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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

SERBIA

FROM 15 TO 19 APRIL 2013

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

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in Serbia, carried out from 15 to 19 April 2013, as part of the published programme of FVO audits on the monitoring of residues in live animals and animal products in European Union (EU) Member States and in third countries.

The objective of the audit was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, in order to assess whether these systems offer adequate assurance that the products and animals concerned are within the specified residue limits laid down in EU legislation. Since the authorisation, distribution and use of veterinary medicinal products and feed additives have an impact on the monitoring of residues, the national rules governing the control systems in these areas were also part of the audit. The audit assessed the performance of the competent authorities and other officially authorised entities involved in residues and veterinary medicinal product controls and the legal and administrative measures put in place to give effect to the relevant EU requirements. Attention was also paid to examining the implementation of corrective actions promised in response to recommendations made in the report of a previous FVO residues audit to Serbia in November-December 2009.

It is concluded that the Residue Monitoring Plan (RMP) is generally in line with Council Directive 96/23/EC. Sampling under the RMP has been carried out in line with the planned arrangements, generally fulfils EU requirements and the supervision of implementation is effective. Follow-up investigations are generally carried out in a timely manner, are well co-ordinated and comprehensive. However, some issues such as the limited scope of testing in some areas, inadequate sampling strategy for comingled milk and shortcomings in follow-up procedures with regard to coccidiostats in poultry weaken the effectiveness of the residue control plan.

The laboratory analysing all samples under the RMP is accredited to ISO 17025, with almost all methods being included in the accreditation scope. In addition, generally successful participation in regular proficiency testing and adequate quality control procedures in place provide assurances of good laboratory performance. However, deficiencies in method validation - a problem identified during the previous FVO residue audit - have the potential to weaken the effectiveness of residue controls.

Most of the national requirements with regard to authorisation, distribution and use (including treatment records) of veterinary medicinal products are broadly equivalent to EU legislation and there is an operational system in place for official controls. However, the reporting form structure does not facilitate the verification that certain national requirements on the keeping of prescriptions and respecting of withdrawal periods are met.

Whilst the majority of horses have been electronically identified, the absence of passports and, regarding exports of live equidae to the EU, lack of traceability between animal health certificates makes it difficult for the competent authority to ensure that exported equidae have not been treated with substances which would exclude them from human consumption.

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

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Abbreviations and definitions used in this report

Abbreviation	Explanation
AAS	Atomic Absorption Spectroscopy
CCα / CCβ	Decision Limit / Detection Capability
CVO	Chief Veterinary Officer
DG(SANCO)	Health and Consumers Directorate-General
DVI	Department for Veterinary Inspection
DVO	District Veterinary Office
DVPH	Department for Veterinary Public Health
EC	European Community
EEC	European Economic Community
ELISA	Enzyme-linked immuno-sorbent assay
EU	European Union
EU RL	European Union Reference Laboratory
FVO	Food and Veterinary Office
GC - ECD	Gas chromatography – electron capture detection
GC - MS	Gas Chromatography - Mass Spectrometry
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC:
HACCP	Hazard Analysis Critical Control Point system
HPLC – UV/PDA/FI	High Performance Liquid Chromatography with Ultraviolet / Photo diode array / Fluorescence detectors
ICP-MS	Inductive Coupled Plasma Mass Spectrometry
IMHT	Institute of Meat Hygiene and Technology
IPHS	Institute of Public Health of Serbia
ISO	International Organisation for Standardisation
LC-MS/MS	Liquid Chromatography-(Tandem) Mass Spectrometry
LoD, LoQ	Limit of Detection, Limit of Quantification
LVI	Local veterinary inspector
MAFWM	Ministry of Agriculture, Forestry and Water Management
MH	Ministry of Health
ML	Maximum Limit
MMDAS	Medicines and Medical Devices Agency of Serbia

MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
NRL	National Reference Laboratory
NSAIDs	Non-steroidal Anti-inflammatory Drugs
QC	Quality control
PCBs	Polychlorinated biphenyls
RASFF	Rapid Alert System for Food and Feed
RMP	Residue Monitoring Plan
SOP	Standard Operating Procedure
TAIEX	Technical Assistance and Information Exchange instrument of the European Commission

1 Introduction

The audit took place in Serbia from 15 to 19 April 2013. The audit team comprised two auditors from the Food and Veterinary Office (FVO) and one expert from a European Union (EU) Member State. The audit was undertaken as part of the FVO's audit programme, evaluating control systems and operational standards in the residues sector.

Representatives from the central competent authority responsible for control of residues in animals and animal products accompanied the audit team during the audit. An opening meeting was held on 15 April 2013 with the central competent authority responsible for implementing residue monitoring in live animals and animal products and representatives of the competent authority responsible for the authorisation of veterinary medicinal products. At this meeting, the objectives of, and itinerary for, the audit were confirmed and the control systems were described by the authorities.

2 Objectives

The objective of the audit was to evaluate the effectiveness of implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, in order to assess whether these systems offer adequate assurance that the products and animals concerned are within the specified residue limits laid down in EU legislation. Since the authorisation, distribution and use of veterinary medicinal products and feed additives have an impact on the monitoring of residues, the national rules governing the control systems in these areas were also part of the audit. The audit focussed on the roles of the competent authorities at central and regional levels, the legal and administrative measures in place to give effect to the relevant EU requirements, controls with regard to residues and veterinary medicinal products and their operation, and the performance of residue laboratories. Attention was paid to examining the implementation of corrective actions promised in response to recommendations made in the report of a previous FVO residues audit to Serbia (DG (SANCO)/2009-8194 – MR Final) in November-December 2009. The table below lists the sites visited and meetings held in order to achieve that objective.

Meetings/Visits		N	Comments
Competent Authorities	Central	3	Opening and closing meetings with the competent authorities and an additional meeting to collate and discuss documents requested by the audit team
	Regional	1	Meeting at the District Veterinary Office in Sremska Mitrovica
Laboratories		1	Visit to the Institute of Meat Hygiene and Technology
Farms		1	Visit to a dairy farm (bovines)
Establishments		1	Visit to a slaughterhouse (bovines, pigs)
Other Sites		3	Visits to a veterinary pharmacy, a feed mill producing feed with coccidiostats and a veterinary practice

3 Legal Basis

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

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

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

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

4 Background

4.1 Country status in relation to EU-approval of residue monitoring plans

Commission Decision 2011/163/EU indicates that Serbia's residue monitoring plan is approved in accordance with Council Directive 96/23/EC for bovine, porcine, ovine/caprine, live *equidae* for direct slaughter in the EU, poultry, aquaculture, wild game, milk, eggs and honey.

4.2 Summary of previous FVO audit reports

Residues in food of animal origin was last audited by the FVO in 2009. The report of this audit (DG(SANCO)/2009-8149 MR Final, henceforth referred to as the 2009 FVO audit) has been published on the website of the Directorate – General for Health and Consumers here: http://ec.europa.eu/food/fvo/ir_search_en.cfm. The report concluded that in general the system of residue controls in Serbia offered guarantees with an effect equivalent to those provided for by EU rules. Nevertheless its effectiveness was compromised by some deficiencies related to, inter alia, a limited scope of testing for some commodities, poor traceability of milk samples to the farm level and weaknesses in method validation for some analytes. Whilst a strictly regulated and comprehensive control system for distribution and use of veterinary medicines was in place, the operation of the system was not always effective. The process of mandatory identification of *equidae* in line with EU rules had begun but there was no system in place to permanently exclude horses from the food chain if they had been treated with medicines not authorised for food producing animals.

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

Since the 2009 FVO audit there has been one RASFF notification for residues of veterinary medicinal products to date (sulphonamides in honey).

4.4 Production and Trade Information

According to the data supplied by the Veterinary Directorate of the Ministry of Agriculture, Forestry and Water Management, Serbia mainly exports honey, dairy products (ice cream) and bovine meat to the EU.

5 Findings And Conclusions

5.1 Residue monitoring

5.1.1 Elaboration of residue monitoring plan

Legal Requirements

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

The residue plan should take account of the results of monitoring from the previous year and should be revised annually and updated at the request of the Commission, particularly when checks carried out by the Commission render it necessary. Article 29 of said Directive states that guarantees must have an effect at least equivalent to those provided for in the Directive and must, in particular, meet the requirements of Article 4 and specify the particulars laid down in Article 7 and meet the requirements of Article 11(2) of Directive 96/22/EC. Articles 3 to 7 of Council Directive 96/23/EC deal with the requirements for residue monitoring plans. The levels and frequencies of sampling for residues are specified in Annex IV to Council Directive 96/23/EC and Commission Decision 97/747/EC.

Article 11 of Regulation (EC) No 178/2002, laying down the general principles and requirements of food law, specifies that food and feed imported into the EU for placing on the market within the EU shall comply with the relevant requirements of food law or conditions recognised by the EU to be at least equivalent thereto. In relation to maximum levels of residues and contaminants in food, Regulation (EC) No 470/2009 of the European Parliament and of the Council lays down Maximum Residue Limits (MRLs) for residues of pharmacologically active substances in food which are listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010. Regulation (EC) No 396/2005 lays down maximum residue levels of pesticides in or on food and feed of plant and animal origin. Commission Regulation (EC) No 1881/2006 lays down Maximum Levels (MLs) for contaminants in food. Minimum Required Performance Limits (MRPLs) are defined in Article 4 of Commission Decision 2002/657/EC.

In accordance with Article 29 of Council Directive 96/23/EC, Commission approval of every third country's residue monitoring plan is necessary if that country is to remain on the list of third countries from which EU Member States may import animals and animal products. The list of countries and commodities with approved residue monitoring plans is in the Annex to Commission Decision 2004/432/EC.

Findings

The Department for Veterinary Public Health (DVPH) within the Veterinary Directorate of the Ministry of Agriculture, Forestry and Water Management (MAFWM) is responsible for elaboration of the residue monitoring plan (RMP). The RMP is prepared by an (ad-hoc) working group composed of experts from the Veterinary Directorate (DVPH and Department for Veterinary Inspection - DVI) and from the Institute of Meat Hygiene and Technology (IMHT). In addition, experts from the Veterinary Medicine Department of the Medicines and Medical Devices Agency of Serbia (MMDAS) and university experts can be consulted. Drafting of the plan starts at the end of the previous year in order to be finalised in the second half of March and approved by the Director of the Veterinary Directorate (Chief Veterinary Officer – CVO). Sampling in the first quarter of the year is carried out on the basis of the previous year's plan.

Data on national production are sourced from (quarterly) reports sent to DVPH from the 25 District Veterinary Offices (DVOs) and the DVI. The finalised plan is first allocated to the districts on the basis of regional production and then to individual establishments and holdings (see Section 5.1.2.).

The main national legal basis for the RMP is enshrined in several laws, regulations and decisions. These are:

- *Law on veterinary matters*
- *Food safety law*
- *Law on medicinal products and medical devices*
- *Regulation on setting forth the programme of systematic monitoring of residues of pharmacologically active substances, hormones and other harmful matters in live animals, products of animal origin, foodstuffs of animal origin and animal feedingstuffs*
- *Decision on the ban on use of certain substances of veterinary medicinal products in veterinary medicine for treatment of food producing animals.*

The latter two are generally aligned with Council Directives 96/23/EC and 96/22/EC, respectively.

National MLs for residues and contaminants are provided by *Regulation on the quantities of pesticide, metals, metalloids, and other toxic substances, drugs, anabolics and other substances that could be found in foods* and *Rulebook on maximum residue levels of pesticides in or on food and feed of plant and animal origin*.

Currently there are no national MRLs or MLs (for carry-over tolerances) in place for coccidiostats. Any finding of these substances in food (and non-target feed) is considered non-compliant. According to the Veterinary Directorate an EU-harmonised feed legislation package has been drafted but its adoption is pending the amendment of Law on medicinal products and medical devices to allow the legal classification of coccidiostats and histomonostats as feed additives and not only as veterinary medicines. Nevertheless, coccidiostats have already been listed in *Rulebook on feed quality* (OG RS, No. 4/2010, amended in 2012) as authorised feed additives for prophylactic use.

The audit team noted that:

- All relevant bodies are involved in the elaboration of RMP and there was documented evidence showing this. This is in line with Article 14 of Council Directive 96/23/EC.

- Previous non-compliant residue results are taken into account for RMP elaboration, generally resulting in an increased number of analyses for the substances in question (e.g. mycotoxins in milk in 2013) and scheduling of farms/establishments with non-compliant results for repeated sampling in the following year's plan.

- In the framework of RMP elaboration updated lists of authorised veterinary medicinal products are provided by the MMDAS to the DVPH. The MMDAS also collects data on sales of veterinary medicinal products from marketing authorisation holders but these data (available from MMDAS on request) have not been used for elaboration of the RMP to date.

- The 2013 RMP includes all relevant commodities except caprine meat and eggs from species other than hens. The latter were included in the 2012 RMP but were not sampled. According to the DVPH, this was due to low production of these commodities and the limited availability of samples for 'other' eggs. The complete absence of sampling for these commodities is not in line with Council Directive 96/23/EC.

- Notwithstanding the above, with the exception of group B2b in *equidae*, the RMP covers all substance groups specified in Annex II to Council Directive 96/23/EC and the required minimum number of samples as well as their distribution between substance groups is respected.

- In comparison to the 2009 FVO audit, improvements have been made to the scope of testing with the inclusion of, inter alia, dexamethasone, closantel, toltrazuril and robenidin in several commodities, beta-lactams and aminoglicosides in eggs, methyltestosterone in aquaculture and amitraz in honey. Nevertheless some frequently used veterinary medicines noted on-the-spot by the audit team are not currently included e.g. clavulanic acid, prednisolone and bacitracin in the milk RMP. Furthermore the scope of testing remains limited for Group A3 (steroids, except for bovines), Group A4 (resorcyclic acid lactones), Group A5 (beta-agonists) and Group B2e (non-steroidal anti-inflamatory drugs - NSAIDs). **Recommendation No. 1** of the 2009 FVO audit report has therefore been partially addressed.

- In some cases an incorrect marker residue is tested for. For example, milk is analysed for flunixin, whereas the marker metabolite for milk is hydroxy-flunixin.

- As in 2009 there are still no national MRLs for antimicrobials (except for sulphonamides), anthelmintics, anticoccidials, corticosteroids, sedatives and NSAIDs. A CVO Decision of March 2013 has established a working group for drafting of a Rulebook on MRLs for veterinary medicinal products which will take into account international standards. A deadline of two months has been set for the completion of this task.

- Currently Limits of Detection (LoDs) of the analytical methods are used as action levels for the above substances. The LoDs are generally equal to or lower than corresponding EU MRLs (see also Section 5.2.) though for several pharmacologically active substances,

pesticides and contaminants, discrepancies with EU MLs and MRLs were seen.

- RMPs since 2010 have repeatedly indicated that the IMHT will subcontract an accredited EU laboratory for carrying out confirmatory methods for substance groups A1, A3, A4 and A5. No such subcontracting has taken place to date although the definition of a non-compliant result in national rules includes confirmation by confirmatory methods. Apart from this, sufficient details are generally provided in the RMP to allow for its assessment. Therefore **Recommendation No. 4** of the 2009 FVO audit report has been addressed.

Conclusions on elaboration of the residue monitoring plan

The RMP structure is, with few exceptions, generally in line with Council Directive 96/23/EC. The elaboration of the RMP is carried out in a timely manner, involves all relevant parties and takes into account most of the relevant data available. Whilst the coverage of the plan has improved relative to previous years, the limited scope of testing in some areas, plus instances where incorrect marker residues are analysed, has the potential to weaken its effectiveness.

5.1.2 Implementation of the residue monitoring plan

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive and must, in particular, meet the requirements of Article 4 and specify the particulars laid down in Article 7. Article 4(2)(b) and (c) of Council Directive 96/23/EC lays down the requirements for central competent authorities in co-ordinating the activities of all bodies involved in residues controls. Articles 5 and 12 of Council Directive 96/23/EC deal with aspects pertaining to the implementation of the residue monitoring plan. Sampling requirements are specified in Annex IV to Council Directive 96/23/EC and Commission Decision 97/747/EC and Commission Decision 98/179/EC lays down the rules for official sampling under the residue monitoring plan. EU methods of sampling for the official control a wide range of residues in products of animal origin are laid down in several pieces of EU legislation: Commission Directive 2002/63/EC (pesticides); Commission Regulation (EC) No 1883/2006 (dioxins and dioxin-like PCBs); Commission Regulation (EC) No 333/2007 (certain chemical elements); Commission Regulation (EC) No 401/2006 (mycotoxins).

Findings

The DVPH is responsible for the co-ordination and supervision of RMP implementation at central level. Weekly sampling orders are sent to the chiefs of the DVOs who in turn forward them to the Local Veterinary Inspectors (LVIs) responsible for sampling in the establishments/farms indicated in the sampling orders. Samples should be collected within stipulated deadlines (one week). Upon sampling, the analysis request form for the laboratory and the sampling report for the DVPH and the establishment/farm in question are completed by the LVIs. According to the sampling instructions in place, the LVIs should send monthly reports on sampling to the respective chiefs of DVOs who in turn have to prepare monthly reports for the DVPH and the DVI. Test reports from the laboratory should be sent to the DVPH and to the LVI who has taken the sample. In addition the IMHT sends comprehensive monthly reports to the DVPH on testing carried out under the RMP.

In line with the sampling instructions in place, a general turnaround time of 30 (calendar) days for

laboratory analyses has been agreed in the contract between the Veterinary Directorate and the IMHT.

The audit team noted that:

- Since 2010 annual training on RMP implementation and official controls on veterinary medicinal products has been provided by the Veterinary Directorate to central, district and local staff. In addition, an expert mission was carried out in Serbia through the Technical Assistance and Information Exchange instrument (TAIEX) of the European Commission in 2010, followed-up by a study visit in an EU Member State in 2011. The Veterinary Directorate central staff also participated in relevant training organised by the Better Training for Safer Food Initiative of the European Commission in 2012 and 2013.

- Selection of sampling sites (establishments/farms) is done weekly by the DVPH on the basis of their production, export status, previous non-compliant results and consultations with the DVOs responsible for official controls of these facilities. Data including production type and numbers of animals on the farms and production capacities of establishments were available to the audit team at the DVPH.

- All sampling is carried out by official staff and samples are transported to the laboratory by the IMHT staff/vehicles at the latest within two days from sampling. Adequate sampling materials and equipment were used including tamper-proof bags. This addresses **Recommendation No. 2** of the 2009 FVO audit report.

- Comprehensive records of sampling implementation were seen in the DVO visited and at the DVPH. Supervision of RMP implementation at the central level is mainly based on the IMHT monthly reports and on sampling reports submitted by the LVIs.

- According to the records examined at the DVPH, sampling and analyses in 2012 and 2013 (to date) has generally been carried out in accordance with planned arrangements. Target turnaround times for laboratory analyses were respected. Sampling covered all districts and was evenly spread over the year. This is in line with the point 2.1 in the Annex to Commission Decision 98/179/EC.

- There was evidence at the DVPH that in cases where the requested sampling was not possible, this was re-allocated or postponed. In addition, documents showed that the IMHT informs the DVPH on unsuitable samples received and that the DVPH informs the DVOs on detected deficiencies concerning sampling.

- There are detailed instructions in place (No. 323-07-01577/2010-05) for residue sampling of all commodities which include, inter alia, provisions on targeted sampling of live animals - an improvement relative to 2009. Sampling has to be carried out without prior warning as required by Article 12 of Council Directive 96/23/EC.

- Whilst targeting criteria were well described, some of the LVIs interviewed on-the-spot had limited knowledge of targeting criteria for live animals

- According to the DVPH and DVO visited, milk samples are mainly taken on farms and this was noted also in the relevant follow-up files examined by the audit team. However

sampling instructions allow for sampling of milk on farms and of blended milk at collection points or transportation tanks before discharging at dairy plants. Although all contributing farms to the blended milk must be identified to ensure traceability in case of non-compliant results, this sampling strategy reduces the possibility to detect residue violations (due to dilution). Consequently, **Recommendation no. 3** of the 2009 FVO audit report has not been fully addressed.

- The sampling instructions define suspect sampling. This is in line with EU requirements. The LVI in the slaughterhouse visited was aware of situations where such sampling would apply but stated that there were no such indications to date. The results of suspect sampling are generally not reported to the DVPH.

Conclusions on implementation of the residue monitoring plan

Sampling under the RMP has been carried out in line with the planned arrangements, generally fulfils EU requirements and the supervision of implementation is effective. However the sampling strategy for comingled milk militates against the detection of residues and weakens the effectiveness of the plan.

5.1.3 Other residues monitoring programmes

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive. Article 11 of Council Directive 96/23/EC gives the option of conducting other residues testing, particularly in relation to detection of illegal treatment of food producing animals. Article 9 of Council Directive 96/23/EC foresees the application of own-checks by food business operators.

5.1.3.1 Other official residues control programme

Findings

The Ministry of Health (MH) is responsible for the annual monitoring of food in accordance with the division of competencies between the MH and the MAFWF, as provided by the *Food safety law.* The monitoring is prepared by the Institute of Public Health of Serbia (IPHS) and is implemented by regional Public Health Institutes. Summarised results are published on the IPHS website.

The monitoring covers, inter alia, pesticides in dietetic foods, food additives and enzymatic preparations intended for food products. The rate of non-compliant results for pesticides has been low (two per year in 2011 and 2010). According to the Department of Sanitary Inspection of MH, these analyses are carried out in accredited laboratories and non-compliant results are investigated by sanitary inspectors including taking of administrative measures as necessary.

Pesticide monitoring in various products of plant and animal origin, co-ordinated by the Plant Protection Directorate of the MAFWF, is foreseen to start in 2013. In addition, a feed monitoring programme for residues is planned this year by the Veterinary Directorate under a twinning project with an EU Member State.

5.1.3.2 Establishment own-checks

Findings

According to national legislation, food business operators dealing with food of animal origin have to implement a Hazard Analysis Critical Control Point system (HACCP). The scope and frequency of own-checks are based on hazard analysis and risk evaluation carried out by the food business operators. Results of own-checks are available to the competent authority during official controls.

The DVI stated that most dairy and honey processing establishments carry out testing for antimicrobial substances under their own-check programmes.

The audit team noted that:

- In the slaughterhouse visited, an own-check programme for residues (chloramphenicol, sulphonamides, tetracyclines and heavy metals) has been in place for fresh meat since 2012. Two and four samples were taken in 2012 and 2013 respectively. Analyses are carried out at IMHT and there were no non-compliant results to date.

Conclusions on other residues monitoring programmes

Cumulatively, other residue monitoring programmes provide additional guarantees on the residues status of food exported to the EU.

5.1.4 Follow-up of non-compliant results

Legal Requirements

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

Findings

According to the official instructions in place, the laboratory must immediately inform the DVPH of non-compliant results. The DVPH must issue without delay an order for re-sampling and investigation to the chief of the DVO concerned, who in turn forwards this order to the relevant LVI. The latter is responsible for carrying out sampling and investigation. The LVI has to inform the respective DVO chief about the results of the investigation and the measures taken and to submit copies of all relevant documents to the DVPH.

The audit team noted that:

- Comprehensive instructions for follow-up procedures are included in the sampling instructions (see Section 5.1.2.). National legislation provides legal powers to the LVIs to carry out investigations in case of residue violations and to take measures.

- There were 120 non-compliant residue results under the 2012 RMP (chloramphenicol,

antimicrobials, anthelmintics, coccidiostats and heavy metals in various commodities). The latter two substance groups accounted for the majority of these results. Under the 2013 RMP (to date) there have been 41 non-compliant results (coccidiostats, heavy metals and aflatoxin M1). The audit team examined eight follow-up cases. Follow-up files were available at the DVPH and were generally complete.

- Regarding three non-compliant results for residues of veterinary medicinal products in the 2013 RMP, the follow-up procedures were timely and comprehensive and included on-farm investigations, additional sampling of animals/products and feed, checking of treatment records and temporary suspensions of animal movements and/or placing products on the market from farms. Whilst the reason for the infringements was not confirmed in any of these cases, the farms were included in the 2013 RMP (two had already been sampled).

- Regarding coccidiostat residues, the number of non-compliant results in eggs, poultry meat and feed (for broilers and laying hens) has increased since 2011. The majority of non-compliant results were below EU MRLs/MLs (there are no national tolerances in place for coccidiostats – see also Section 5.1.1.). Follow-up investigations were carried out for several of the results below EU MLs and for most of those above them. In one case (maduramycin in eggs) the follow-up was comprehensive and extended to the feed mill with several measures being imposed (see also Section 5.3.2.2.). However, the follow-up for diclazuril in eggs was closed too early (i.e. after an initial on-farm investigation as there were no eggs found on the farm) and two findings of maduramycin in feed were not investigated.

- In February 2013 there was widespread mycotoxin contamination of milk (Aflatoxin M1) due to fungal contamination of fodder. Additional sampling on farms has been included in the RMP. In one case examined by the audit team the investigation was prompt and comprehensive. The ban on placing milk on the market was lifted after results of follow-up milk samples showed compliance with the national ML which, as of 1 March 2013, is ten times higher than in the EU. The DVI stated that dairy establishments approved for export to EU operate systems to separate EU-compliant milk from nationally-compliant milk regarding hygiene requirements (recently extended to cover requirements for Aflatoxin M1).

- In relation to the actions taken, action plans were prepared by the affected dairy establishments and documentary evidence of the actions taken in one of them was seen. This included sampling of milk by the food business operator for analysis at IMHT, performing of rapid tests by the dairy's internal laboratory to separate EU-compliant milk from the rest and official controls with occasional sampling of separated EU-compliant milk. According to the DVI, other (State aid) measures taken included the supply of non-contaminated maize and mycotoxin absorbents to affected farms.

- The follow-up of the 2010 RASFF notification (sulphonamides in honey) was prompt and included a number of official controls in the processing plant concerned and imposing of measures (e.g. export ban pending the implementation of internal controls including analysis in relevant EU laboratories). No on-farm investigation was carried out due to a lack of traceability to farm level. According to records of official controls this lack of traceability has been subsequently rectified by the food business operator.

Conclusions on follow-up investigations/actions

In general, the legal and administrative framework for follow-up of non-compliant residues results is in line with the relevant provisions of Council Directive 96/23/EC. Follow-up investigations are generally carried out in a timely manner, are well co-ordinated and comprehensive, though, with regard to the coccidiostats problem in poultry, have not always been effective.

5.2 LABORATORIES

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive. Article 15 of Council Directive 96/23/EC requires that official samples are examined in approved laboratories. Requirements for accreditation of laboratories are laid down in Point 1.2. of the Annex to Commission Decision 98/179/EC. The rules for analytical methods to be used in the testing of official samples taken pursuant to Article 15(1) of Council Directive 96/23/EC are laid down in Commission Decision 2002/657/EC – in particular Articles 3, 4, 5 and 6 which cover inter alia, validation requirements and quality control. More specific requirements for analytical methods for certain substances are laid down in the annexes to Commission Regulation (EC) No 1883/2006 (dioxins and dioxin-like PCBs in foodstuffs), Commission Regulation (EC) No 333/2007 (chemical elements in foodstuffs) and Commission Regulation (EC) No 401/2006 (mycotoxins).

Findings

As described in the 2009 FVO audit report, all samples under the RMP are analysed in the IMHT which is the National Reference Laboratory (NRL) for Serbia.

The legal basis for the designation of laboratories for official controls is provided by Article 21 of *Law on veterinary matters* and Article 21 of *Food safety law.*

The audit team visited two laboratories within the IMHT (i.e. the microbiology and residue laboratory) which for the purpose of this report are dealt with as a single laboratory and noted that:

- The IMHT holds a certificate of conformity with the ISO 9001 standard for quality management systems and is accredited to ISO 17025 by the Accreditation Body of Serbia which is a member of the European cooperation for accreditation and International Laboratory Accreditation Cooperation. All methods currently included in the RMP are within the scope of accreditation, except for Group B3b (organophosphorous compounds). The current accreditation certificate is dated 1 March 2012 and is valid until 29 Feb 2016. It was issued on the basis of a favorable evaluation which revealed no significant scientific or operational deficiencies.

- Screening tests for antibiotics and ELISA assays for steroids are carried out in the IMHT microbiology laboratory whilst the residue laboratory is responsible for all other analyses.

- Laboratory facilities for analyses are adequate and several instruments are used for RMP analyses i.e. two LC-MS/MS, one ICP MS, one GC-MS, two GC-ECD, five HPLC (with UV, PDA and FL detectors), two AAS and three ELISA readers. LC-MS/MS is the current technique of choice for confirmation. The two such systems available are aged two and seven years, respectively. Since the laboratory combines the tasks of both a routine laboratory (analyses of routine samples) and an NRL (development and validation of

analytical methods), this is considered limited.

- Laboratory staff were competent and have attended workshops, seminars and meetings organised by EURLs. This, together with access to scientific literature, assures adequate training of staff.

- Sample acceptance criteria are included in the sampling instructions (see Section 5.1.2.) and samples are inspected for integrity upon registration. After initial processing they are stored at the requested temperature in an adequate storage facility.

- The analysis request form (accompanying the sample to the laboratory) does not indicate the sampling site or the owner of sampled animals/products. In addition, information available to laboratory technicians is limited to matrix, analytes to be analysed and due dates. Therefore the anonymity of samples is ensured.

- The laboratory has a procedure in place for internal quality control (QC) which describes the verification of method performance and the use of control samples in routine analyses. There is also an adequate system in place for recording the availability and use of analytical standards. Reference materials are used when available. In addition, a procedure has been established for verification of the raw analytical results by supervisors and subsequently of the final result by the responsible staff member.

- Since 2010, the laboratory has participated in a number of proficiency testing schemes for residues and contaminants, with mostly satisfactory results.

- There is a standard operating procedure (SOP) in place for validation of analytical methods. This procedure includes two options: "In-house validation" and "Validation according to Commission Decision 2002/657/EC". The scope of the "In-house validation procedure" is limited and does not cover essential parameters for screening and confirmatory methods as included in Commission Decision 2002/657/EC. In-house validation includes the determination of the LoD, Limit of Quantification (LoQ) and a limited evaluation of the repeatability and within-laboratory reproducibility. According to the information provided to the audit team, a number of analytical methods are not yet validated in line with Commission Decision 2002/657/EC.

- The contract between the Veterinary Directorate and the IMHT states that results for RMP analyses have to be reported within 30 days (see also Section 5.1.2.). In practice this has proven to be feasible. The contract also stipulates that methods should be accredited, but does not specify Commission Decision 2002/657/EC as the basis for validation.

The audit team examined several methods including validation files and noted that:

- Both methods for tetracyclines - screening by five-plate microbial growth inhibition test (based on a commercially available test) and confirmation by LC-MS/MS - have been validated according to Commission Decision 2002/657/EC. The validation file for the five-plate test was available but most of the data were from before 2010 and not all records were traceable, only the overview validation report. This validation file demonstrated adequate performance at levels below 0.5 MRL for most compounds. Groups of antibiotics for which LoD values were too high were (correctly) not included in the scope of this test. The

laboratory participated in a proficiency test for tetracyclines using the five-plate method, with good results.

- The confirmatory method for tetracyclines was originally described in 2007 and includes both UV- and MS-detection. Sample preparation is the same for both detection systems. Validation and accreditation data were obtained using UV-detection and therefore do not fully reflect the actual situation today. By using UV-detection (single wavelength), the method does not fulfill the criteria for confirmation.

- The validation of both (screening and confirmatory) methods for tetracyclines cannot be regarded as a full validation according to Commission Decision 2002/657/EC since several parameters were not included i.e. rate of occurrence of false positive results, rate of possible occurrence of false negative results and robustness. Moreover, validation data were only available for bovine matrices, whereas the application of the method is wider.

- However, systematic collection of QC data for tetracyclines is in place, including the results of negative and positive control samples. The results demonstrate adequate system stability and these QC-data could be used to further complete the validation file.

- Regarding the screening and confirmatory method for thyreostats in urine by LC-MS/MS, the value for CC-beta is 12 µg/kg which is just higher than EURL´s recommended concentration of 10 µg/kg. Validation is based on Commission Decision 2002/657/EC but until now has been limited to CC-beta and repeatability. Method implementation was verified by the audit team and proved to be in good order. The laboratory will participate in 2013 in a relevant proficiency test organised by the EURL.

- All of the screening methods for steroids are based on ELISA assays (commercial kits). For example, whilst the target analyte for the screening assay for boldenone is beta-boldenone, there is acceptable cross-reactivity for the main metabolite alpha-boldenone. However, the procedure does not include enzymatic de-conjugation which is not logical as this compound is strongly conjugated during excretion. Some validation data are included in the leaflet of the reagent kit. The laboratory has verified that there is no overlap between the response in blank samples and samples at the relevant action level (2 µg/kg), implicitly verifying that the rate of false positive results is limited. Nevertheless the lack of a deconjugation step would suggest that false negative results are a real possibility.

- For the screening assays for nortestosterone and trenbolone, the observations are similar to those for boldenone. However, here the procedures do (correctly) include an enzymatic de-conjugation.

- Currently there are no confirmatory methods in place for steroids, stilbenes, resorcyclic acid lactones and beta-agonists. To date, no laboratory has been subcontracted to carry out these confirmatory tests (see also Section 5.1.1.) though, according to the IMHT, there were no screening-positive results for these substance groups to date.

- The laboratory reported a non-compliant result for chloramphenicol (3 µg/kg) in poultry muscle in 2012. Laboratory records showed adequate confirmatory analyses fulfilling all criteria for confirmation. Control data were in place and did not indicate any anomalies.

- Overall, limited progress has been made in relation to validation of methods relative to the situation described in the 2009 FVO audit report, with most of the methods being validated to a limited extent compared to the requirements of Commission Decision 2002/657/EC. Therefore **Recommendation No. 5** of the 2009 FVO audit report has not been fully addressed.

- The laboratory has implemented an SOP for Quality Assurance of analytical methods, which includes guidelines for QC of routinely performed methods. It was demonstrated to the audit team that these procedures have been adequately implemented in the daily activities. Quality control data are recorded and evaluated. Therefore, **Recommendation No. 6** of the 2009 FVO audit report has been adequately addressed.

Conclusions on laboratories

The accreditation of almost all methods used for the residue monitoring plan, generally successful participation in regular proficiency testing and adequate quality control procedures in place provide assurances of good laboratory performance. Notwithstanding those positive aspects of laboratory performance, deficiencies in method validation - a problem identified during the previous FVO residue audit - have the potential to weaken the effectiveness of residue controls. Furthermore, the absence of an enzymatic deconjugation step for some of the screening assays for steroids in urine risks failing to identify abuse of the analytes in question.

5.3 VETERINARY MEDICINAL PRODUCTS AND MEDICATED FEEDINGSTUFFS

5.3.1 Authorisation, distribution and use of veterinary medicinal products

Legal Requirements

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

Article 7 of Council Directive 96/23/EC provides for legislation on the use of (pharmacologically active) substances listed in Annex I to the Directive and, in particular, provisions on their prohibition or authorisation, distribution and placing on the market and the rules governing their administration. Articles 4, 5 and 7 of Council Directive 96/22/EC establish conditions for the administration of substances, referred to in its Annex II, List B and Annex III, to farm and aquaculture animals.

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

The relevant provisions in EU law governing the marketing authorisation of veterinary medicinal products are laid down in Articles 5-15, 21-30, 58-62 and 83 of Directive 2001/82/EC and for

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

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

Findings

All veterinary medicinal products require marketing authorisation and the Veterinary Medicines Department within the MMDAS is responsible for issuing them. New authorisations are valid for five years. With regard to authorisation of veterinary medicinal products, the audit team noted that:

- *Law on medicines and medical devices* contains national requirements for the authorisation and use of veterinary medicinal products (including medicated feedingstuffs) which are similar to the requirements of Directive 2001/82/EC.

- *Decision on the ban on use of certain substances of veterinary medicinal products in veterinary medicine for treatment of food producing animals* contains a list of pharmacologically active substances prohibited to be used in food producing animals. It is in line with the requirements of Directive 96/22/EC and Table 2 of the Annex to Regulation (EC) No 37/2010.

- All pharmacologically active substances currently used in nationally authorised products are listed in the Annex I to Regulation (EC) No 37/2010, with one exception - dantron, for which the marketing authorisation has already expired and products can only be used for an additional period of six months. In general, authorisations of products are in line with Annex I to the above Regulation.

- *Law on medicines and medical devices* stipulates that veterinary medicinal products should only be authorised if they contain pharmacologically active substances with established MRLs. The adoption of a Rulebook on MRLs for veterinary medicinal products in foodstuff of animal origin was planned for the end of 2012 but has been delayed (see also Section 5.1.1.). According to MMDAS, EU MRLs are used to establish withdrawal periods.

- National labelling requirements for veterinary medicinal products, provided in *Law on medicines and medical devices* and *Rulebook on the content and method of labelling the outer and immediate packaging of a medicine, additional labelling and content of the package leaflet* are equivalent to the provisions of Directive 2001/82/EC.

Based on national legislation, all establishments distributing veterinary medicinal products have to

be authorised. The Unit for Veterinary Services within the Veterinary Directorate is responsible for the authorisation of marketing authorisation holders (manufacturers and importers/wholesalers) and for authorisation/registration of veterinary pharmacies. The Veterinary Directorate has an electronic register of all authorised establishments. At present, 123 wholesalers and 280 veterinary pharmacies are authorised. With regard to the distribution and use of veterinary medicinal products, the audit team noted that:

- Authorisations of wholesalers and pharmacies are of unlimited duration, but the DVI can request the Unit for Veterinary Services to revoke an authorisation if the result of official controls would require this.

- *Law on medicines and medical devices* governs the distribution of veterinary medicinal products. Manufactures and importers/wholesalers can sell to veterinary pharmacies and veterinary practices/organisations but not directly to farmers. According to *Law on veterinary matters*, veterinary pharmacies and veterinary practices with a veterinary pharmacy are entitled to sell veterinary medicines for oral or topical application only. All other products have to be applied by a veterinarian and cannot be sold to a farmer.

- The requirement to keep treatment records on farms is stipulated in Regulation aligning national rules with Directive 96/23/EC (see Section 5.1.1.) whilst the minimum time for keeping of prescriptions on farms is laid down in *Law on veterinary matters* (one year). For veterinary medicinal products applied by veterinarians, *Rulebook on the content and keeping of veterinary records and their reporting* requires that the veterinarian records the treatment in a record book. However, the prescribed template for this book does not require recording of withdrawal periods. At the farm visited, all veterinary medicinal products were applied by veterinarians who kept the record book and demonstrated to the audit team by means of other treatment records that the relevant withdrawal periods for milk and meat of treated animals had been respected.

- Instruction No. 323-06-5157/1/2009-05 requires veterinary practitioners to issue treatment receipts to farmers, in which the practitioner records treatments and respective withdrawal periods. Farmers have to sign these receipts and veterinarians are required to inform farmers about their obligation to keep them for one year.

- *Law on medicines and medical devices* requires a veterinary prescription for all veterinary medicines intended for use in food producing animals. However, the updated list of authorised veterinary medicinal products contains a number of products which can be sold for use in food producing animals without a prescription. The Veterinary Directorate stated that Article 54 of the above Law provides for a derogation from the general rule in line with EU legislation (Directive 2006/130/EC). Most of the products exempted from prescription are for topical or oral use and apart from one example no withdrawal period has to be respected. Law on medicines and medical devices also provides for off-label use of veterinary medicinal products.

- *Rulebook on the form and content of a prescription for veterinary medicinal products* provides for the minimum information to be included in a veterinary prescription. At the veterinary pharmacy visited, the majority of prescriptions were issued for antibiotic powders having withdrawal periods. However, none of the prescriptions fulfilled the national requirements as withdrawal periods, instructions for use of the product, sex and age of animals were not indicated.

- According to national legislation, veterinary pharmacies and farms have to keep (copies of) prescriptions for one year (in EU this is required for five years). At the pharmacy visited, the prescribing veterinarian stated that farmers do not receive copies of prescriptions (from this pharmacy), but have to obtain relevant information from the label of the veterinary medicinal product. This is not in line with national requirements.

- National legislation requires that the veterinary practitioner from a veterinary station, contracted by the Veterinary Directorate to carry out annual Programme of Animal Health Measures at the farm, issues the prescribed animal health certificate whenever an animal leaves the farm. This certificate includes a statement in which the issuing veterinarian indicates treatments. The certificate requires inclusion of information (number) of the previous certificate issued for this animal. If the animal is sent to a slaughterhouse, the owner (in addition to the issuing veterinarian) confirms in this certificate that the animal has not been treated or that, if treated, withdrawal periods have been respected (in line with Instruction No. 323-07-2850/1/2010-05). In this case, the certificate serves as food chain information as laid down in Annex II, Section III, point 3(c) to Regulation (EC) No 853/2004, and therefore the respective part of **Recommendation No. 7** of the 2009 FVO audit report has been addressed.

- At present, national requirements equivalent to the provisions of Directive 90/167/EEC for medicated feedingstuffs, are not yet implemented, as *Rulebook on conditions for preparation, placing on the market and use of medicated feedingstuffs* is still in the legal procedure for adoption. Therefore **Recommendation No. 9** of the 2009 FVO audit report will only be addressed after the adoption and implementation of the drafted Rulebook. According to the Veterinary Directorate, four out of about 360 existing feed mills have expressed an interest for authorisation to produce medicated feedingstuffs.

Conclusions on authorisation, distribution and use of veterinary medicinal products

Most of the national requirements with regard to authorisation, distribution and use (including treatment records) of veterinary medicinal products are broadly equivalent to EU legislation.

5.3.2 Controls on the distribution and use of veterinary medicinal products

Legal Requirements

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

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

rules governing control functions by the competent authorities are laid down in Articles 4, 9 and 13 of said Directive.

5.3.2.1 Controls at wholesale and retail level and on farms

Findings

The DVI is responsible for official controls of manufacturers and wholesalers/importers of veterinary medicinal products. Controls of veterinary retailers/pharmacies are carried by LVIs or as joint inspections by staff from the central level and LVIs. In 2012, the DVI controlled 77 wholesalers and 18 veterinary pharmacies and noted ten non-compliances for wholesalers and six for pharmacies, mainly related to the maintenance of facilities and elapsed expiry dates (for the individual product or its marketing authorisation).

The 25 DVOs and corresponding LVIs are responsible for official controls on farms. Legal requirements on the use of veterinary medicinal products are controlled on farms as part of official controls on cross-compliance.

Official controls are carried out on the basis of a monthly established control plan. Instruction No. 323-06-3963/2009-05 requires checking of data related to animal treatments including withdrawal periods. Standardised checklists are used for all controls and also serve to record the results. The operators/farmers receive a copy of the record.

Food chain information for all food producing animal species is implemented by means of animal health certificates (see Section 5.3.1.).

The audit team noted that:

- The last official control in the veterinary pharmacy visited took place in December 2012 and the standardised checklist was used to record the results of this control. The report indicated that the pharmacy had not kept veterinary prescriptions and did not maintain the required register of veterinary medicinal products sold on veterinary prescription. The responsible veterinarian of the pharmacy had rectified the shortcomings noted but the prescriptions kept did not meet the national requirements - see Section 5.3.1.

- The last official control of the dairy farm visited took place in November 2012 with the results recorded on the standardised checklist (for large farms). The officials had misinterpreted part II of the checklist which relates only to the use of veterinary medicinal products by the veterinarians of an on-farm veterinary station. Due to that, some of the results recorded with regard to treatment records and use of veterinary medicinal products were contradictory and did not reflect the procedures established on this farm.

- The checklist for small farms and the other parts of the checklist for large farms – except part II – do not contain detailed questions related to medicinal treatments, recording of respective withdrawal periods or if withdrawal periods had been respected before animals went for slaughter. Therefore all of the requirements of Instruction No. 323-06-3963/2009-05 are not reflected in sufficient detail in these checklists. The questions on the checklist would not facilitate officials to verify that national requirements have been met regarding keeping of prescriptions or treatment receipts by farmers and respecting withdrawal periods.

- Results of official controls – including those related to use of veterinary medicinal products – are kept centrally and the Veterinary Directorate verifies the implementation and efficiency of official controls. In 2012, 137 non-compliances related to use of veterinary medicinal products have been detected, 16 of which were brought to court in order to enforce corrective actions.

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

Findings

LVIs will be responsible for official controls of authorised/registered feed mills producing medicated feedingstuffs when relevant legislation is adopted (see Section 5.3.1.). The audit team visited one feed mill and noted that:

- To date, the feed mill has not produced medicated feedingstuffs but does manufacture feedingstuffs with additives (coccidiostats). There are procedures in place to avoid cross-contamination of non-target feed with coccidiostats. The effectiveness of these procedures for the production of compound feedingstuffs has been verified by the feed mill.

- The responsible LVI had visited the feed mill in September and October 2012 as part of the follow-up investigation of non-compliant results for coccidiostats in eggs (see Section 5.1.4.). The implementation of required corrective actions had been followed-up by the official staff.

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

While the system of official controls on the distribution and use of veterinary medicinal products with regard to wholesalers, pharmacies and veterinarians is functioning, the structure of the reporting form used to record the outcome of such controls does not facilitate the verification that certain national requirements on the keeping of prescriptions and respecting of withdrawal periods are met.

5.3.3 Identification of equidae and medicines records requirements

Legal Requirements

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

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

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

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

Findings

The audit team noted that:

- *Rulebook on identification and registration of equidae and official controls on identification and registration of equidae* provides requirements similar to those stipulated in Regulation (EC) No 504/2008.

- The Veterinary Directorate estimates that approximately 80% of the existing 20 – 23,000 horses are identified by means of transponders. This has been carried out by contracted veterinary stations (responsible for the annual Programme of Health Measures). The Veterinary Directorate stated that it has not yet issued horse passports due to the fact that the electronic database is not yet functional and due to financial restrictions. Therefore **Recommendation No. 10** of the 2009 FVO audit report has not been addressed. However, it stated that three breeding organisations have issued around 1500 horse passports for registered horses. The Veterinary Directorate intends to issue duplicate passports for these horses when the electronic database is fully functional.

- In 2012, 91 horses were exported to a Member State from one authorised quarantine (collection) centre where horses stayed for at least 30 days before an export certificate was issued. Horses entering the quarantine centre should be accompanied by the animal health certificate (see Section 5.3.1.). Another animal health certificate was issued for each horse, for the period the horses stayed in the quarantine centre, and was attached to the export certificate. In the last animal health certificate it was not explicitly stated that the horse had not been treated for (at least) the last six months with veterinary medicinal products which would - according to EU legislation - exclude the animal from the food chain. In addition, in documents related to one export consignment examined by the audit team, the last animal health certificates (covering the last 30 days prior to export) did not include any link to the previous certificates accompanying the horses to the quarantine centre.

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

Whilst the majority of horses have been electronically identified, the absence of passports and,

regarding exports of live *equidae* to the EU, lack of traceability between incoming and outgoing animal health certificates makes it difficult for the competent authority to ensure that exported *equidae* have not been treated with substances which would exclude them from human consumption.

5.4 Follow-up of relevant recommendations made in previous FVO report on residues (DG(SANCO) 2009-8194 - MR Final)

N	Recommendation	Findings
1	Ensure that scope of testing carried out under the national residue control plan includes all relevant substances in line with the range of veterinary medicinal products on the market in order to give guarantees equivalent to those foreseen in Article 7 of Council Directive 96/23/EC and that all taken samples are analysed.	The recommendation has been partially addressed (see Section 5.1.1.).
2	Ensure that sampling and the integrity of samples is in line with the principles laid down in Annex III of Council Directive 96/23/EC and Commission Decision 98/179/EC.	The recommendation has been addressed (see Section 5.1.2.).
3	Ensure that milk samples taken under the national residue control plan are traceable to the farm of origin in line with Chapter 1, point 1.A of the Annex to Commission Decision 97/747/EC in order to facilitate effective follow-up investigations which are at least equivalent to those described in Council Directive 96/23/EC.	The recommendation has been partially addressed (see Section 5.1.2.).
4	Ensure that the national residue control plan submitted to the Commission provides all of the details necessary to permit a complete assessment against requirements of Council Directive 96/23/EC.	The recommendation has been addressed (see Section 5.1.1.).
5	Ensure that all analytical methods used for the national residue control plan are validated to a standard equivalent to that required by Article 3 of Commission Decision 2002/657/EC and are capable of detecting residues at Community MRLs in line with the requirements of point 3 in Annex III to Council Directive 96/23/EC and point 2.2. (b) in the Annex to Commission Decision 98/179/EC.	This recommendation has not been fully addressed (see Sections 5.2. and 5.1.1.).
6	Ensure that appropriate laboratory quality control procedures are carried out to a standard equivalent to that required by Article 5 of	This recommendation has been addressed (see Section 5.2.).

	Commission Decision 2002/657/EC.	
7	Ensure that animals within drug withdrawal periods may not be accepted for slaughter and all authorised veterinary medicinal products are labelled according to the standards equivalent to the requirements of Article 58 of Directive 2001/82/EC.	This recommendation has been adequately addressed (see Section 5.3.1.).
9	Ensure that requirements for the production of medicated feedingstuffs and controls on the production and distribution of medicated feedingstuffs provide guarantees equivalent to those foreseen by Council Directive 90/167/EEC.	The implementation of relevant EU requirements is pending the adoption of (already drafted) respective national legislation. However, at present this Recommendation has not been addressed (see Section 5.3.1.).
10	Ensure that all equidae are identified according to the plan provided to Commission services on 26/10/2009 and that the equidae identification system can offer guarantees equivalent to those provided for by Commission Regulation (EC) No 504/2008.	This recommendation has not been completely addressed (see Section 5.3.3.).

6 Overall Conclusions

It is concluded that the Residue Monitoring Plan (RMP) is generally in line with Council Directive 96/23/EC. Sampling under the RMP has been carried out in line with the planned arrangements, generally fulfils EU requirements and the supervision of implementation is effective. Follow-up investigations are generally carried out in a timely manner, are well co-ordinated and comprehensive. However, some issues such as the limited scope of testing in some areas, inadequate sampling strategy for comingled milk and shortcomings in follow-up procedures with regard to coccidiostats in poultry weaken the effectiveness of residue control plan.

The laboratory analysing all samples under the RMP is accredited to ISO 17025, with almost all methods being included in the accreditation scope. In addition, generally successful participation in regular proficiency testing and adequate quality control procedures in place provide assurances of good laboratory performance. However, deficiencies in method validation - a problem identified during the previous FVO residue audit - have the potential to weaken the effectiveness of residue controls.

Most of the national requirements with regard to authorisation, distribution and use (including treatment records) of veterinary medicinal products are broadly equivalent to EU legislation and there is an operational system in place for official controls. However, the reporting form structure does not facilitate the verification that certain national requirements on the keeping of prescriptions and respecting of withdrawal periods are met.

Whilst the majority of horses have been electronically identified, the absence of passports and, regarding exports of live *equidae* to the EU, lack of traceability between animal health certificates

makes it difficult for the competent authority to ensure that exported *equidae* have not been treated with substances which would exclude them for human consumption.

7 Closing Meeting

A closing meeting was held on 19 April 2013 with representatives of the central competent authority. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities did not express disagreement with the presented main findings and preliminary conclusions.

8 Recommendations

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

N°.	Recommendation
1.	Ensure that scope of testing carried out under the RMP includes all relevant substances in line with the range of veterinary medicinal products on the market taking into account the requirements of Article 7 of Council Directive 96/23/EC, that the correct marker residues are analysed for and that the scope of testing in substance groups A3, A4 and A5 is broadened.
2.	Ensure that all milk samples taken under the RMP are directly traceable to the farm of origin (i.e. taken from farms or at dairy plants from non-blended milk), as intended by Chapter 1, point 1.A of the Annex to Commission Decision 97/747/EC, in order to facilitate detection of residue violations.
3.	Ensure that the follow-up of non-compliant results is effective as required by the relevant requirements of Council Directive 96/23/EC.
4.	Ensure that all analytical methods used under the RMP for monitoring residues of veterinary medicinal products are validated to a standard equivalent to Article 3 of Commission Decision 2002/657/EC and are fit for purpose.
5.	Ensure that the implementation and official controls of national requirements relating to the prescription and application of veterinary medicinal products to food producing animals provide guarantees equivalent to those provided for by Article 10 of Directive 96/23/EC i.e. that farmers receive and keep (completed) veterinary prescriptions in line with national legislation and that the checklist for official controls is sufficiently detailed in this regard.
6.	Ensure that equidae exported to the EU for direct slaughter are not derived from animals treated with pharmacologically active substances not listed in Table 1 of the

N°.	Recommendation
	Annex to Commission Regulation (EU) No. 37/2010 or in Commission Regulation (EC) No. 1950/2006 and that withdrawal periods have been respected for treated animals i.e. ensure that a system of identification, traceability and treatment records is implemented in order to provides guarantees at least equivalent to those provided by Regulation (EC) No. 504/2008.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6763

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Audits by the Commission Services		
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Food Law		
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Monitoring and sampling of residues in food of animal origin		
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC

Legal Reference	Official Journal	Title
Dec. 97/747/EC	OJ L 303, 6.11.1997, p. 12-15	97/747/EC: Commission Decision of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products
Dec. 98/179/EC	OJ L 65, 5.3.1998, p. 31-34	98/179/EC: Commission Decision of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products
Approval of residue monitoring plans submitted by third countries		
Dec. 2011/163/EU	OJ L 70, 17.3.2011, p. 40-46	2011/163/EU: Commission Decision of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC
Validation of analytical methods for residues and Minimum Required Performance Limits		
Dec. 2002/657/EC	OJ L 221, 17.8.2002, p. 8-36	2002/657/EC: Commission Decision of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results
Bans on the use of hormones and beta-agonists for growth promotion in food producing animals		
Dir. 96/22/EC	OJ L 125, 23.5.1996, p. 3-9	Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
Maximum Residue Limits for veterinary medicinal products in food of animal origin		

Legal Reference	Official Journal	Title
Reg. 470/2009	OJ L 152, 16.6.2009, p. 11-22	Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council
Reg. 37/2010	OJ L 15, 20.1.2010, p. 1-72	Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin
Maximum Residue Levels for pesticide residues in food of animal origin		
Reg. 396/2005	OJ L 70, 16.3.2005, p. 1-16	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
Maximum Levels for contaminants in food		
Reg. 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Authorisation of veterinary medicinal products		
Dir. 2001/82/EC	OJ L 311, 28.11.2001, p. 1-66	Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

Legal Reference	Official Journal	Title
Dir. 2006/130/EC	OJ L 349, 12.12.2006, p. 15-16	Commission Directive 2006/130/EC of 11 December 2006 implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription
Reg. 726/2004	OJ L 136, 30.4.2004, p. 1-33	Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
Medicated feedingstuffs and additives		
Dir. 90/167/EEC	OJ L 92, 7.4.1990, p. 42-48	Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community
Reg. 1831/2003	OJ L 268, 18.10.2003, p. 29-43	Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition
Reg. 183/2005	OJ L 35, 8.2.2005, p. 1-22	Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene
Sampling methods and methods of analysis for contaminants in foodstuffs		
Reg. 333/2007	OJ L 88, 29.3.2007, p. 29-38	Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs
Reg. 401/2006	OJ L 70, 9.3.2006, p. 12-34	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs

Legal Reference	Official Journal	Title
Reg. 252/2012	OJ L 84, 23.3.2012, p. 1-22	Commission Regulation (EU) No 252/2012 of 21 March 2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006
Sampling methods for pesticides in foodstuffs		
Dir. 2002/63/EC	OJ L 187, 16.7.2002, p. 30-43	Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC
Horse identification (passport)		
Reg. 504/2008	OJ L 149, 7.6.2008, p. 3-32	Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae
Medicines essential for the treatment of equidae		
Reg. 1950/2006	OJ L 367, 22.12.2006, p. 33-45	Commission Regulation (EC) No 1950/2006 of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae