;
- the tender documents for the 2007-2009 period were extremely prescriptive as regards the analytical standards that needed to be met by the successful bidders;
- all of the laboratories could be considered state of the art and were well equipped with appropriate instrumentation and an adequate number of staff for the tasks in hand;
- comprehensive quality assurance programmes were in operation in each of the laboratories which were functioning as expected of laboratories accredited to ISO 17025;
- in each case the laboratories had been subject to an ISO 17025 audit by SCC within the last three years. When non-compliances had been noted in the SCC report, these had been acted upon satisfactorily by each of the laboratories.

5.2.2. On the spot visits in the laboratories

The mission team visited four laboratories – two governmental laboratories (CFIA Saskatoon and CFIA Calgary) and two private laboratories designated ‘A’ and ‘B’ which are carrying out the bulk of analyses for residues of veterinary medicines in the NCRMP. Both of the CFIA laboratories and private laboratory ‘A’ had also been visited previously during the 2000 FVO residues mission.

5.2.2.1. CFIA Saskatoon

The laboratory is responsible for analysing samples taken under the meat programme and bovine samples taken under the HGP-free programme (on farm and slaughterhouse urine samples).

The mission team noted that:
laboratory personnel have expertise in residue chemistry and have access to up to date relevant scientific literature. The number of staff is commensurate with the activities being performed. The laboratory is active in the development and publication of analytical methods and has an international reputation in this regard.

in contrast to the findings of the 2000 mission, the laboratory undertakes inter alia, one of the key roles of an EU National Reference Laboratory – namely the organisation of proficiency tests for the laboratories in the Canadian network which are analysing animal tissue samples. Laboratories in other countries may also participate in these tests. For this role a dedicated team had been established and there was a regular schedule covering a comprehensive range of analytes (6 classes of analyte covering 10-14 test methods in a rolling cycle three times per year) at appropriate concentrations. It was stated that accreditation of this activity to ISO Guide 43 (for proficiency tests) is being considered.

performance of the laboratory in its own proficiency test programme in the three rounds in 2006 was satisfactory in one. In the remaining two, transcription errors accounted for the unsatisfactory results and corrective measures had been taken and documented in accordance with ISO 17025 requirements;

there is a Standard Operating Procedure (SOP) for validation of methods which is in the process of being revised. The current SOP is non-prescriptive but establishes performance criteria that are to be met. All data are corrected for analytical recovery (either by use of internal standards where applicable or by the use of matrix matched standard curves);

There are currently 23 test methods for residues of veterinary drugs and hormones which are included in the scope of accreditation which can be downloaded from the SCC website at [http://palcan.scc.ca/specs/pdf/307_e.pdf](http://palcan.scc.ca/specs/pdf/307_e.pdf) Three of these were chosen at random by the mission team and were examined in more detail. The mission team noted that:

the multi -amphenicol LC-MS screening method was comprehensively validated and was capable of detecting residues of chloramphenicol at concentrations below the Community Minimum Required Performance Limit (MRPL) of 0.3 µg/kg. There is an LC-MS-MS confirmatory method which is a non-routine method. Under the accreditation, the exceptional use of non-routine methods is permitted. The confirmatory method has not been fully validated however the number of identification points (parent ion + 2 product ions) meets Community requirements (Commission Decision 2002/657/EC). As the lowest spiking level in the method was 2.5 µg/kg of chloramphenicol it could not be determined if the method would reliably confirm this residue at the Community MRPL;

the screening GC-MS method for estradiol 17β in bovine urine did not cover the main metabolite in cattle – the 17α epimer. Full validation had been carried out for estradiol 17β and the limit of quantification (LoQ) of the method was < 1 µg/L with adequate repeatability. However, in the absence of testing for estradiol 17α, the method is not suitable for detecting the administration of estradiol 17β in cattle;

the screening GC-MS method for zeranol and stilbenes in bovine urine covered all of the stilbenes (in contrast to the situation observed in the 2000 mission) but still did not include the main zeranol metabolite, taleranol (though this is included in the corresponding method for tissues). The lowest spike in the standard curve for each of the analytes was 1 µg/L and the LoQ (1.5 µg/L) was
consistent with the levels expected to be seen in cases of use of this substance. Again, the absence of taleranol in the method risks not identifying the administration of zeranol in cattle;

- the marker residue for carbadox which is analysed in the laboratory is desoxycarbadox. In all of the other laboratories testing for this residue, a different marker residue is looked for – QCA. Laboratory staff stated that a finding of QCA may not necessarily indicate treatment with carbadox alone as this marker residue has also been associated with other substances reported in the scientific literature.

### 5.2.2.2. CFIA Calgary

The laboratory is responsible for analysing samples taken under the dairy, egg and honey programmes.

The mission team noted that:

- laboratory personnel have expertise in residue chemistry and have access to up to date relevant scientific literature;
- the laboratory participates in an internationally recognised proficiency test programme for veterinary drug residues in foodstuffs (Food Analysis Performance Assessment Scheme – FAPAS). In the twelve FAPAS rounds in which the laboratory has participated, performance was satisfactory in all except two. In one of these (sulphonamides and tetracyclines in pig muscle), this tissue is not routinely analysed in this laboratory and low recoveries had been seen though performance in a subsequent round with this material was satisfactory. In the second example (tetracyclines standard ‘mix’), the recoveries for all of the tetracyclines were all reduced by a factor of three, suggesting a systematic error. Corrective measures had been taken and documented in accordance with ISO 17025 requirements but these did not include re-analysis of further material;
- there is an SOP for validation of methods which is in the process of being revised. The current SOP does not emphasise the importance of repeatability and reproducibility criteria. All data are corrected for analytical recovery (either by use of internal standards where applicable or by the use of matrix matched standard curves);

There are currently 19 test methods for residues of veterinary drugs which are included in the scope of accreditation listed on the SCC website at: [http://palcan.scc.ca/specs/pdf/132_e.pdf](http://palcan.scc.ca/specs/pdf/132_e.pdf)

Three of these methods were chosen at random by the mission team and examined in more detail. The mission team noted that:

- the validation files in each case were well presented. Whilst the limit of detection (LoD) and LoQ had been calculated for the methods, repeatability and reproducibility data were not always available in the validation file even when these parameters could have been calculated. Laboratory staff indicated that this aspect was one of the issues to be addressed in the revision of the validation SOP. However, it could be seen that in each case, quality control charts for recovery were being maintained for each of the methods;
- in this laboratory there was a practice whereby the validation file was critically examined by an independent analytical chemist from another section in the laboratory who had not been involved in the method development and a report of this was appended to the file;
the LC-MS-MS screening method for amphenicols in honey had been comprehensively validated. In this case repeatability data had been calculated and the method was capable of detecting residues of chloramphenicol at concentrations below the Community MRPL of 0.3 µg/kg. The quality control chart plotted the recovery of analyte from samples spiked (fortified) at this concentration and the method was in full statistical control for chloramphenicol. With regard to thiamphenicol, the quality control chart showed that the method was out of control on three occasions (higher recoveries) but the analytical runs had not been rejected and the assay repeated as specified in the method SOP as there had been no non-complaint results in these analytical runs;

the LC-MS-MS confirmatory method for ionophore coccidiostats and nicarbazin in eggs was fully validated. The calculated LoQ for each analyte (range 1.2 – 5.2 µg/kg) allowed the detection of low level contamination of eggs with these substances and the number of identification points (parent ion + 2 product ions) meets the requirements of Commission Decision 2002/657/EC. The independent and extremely detailed review of the validation data which had been conducted in February 2007 concluded that the method was not reliable for the detection of nicarbazin. Laboratory staff indicated that this does not preclude the continued use of a method and it could be seen that for several other methods where agreed changes in protocol could be made to address accepted criticisms, these had been done;

the validation file for the screening LC-MS method for twenty sulphonamides (plus dapsone) in bovine milk and eggs showed that the LoQ had been determined for each of the analytes in both matrices. For those few sulphonamides which had a very high LoQ (e.g. sulphaguanidine and sulphanilamide) in the validation phase, these were not included in the assay as applied to real samples. Repeatability/reproducibility data were not calculated, though the individual quality control charts selected at random by the mission team showed that the recoveries of several sulphonamides in both matrices were in full statistical control over time. There is as yet no confirmatory method in place for sulphonamides and an LC-MS-MS method is being developed.

5.2.2.3. Private Laboratory ‘A’

The laboratory is responsible for analysing samples taken under the meat, dairy, egg and honey programmes and delivers the bulk of testing for these commodities under the NCRMP.

The mission team noted that:

- there are presently 82 analytical methods for testing food of animal and plant origin for inter alia, veterinary drug and pesticide residues, which are included within the scope of accreditation;
- Laboratory Information Management System (LIMS) software developed in this laboratory allowed the National Manager, Chemical Hazards at central CFIA to have access to raw data (chromatograms etc) for reported results;
- performance in proficiency tests organised by CFIA and the Association of Official Analytical Chemists was satisfactory in the majority of cases. On the one occasion when a result was unsatisfactory, appropriate corrective action had been taken and documented;
- a validation SOP was in place, which in contrast to that in CFIA Calgary, included requirements for the determination of inter alia, LoD, LoQ,
repeatability, reproducibility and ruggedness. In a selection of analytical methods’ validation data examined by the mission team, the method performance parameters had been calculated according to the SOP for all of the above parameters with the exception of ruggedness – a relatively recent addition to the validation SOP. All of the methods examined (chloramphenicol in animal tissues, dairy products and honey, phenylbutazone and flunixin in dairy products, carbadox in pig liver, and trenbolone (alpha and beta) in bovine liver) were fit for purpose with appropriate criteria for the acceptance/rejection of results, and were sufficiently sensitive to detect trace quantities of these analytes;

- quality control charts for each method were maintained and it could be seen that when a method was out of statistical control (recoveries of spikes outside acceptable range), appropriate action had been taken and documented;

5.2.2.4. Private Laboratory ‘B’

The laboratory is responsible for analysing samples taken under the meat, dairy, egg and honey programmes under the NCRMP. The mission team noted that:

- there are presently 90 analytical methods for testing food of animal and plant origin covering veterinary drug and pesticide residues, which are included within the scope of accreditation;

- performance in proficiency tests organised by CFIA was satisfactory in the majority of cases. On the one occasion when a result was unsatisfactory (for tranquilisers), the fault had been traced to the storage conditions of the solid phase extraction columns immediately prior to analysis of the sample and appropriate corrective action had been taken and documented;

- a validation SOP was in place and in a selection of analytical methods’ validation data examined by the mission team, the method performance parameters had been calculated according to the SOP for each of the matrices tested in the NCRMP. All of the methods examined - gestagens in animal tissues by LC-MS-MS, beta-agonists in animal tissues by LC-MS-MS, and endectosides (avermectins) by LC-fluorescence in bovine liver and dairy products, were fit for purpose with appropriate criteria for the acceptance/rejection of results and were sufficiently sensitive to detect residues of these analytes at appropriate concentrations. It was noted that there was as yet no mass spectrometric confirmatory method in place for the avermectins. In the event of ‘positive’ result by LC-fluorescence, the laboratory management stated that a duplicate portion of sample would be re-extracted and re-run using the same method. If this was again ‘positive’ the result would be reported as ‘non-compliant’ to CFIA;

- quality control charts for each method were maintained. In the gestagens method (covering *inter alia*, melengestrol acetate and megoestrol acetate), it could be seen that the method was quite frequently out of statistical control (low recoveries of spikes outside the acceptable recovery range - < 65%). There were delays in the issuing of corrective action requests by the quality assurance team and the problem persisted. Using this method, the laboratory had reported a non-compliant melengestrol acetate result, though the spike recoveries during this time period were within the acceptable range of recoveries. Laboratory staff recognised the need to take more prompt corrective actions and there was now a policy for the analysts to initiate and document corrective actions rather than wait for the quality assurance staff to detect the problem and issue the request.
5.3. VETERINARY MEDICINAL PRODUCTS (VMPs) AND MEDICATED FEEDINGSTUFFS

5.3.1. Authorisation of VMPs

Under the Canadian Food and Drug Regulations (the Regulations), all veterinary medicines must be authorised (at federal level) by the Veterinary Drugs Directorate (VDD) within Health Canada prior to being placed on the market. VDD determines the conditions of sale and label requirements for VMPs. Once approved at the federal level, the provinces/territories can further regulate the sale and distribution of veterinary medicines in their province. Provincial authorities can not apply less stringent requirements than those imposed by Health Canada, however they can be more strict. For example in the province of Québec, all VMPs require a veterinary prescription even though Health Canada has approved many VMPs as over-the-counter medicines.

In addition, VMPs which have not been evaluated by Health Canada can be sold in Canada to veterinary practitioners through the ‘Emergency Drug Release Programme’ administered by Health Canada for the treatment of a medical emergency of animals under their direct care or supervision. Special authorisation for investigational studies in the form of ‘Experimental Studies Certificates’ or ‘Investigational New Drugs’ from Health Canada may also govern the sale of drugs for experimental purposes in animals and for generation of efficacy and residue data.

Under current law, VMPs which have not been approved by Health Canada may be imported for the treatment of a person's own animals, provided the drug is - not re-sold, not listed for prescription-only, and clearly marked “for veterinary use only”.

Some active pharmaceutical ingredients (i.e. pharmacologically active raw substances) could potentially be offered for sale and administered as drugs directly to food animals in Canada. Active pharmaceutical ingredients are defined as bulk, pharmaceutically active substances that are used in the formulation of drugs in dosage form. There are few restrictions or controls in place regarding the importation and sale of active pharmaceutical ingredients in Canada. However, Health Canada is actively working to close this loophole and prohibit the importation of drugs for food-producing animals under the “own use” provision and there is a position paper posted on the Health Canada website: http://www.hc-sc.gc.ca/dhp-mds/comp/cons/int/export-import/pol_18_import_sale_api_vet_ltr-doc_e.html#1

It was noted that:

- in contrast to the situation in the EU, the majority of VMPs authorised by Health Canada for use in food producing animals are available over the counter, without the need for a veterinary prescription;
- as observed in 2000 and in contrast to the situation in the EU, VMPs authorised for use in food producing animals in Canada do not necessarily need to have an MRL elaborated for the pharmacologically active principles in advance of a marketing authorisation being granted. Many VMPs authorised for use in food producing animals in Canada have so called Administrative MRLs (AMRLs). VDD and CFIA reached an agreement in 2002 to use AMRLs to alleviate the delays of promulgation of MRLs in the Food and Drug Regulations. However, for some VMPs there are neither MRLs nor AMRLs established (e.g. tilmicosin in sheep – MRL only for cattle, streptomycin in cattle, poultry and pigs – MRL only for milk). It was noted however that drug withdrawal times were specified
for those VMPs containing the pharmacologically active substances listed above;

- Health Canada does not regulate the practice of veterinary medicine and the use of drugs by veterinarians, including so-called ‘extra-label drug use’. Such use falls under the practice of veterinary medicine which is regulated by provincial law and existing federal regulation does not prevent veterinarians from using their discretion when prescribing drugs;

- for those VMPs available over the counter without prescription, extra-label drug use by the farmer is also legally permissible, as was the case in 2000;

- the policy and regulatory issues arising from extra-label drug use do however fall under Health Canada’s mandate and the mission team was informed that VDD is working on an extra-label drug use policy paper and is at present considering options to address this issue in conjunction with an Advisory Committee on extra-label drug use and partners in the provincial administrations. This policy will be released for public consultation in the near future. The 2000 mission report also highlighted potential residues problems arising from the practice of extra-label drug use and in the action plan to that report, a number of measures were proposed to address the issue (e.g. education of veterinarians and livestock producers etc). It could not be ascertained whether these measures had any effect on the practice of extra-label drug use;

- in contrast to Community law (Directive 2001/82/EC) where there are strict rules for the use of drugs for food producing animals under the ‘cascade’ principle and default withdrawal periods for extra-label use, no such system exists in Canada. The decision on an appropriate drug withdrawal period (in order to satisfy MRLs or AMRLs where these exist) following extra-label use lies with the veterinarian (if he/she has been involved) though some guidance on this issue is available for registered veterinarians (not stock owners) 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, Quebec. Details of the programme are available at [http://www.oabp.ca/gFARAD.htm](http://www.oabp.ca/gFARAD.htm);

- in common with the situation in the EU, stilbenes and thyrostats are prohibited from use in food producing animals. In 2000, only diethylstilbestrol had been prohibited;

- in common with the situation in the EU, those substances listed in Annex IV to Council Regulation (EEC) No 2377/90 are not authorised for use in food producing animals in Canada (e.g. nitrofurans, chloramphenicol, nitroimidazoles etc.) [http://www.hc-sc.gc.ca/dhp-mps/vet/banned_drugs_list_interdit_medicaments_e.html](http://www.hc-sc.gc.ca/dhp-mps/vet/banned_drugs_list_interdit_medicaments_e.html) However there are three nitrofuran products (containing either nitrofurantoin or nitrofurazone) available for oral, intrauterine and topical use in horses. Each has a clear label indication – not for use in food producing animals. In contrast with the position in the EU where a ‘horse passport’ is compulsory to identify food-producing from non-food producing horses (Commission Decision 2000/68/EC), there is no equivalent system in Canada;

- in the 2000 report, horses were not recognised as a food producing animals and Health Canada did not require drug companies (sponsors) to submit residue depletion studies for this species. In the action plan to that report it was stated that Health Canada would include horses a food producing animals in the review of submissions for pre-market drug approval. This does not appear to have happened as all current VMPs authorised for use in horses do not have any
withdrawal times listed nor are there any MRLs or AMRLs for this species. Many labels specify ‘not for use in horses intended for human consumption’ even for those substances which are commonly used world-wide in horses such as injectable penicillin for which Community MRLs exist for horse meat;

- in contrast to the situation in 2000, no products containing the EU-banned feed additives, carbadox or olaquindox are authorised in Canada for administration to food producing animals;

- in contrast to the EU, no distinction is made in Canada between those substances which are classified as veterinary medicinal products (medicated premixes) under Community law (Directive 2001/82/EC) and those substances classified as feed additives (Regulation (EC) No 1831/2003). The Compendium of Medicated Ingredient Brochures (CMIB) is available on the Health Canada website and lists all of those substances which are authorised for use in animal feedingstuffs in Canada. In common with Community policy on feed additives, all of the substances listed in the CMIB may be added to animal feedingstuffs without a veterinary prescription;

- as was the case in 2000, a number of substances which are either not authorised for use as feed additives in animal feedingstuffs in the EU or have been expressly prohibited for use as feed additives for food producing animals in the EU are authorised in Canada e.g. arsanilic acid, bacitracin zinc, flavomycin and virginiamycin. It should be noted that testing for virginiamycin residues is being included for the first time in the 2007-2008 NCRMP;

- the in-feed hormonal growth promotant melengestrol acetate (for use in cattle) and the beta-agonist ractopamine (for use in pigs) are listed in the CMIB though the use of these substances in animals destined for the EU market is not allowed under the terms of the HGP-free beef and ractopamine-free pork programmes;

- HGP s are authorised for use in cattle in Canada and (Québec excepted) are available over the counter. These include products containing the active substances trenbolone acetate, estradiol benzoate, testosterone propionate, progesterone and zeranol, either singly or in combination. There is a ‘split system’ in place for beef to be exported to the EU which guarantees that the cattle slaughtered for the EU market have never received HGP s (see 5.1.4.1.);

- there are no HGP s authorised for use in bison, swine and horses. According to CFIA the presence of residues in these species would constitute a violation of the Food and Drug Regulations. However, there is no federal legal basis to prevent extra-label drug use with such substances and there was evidence from the results of the 2004-2005 and 2006-2007 NCRMP that a HGP containing trenbolone acetate has been used in bison;

- there are no HGP s authorised for use in veal calves. In January 2005, Health Canada issued a recommendation not to use HGP s extra-label in veal calves. On the spot it could be seen that the drug labels for these products clearly indicated that they are not authorised for use in this production sector. It is clear that Health Canada has no legal basis to prohibit the extra-label use of HGP s in veal calves;

- a policy document posted on CFIA’s website states that AMRLs can be considered as a factor in the context of the action to be taken where the possible contamination of foodstuffs is suspected or known. CFIA has stated that it will incorporate in its Meat Inspection Regulations AMRLs for those veterinary drugs or related metabolites for which a formal list of approved AMRLs and
related information has been posted by Health Canada, but regulatory approval for the MRL has not yet been obtained;

- in contrast to the situation in the EU where there are no authorised antimicrobials for the treatment of honey bees and no Community MRLs for antimicrobial residues in honey, both oxytetracycline and fumagillin are authorised for use in honey bees in Canada. There is an AMRL of 300 µg/kg for oxytetracycline in honey but none for fumagillin. For each of the authorised VMPs containing these pharmacologically active substances there are clear instructions to discard honey stored during the medication period and honey from the brood area should not be used for human consumption;

- on the CFIA website, so-called ‘working residue limits’ (WRLs) are listed for a number of other antibiotics in honey. The WRL has no legal basis and is usually equivalent to the Limit of Detection of the analytical method;

- for several pharmacologically active substances there are significant differences between the Canadian MRL/AMRLs and Community MRLs. For example, the Canadian MRLs for chlortetracycline for poultry and pig tissues are much greater than either the Community MRLs or Codex Alimentarius MRLs for the same tissues. In the case of poultry muscle, the Canadian MRL is ten times greater. In contrast for ivermectin in cattle liver, the Canadian MRL is 30% lower.

5.3.2. Distribution and use of VMPs

Manufacturers may sell pharmaceuticals in Canada directly to the veterinarians or through distributors or wholesalers. Farmers can either purchase drugs through veterinarians or outlets such as feed mills or agricultural co-operative stores. Farmers can only purchase non-prescription or non-schedule drugs from these outlets and can purchase prescription drugs only from veterinarians or from pharmacists provided that they have a veterinary prescription. Most farmers purchase prescription drugs through a veterinarian. Most authorised VMPs may be obtained over-the-counter for use according to label instructions.

Provinces have the authority to control availability of drugs more strictly than the federal government prescribes. For example, in the province of Québec, all drugs are available to farmers only on prescription.

Regarding medicated feeds, only drugs and drug combinations that are specifically listed in the CMIB are allowed in feed unless accompanied by a veterinary prescription.

The mission team noted that:

- in the wholesaler visited in the province of Québec, it could be seen that VMPs were supplied only to registered veterinarians;

- for those drugs classified by Health Canada as ‘controlled’ (e.g. injectable anabolic steroids and psychotropic drugs), more stringent requirements were put in place by the wholesaler to ensure that these drugs were only supplied to veterinarians. In the veterinary practice visited in the province of Alberta, the veterinarian also stated that the administration of such controlled drugs to animals was restricted to the veterinarian;

- in the veterinary practice visited it was stated that VMPs may only be sold to the clients of the practice and that this is a requirement of the professional body regulating the practice of veterinary medicine in that province – the Alberta Veterinary Medical Association;
all use of VMPs in horses destined for the food chain is extra-label. On the horse feedlot visited the preparation of procaine penicillin which was routinely used was not authorised for this species (there were several preparations authorised for horses but all had label warnings stating that they were not to be sued in horses intended for human consumption) and was therefore used extra-label;

in respect of horses, one preparation containing the anabolic steroid boldenone is authorised but has been classified by Health Canada as a controlled drug and can only be administered by a veterinarian. There is a clear label indication that this drug is not to be used in horses intended for food production;

there are no authorised VMPs for use in bison – all use is therefore extra-label and the veterinarian visited stated that usually VMPs authorised for cattle would be used and the withdrawal periods specified for cattle would be applied to this species.

5.3.3. Controls on the distribution and use of VMPs

The Canada Food and Drugs Act and Regulations require *inter alia* manufacturers and wholesalers who sell drugs in Canada to have an establishment licence which is issued by Health Canada.

5.3.3.1. Controls at wholesale and retail level

The mission team noted that:

- Health Canada issues establishment licences to wholesalers following an on-site inspection by their Health Products and Food Inspectorate. Licences are valid for three years;

- in the wholesaler visited it could be seen that this inspection had been carried out and that corrective actions had been requested and responded to satisfactorily within the timelines specified by Health Canada;

- neither pharmacies nor private veterinarians selling veterinary drugs are inspected by Health Canada as this activity falls under the remit of the relevant provincial professional associations. Pharmacies are licensed by the provincial authorities;

- in the wholesaler and co-operative farm store visited, all of the medicines in stock had a drug identification number indicating that the products had been authorised by Health Canada. Labelling indications were consistent with Community requirements for VMPs (e.g. species indications, dose rate, withdrawal periods etc).

5.3.3.2. Controls in feed mills (medicated pre-mixes and medicated feedingstuffs)

There are an estimated 550 commercial feed mills in Canada. At this time, no authorisation is required to produce medicated feed other than in the province of Québec. There are no federally licensed feed mills though commercial feed mills in Québec are registered with the Québec provincial government.

There are approximately 25,000 on-farm feed mills in Canada, accounting for an estimated 50% of the total feed manufactured in Canada. It is estimated some 19,000 of these on-farm feed mills manufactures medicated feeds. As with the commercial mills, there is currently no authorisation required to produce medicated
feed in these on-farm feed mills other than in the province of Québec. There are no federally licensed on-farm feed mills though on-farm feed mills in Québec are registered provincially.

The CFIA, using the authority of the federal Feeds Act, monitors the use of feed-additive medications primarily through facility inspection, label inspection and feed sampling and testing programmes at feed mills and farms in Canada. These programmes seek to verify that the use of medications complies with drug approval conditions or with the other conditions provided in the federal Food and Drug Regulations and the Feeds Regulations. As part of the Feeds Regulations, detailed conditions and instructions respecting feed-additive medications are set out in the Compendium of Medicating Ingredients Brochures (CMIB) which is maintained and published by the CFIA.

The current Feed Regulations provide limited control on how feeds are manufactured. However, the CFIA plans to publish the Medicated Feeds Regulations later this year to address the manufacture of medicated feeds. The Medicated Feeds Regulations include HACCP-based controls for the manufacture of medicated feeds which will result in an improvement in the overall management of VMPs. The proposed controls include requirements for mixer performance testing, scale and metering device performance testing, implementation of an effective programme for managing drug carryover and improved product identification, traceability and recall procedures consistent with the Codex Code of Good Animal Feeding.

Québec provincial legislation requires that all medicated feed manufacturers obtain permits from the Québec Ministry of Agriculture, Fisheries and Food and adhere to a number of regulatory requirements respecting manufacturing, distribution and record-keeping practices. In Québec, VMPs can only be purchased and used in accordance with a veterinary prescription. The provinces of British Columbia and Ontario have also instituted controls provincially on distribution of VMPs.

During the fiscal year 2006/2007 (April 1, 2006 through March 31, 2007) 546 full inspections and 487 partial inspection were conducted by CFIA at commercial feed mills, 635 inspections were conducted at on-farm feed mills and 800 inspections were conducted at feed retail outlets for the fiscal year 2006/2007.

The mission team noted that:

- Whilst feed mills were not visited in the course of the present mission, comprehensive checklists have been devised by CFIA to ensure that feed manufacturing facilities are inspected in a uniform manner and copies of completed inspections were made available to the mission team.

5.3.3.3. Controls on veterinary practitioners and farms

According to the competent authority, there are currently 821 and 311 veterinary practices involved in mixed practice (companion animals and farm animals) and farm animals respectively.

The mission team noted that:

- neither CFIA nor Health Canada plays any role in checking the storage and use of medicines on farm, except for those farms on which there are facilities for the mixing of medicated feedingstuffs;
- in the veterinary practice visited, the business was regulated and checked by the Alberta Veterinary Medical Association. Any violations for example in the dispensing of VMPs could result in punitive action being taken and there were
reports of a veterinarians licence to practice being removed because of the dispensing of medicines to animals ‘not under his care’;

- in the veterinary practice visited, all of the medicines in stock had a drug identification number indicating that the products had been authorised by Health Canada;

- personnel on the three farms visited by the mission team stated that they had been inspected by CFIA feed inspectors and that these visits were unannounced. Records of the inspections were not available for inspection on the farms;

- in Québec it was seen that the provincial authorities had carried out a detailed inspection of the veal calf unit visited which included checks on use and storage of VMPs and compliance with the requirement not to implant the calves with HGP;

- in contrast to the situation in the EU where Community legislation (Article 10 of Council Directive 96/23/EC) requires stockowners to keep records of the treatment of food producing animals with veterinary medicines, there is no similar federal legal requirement in Canada. However, within different livestock production sectors there are several industry codes of practice for the maintenance of medicines records under the umbrella of the CFIA-reviewed industry-driven ‘On farm food safety programmes’. At present there are no industry recommendations in respect of veal calves, horses, rabbits and honey. With regard to aquaculture, CFIA stated that medicines records are required in accordance with provincial regulations;

- on the farms visited, medicines records were maintained. On the beef feedlot, and veal calf units, the animals were individually identified with, as a minimum, CCIA RFID tags and all treatments were recorded. The medicines held in stock on the farm, were authorised by Health Canada, were consistent with the treatment records examined and with the purchase invoices from the veterinarian supplying medicines to the farm;

- on the farms visited, there was no evidence of active pharmaceutical ingredients or importation of VMPs for own-use;

- on the horse feedlot, the pen in which the animals were kept was seen as the treatment unit in the absence of individual animal identification. On this farm there was a blanket policy of withholding all animals from that pen from slaughter for a period of 120 days after the date of the last treatment (of one or more animals in the pen). Treatments applied to the ‘pen’ were recorded. All treatments were extra-label. The medicines held in storage were consistent with the treatment records on the farm, however, due to confidentiality reasons it was not possible to examine records of what the dispensing veterinarian had supplied to the horse feedlot as release of this information required the permission of the owner of the feedlot who was not present during the visit by the mission team;

- although the use of medicines was well controlled on this feedlot and the default withdrawal period long enough to ensure that residues of administered VMPs would more than likely be undetectable, it can not be guaranteed that horses destined for direct slaughter (either from Canadian farms/markets or imported from the USA) or which enter a feedlot and are fattened prior to slaughter, have

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3 In their response to the draft report the Canadian Competent Authority stated that on-farm quality assurance programmes for horse and rabbit do not exist and that in respect of honey and veal calves, programmes are to be approved shortly.
never been treated with HGPs. However, it is noted that testing for HGP residues is carried out in this species and there were no findings of such residues in the 2006-2007 NCRMP.

6. CONCLUSIONS

6.1. NATIONAL CHEMICAL RESIDUE MONITORING PLAN

(1) The NCRMP is comprehensive in scope and with the exceptions of aquaculture fish and poultry, is equivalent to Council Directive 96/23/EC. The absence of testing of many group A substances for both commodities means that at present, the plans for aquaculture fish and poultry are not equivalent. However for poultry, undertakings have been given to include the ‘missing’ group A substances in a standalone programme which will provide the requisite guarantees of equivalence.

(2) Implementation of the plan is satisfactory for many commodities, particularly for species covered by the meat plan. However, for some commodities, the actual sampling numbers were much less than the plan indicating problems with the supervision of sampling.

(3) Realisation of the plan at laboratory level was also a problem which was exacerbated by the fact that the private laboratories, responsible for the delivery of the majority of the programme, effectively decided which tests to do in any given month with the monthly release of funds for testing being the primary driver for analyte selection and testing. Whilst there are tools in place to allow a regular assessment of the progress being made in testing to be assessed by CFIA, there was no evidence that these had been used and the apparent lack of supervision could have been a contributory factor in the failure to meet the plan targets for several analyte-matrix combinations.

(4) Both the Laboratory Sample Tracking System and the RAMS system are useful tools to monitor progress being made in the implementation of the programme and the implementation of follow-up investigations. The creation of a residues group to regularly discuss actions to be taken and progress being made in cases of non-compliance is a very welcome initiative and is consistent with a residues control system which is functioning effectively. However, the legal ‘loopholes’ in the federal regulatory framework for residues control compromise the ability of the competent authorities to take a range of enforcement actions in cases of non-compliance. Furthermore the often long delays from sampling to analysis to initiation and completion of follow up investigations militate against finding the cause of residues violations and taking effective action.

(5) The fact that official residues samples are not sealed means that the possibility of interference with samples during transport to the laboratory can not be ruled out and would compromise in particular any legal actions which may arise from the finding of a non-compliant result.

(6) Notwithstanding the extensive powers given to CFIA inspectors under the federal Feeds and Regulations, the current loopholes in the federal legal framework governing residues control mean that CFIA’s right of entry onto farms and ability to take further samples from live animals and take other appropriate follow-up measures, is hampered in comparison to what would be achievable in the Member States under the framework of Council Directive 96/23/EC.
6.2. LABORATORIES

(1) The laboratories, both governmental and private, which are providing analytical services under the NCRMP are in general functioning satisfactorily in terms of their analytical capability. The laboratory performance is assured by regular participation in proficiency testing schemes. The tender specifications for the provision of analytical testing by the private laboratories allied with the organisation of the CFIA proficiency testing programme by the CFIA Saskatoon laboratory and the requirement for all methods to be included within the scope of accreditation, are key components in ensuring consistent and acceptable laboratory analytical performance.

(2) Nevertheless, some of the analytical methods examined were either not appropriate in that the marker residue was not being tested for, or, on the basis of continuing quality control charts, not in statistical control. For those methods in particular, these factors reduce the effectiveness of the programme to reliably detect residues of certain analytes.

(3) With regard to the time taken to generate laboratory results, the turnaround times from sampling to analysis in the monitoring programme was in many cases too long to facilitate effective follow up by the competent authorities when these results were non-compliant. A contributory factor would appear to be the freedom of the private laboratories to decide which tests are to be performed in any given month rather than the competent authority specifying which tests are to be performed.

6.3. VETERINARY MEDICINAL PRODUCTS AND MEDICATED FEEDINGSTUFFS

(1) In contrast to the situation in 2000, the fact all of the stilbenes, thyrostats and carbadox are now prohibited from use in food producing animals means that Canada is now completely in line with the position in the EU Member States in this regard.

(2) The centralised procedure for the authorisation of VMPs in Canada is in some ways equivalent to the system in place in the EU. Label indications and dose rates were clear, and, withdrawal periods (where stated) were highlighted. However, the absence of a requirement to elaborate MRLs in advance of issuing a marketing authorisation for using a VMP in food producing species means that effectively a zero tolerance for residues applies and it is not certain whether adherence to label withdrawal periods will be sufficient to ensure the absence of residues in foodstuffs derived from treated animals.

(3) For some species such as equines and bison, the absence of any approved VMPs for use in food producing animals means that both the dose rate to be used and the withdrawal period to be observed are entirely at the discretion of either the veterinarian (for prescription only medicines) or the farmer (for the majority of VMPs available over-the-counter). In the absence of hard data on residue depletion profiles or indeed MRLs in these species, the practice of extra-label drug use could result in residues being present in food derived therefrom. However, (HGP use in bison excepted) this is mitigated by the fact that in general the violation rates for residues detected under the NCRMP is quite low.

(4) Although a ‘split system’ for bison is technically not required since HGPs are not authorised for this species, the fact that extra-label use with these over-the-counter drugs is perfectly legal and the fact that there is no current policy on what to do in the event of evidence of use, means that the supposed HGP-free residue status of bison meat can not currently be assured and as such, exports of this commodity to
the EU may not comply with Community requirements for guaranteeing freedom from administration of HGPs.

(5) Though there was no evidence seen to suggest that HGP-implants had been used in horses ‘extra-label’, the free availability of HGPs and the fact that there is neither the legal basis to prevent extra-label use by farmers nor, as for veal calves, a recommendation not to use HGPs extra-label, means that it is difficult to guarantee that horses have never been treated with HGPs in accordance with the requirements of Article 11 of Council Directive 96/22/EC.

(6) Whilst the standard of medicines record keeping on the horse feedlot visited was good, the absence of any requirement (industry-driven or official) to maintain medicines records for equidae, the absence of any system comparable to the EU ‘equine passport’ system which would facilitate the identification, medicines history and segregation of horses for food production allied with the probability of extra-label drug use in this species, means that CFIA’s guarantees on the residues status of horsemeat rely solely on the results of testing under the NCRMP.

(7) With regard to beef, the HGP-free beef programme is rigorously designed and should deliver the requisite guarantees that beef exported to the EU produced under this programme has been derived from cattle which have never been treated with HGPs.

(8) Although there is no formal HGP-free programme for veal calves, on the basis of the structure of the industry, the farming practices observed, the recommendation not to use HGPs in this sector, the restricted availability of HGPs in the province of Québec where the industry is principally based, the CFIA policy to destroy HGP-implanted veal calves detected at slaughter and the checks carried out by both the provincial authorities and CFIA feed inspectors, it can be concluded that guarantees on freedom from treatment with HGPs can be relied upon for this commodity and veal exported to the EU should meet the requirements of Article 11 of Council Directive 96/22/EC.

6.4. OVERALL CONCLUSION

The residue control system in Canada is comprehensive and well structured. Many improvements in the system have been implemented since the last residues mission in 2000. Strengths include the scope of analytical testing in the national chemical residue monitoring programme, the analytical capabilities of the network of fully accredited residues laboratories, implementation of a comprehensive proficiency testing programme to assure laboratory performance, the establishment of a residues committee to discuss problem cases on a regular basis, the use of a computerised infraction tracking system for violations in meat and objective evidence indicating a low prevalence of violative residues in all domestic food commodities.

However, the effectiveness of the system in practice is weakened by several factors. Firstly, for several analyte-matrix combinations, there were substantial shortfalls in the number of samples taken versus the number planned and the number tested, thereby questioning the supervision of implementation of the programme in terms of monitoring both sampling and analysis. Secondly, in many cases the length of time from sampling to analysis was extremely long, which would reduce the ability of the competent authority to launch prompt follow up investigations. Thirdly, the current federal legislative framework governing residues and veterinary medicines controls has several loopholes – recognised by the competent authority - which restrict the ability of the competent authorities to take certain actions in respect of follow-up and enforcement. Fourthly, in some cases where residues of hormonal growth
promotants were detected in species for which their use is not authorised, investigations had not been carried out.

With regard to controls on the authorisation, distribution and use of veterinary drugs, the systems in place appear to be generally effective. Medicines records, whilst not compulsory by law, were maintained in each of the farms visited and official checks had been performed. In particular the hormonal growth promotant-free beef programme for the EU has been well structured and provides sound guarantees on the residue status of this commodity. However, the fact that extra-label drug use with hormonal growth promotants is legal for bison, the fact that such substances appear to have been used in bison production (albeit with a low incidence), much of which is destined for the EU market, the absence of investigations as to the cause of these violations, and the apparent absence of a coherent policy when such findings are made in this species, indicate that controls in this sector require to be enhanced in order to meet Community requirements.

Aside from the concerns relating to the extra-label use of hormonal growth promotants in bison, on the whole it can be concluded that the residues control system in Canada provides guarantees which are largely equivalent to those provided for by Community legislation.

7. CLOSING MEETING

A closing meeting was held on 7 June 2007 with representatives of the CFIA and Health Canada. At this meeting, the inspection team presented the main findings and preliminary conclusions of the mission. The authorities did not express disagreement. The mission team was informed that investigations into the source of the trenbolone ‘positives’ in bison had now begun. There was a possibility that one of the animals had come from a bison feedlot and the veterinarian (visited by the mission team) who also provided services for this feedlot had submitted a faxed statement to the effect that he had never sold or been asked to supply HGPs or other anabolic preparations to the company. CFIA undertook to update the Commission with progress being made in these cases.

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 25 working days of receipt of a draft of this mission report.

**National Chemical Residue Monitoring Plan**

(1) Address all identified shortcomings in the structure, implementation and supervision of implementation of the NCRMP 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).

(2) 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.
Establish a policy to deal with the extra-label use of HGPs in bison in order to ensure that meat from animals in which HGPs have been used is not exported to the EU in accordance with Article 11 of Council Directive 96/22/EC.

Consider extending the use of the RAMS system to commodities other than meat to permit the collation of data pertaining to non-compliant results and follow-up activities thereby facilitating CFIA at central level to have a comprehensive overview of all such activities and provide guarantees equivalent to those provided for by Article 4 (2) (b) and (c) of Council Directive 96/23/EC.

Ensure that official samples are officially sealed in order to guarantee sample security which would at least be equivalent to that specified in Section 2.6. of the Annex to Commission Decision 98/179/EC.

Laboratories

Ensure that for those analytical methods where performance was questionable or where the marker residues chosen were inappropriate to reliably detect the use of certain VMPs, alterations to the methods are implemented 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.

Consider strategies which will reduce the amount of time taken to generate a laboratory result following receipt of samples in order to optimise the effectiveness of follow-up investigations and thus providing guarantees equivalent to those provided for by Article 16 (1) of Council Directive 96/23/EC.

Veterinary Medicinal Products

With reference to those foods of animal origin exported to the EU, consider the prohibition of HGPs from the extra-label use provisions or take other appropriate measures in order to provide guarantees that these products have not been used in any species or production categories of food producing animal in which HGP use is not authorised in Canada, thus satisfying the provisions of Article 11 of Council Directive 96/22/EC.

With reference to those foods of animal origin exported to the EU, regulate the practice of extra-label use of VMPs by non-veterinarians 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 do not exceed Community MRLs in accordance with the requirements of Article 11 of Regulation (EC) No 178/2002.

With reference to those foods of animal origin exported to the EU, and particularly in those sectors where the voluntary medicines records requirements have not yet been implemented in the CFIA-reviewed industry-driven ‘On farm food safety programmes’ (e.g. horses, veal calves, rabbits and honey), implement a requirement to maintain medicines treatment records in order to provide guarantees equivalent to those provided for by Article 10 of Council Directive 96/23/EC, Annex I, Section III, part 8 (b) to Regulation (EC) No 852/2004 and Annex II, Section III, part 3(c) to Regulation (EC) No 853/2004.

Consider procedures allowing the identification, segregation and maintenance of medicines treatment records for those horses intended for food production and export to the EU in order to provide equivalence to the provisions of the EU equine passport (Commission Decision 2000/68/EC).
9. **COMPETENT AUTHORITY RESPONSE TO RECOMMENDATIONS**

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

### ANNEX: APPLICABLE COMMUNITY STANDARDS:

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<th><strong>Maximum Residue Levels for pesticides in food of animal origin</strong></th>
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<th><strong>Maximum Limits for Contaminants</strong></th>
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<td>Authorisation of veterinary medicinal products</td>
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