FINAL REPORT OF AN AUDIT
CARRIED OUT IN
CROATIA
FROM 10 TO 19 FEBRUARY 2015
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 Croatia, carried out from 10 to 19 February 2015, as part of the published programme of FVO audits.

The objective of the audit was to evaluate the monitoring of residues of veterinary medicinal products, pesticides and contaminants in live animals and animal products and the effectiveness of official controls on the use of veterinary medicinal products in food-producing animals, in the context of preventing, eliminating, or reducing to acceptable levels risks to humans and animals either directly or through the environment.

This first audit on the monitoring of residues after the accession of Croatia as a Member State of the European Union focused on the legal and administrative measures in place to implement the relevant EU requirements and on the performance of the competent authorities in meeting these requirements.

Notwithstanding the absence of residue monitoring in the first two months of the year, the competent authority can have confidence in the effectiveness of the planning process and the implementation of its residue monitoring plan as well as in the follow-up of non-compliant results. Whilst there are a few shortcomings in the implementation of some analytical methods, the competent authority can trust in the laboratory performance and the reliability of analytical results, as all of the laboratories in the network are accredited to ISO 17025, laboratory methods are adequately validated and staff are sufficiently trained. With the exception of the outstanding notification of the list of products exempted from a veterinary prescription, the national marketing authorisation of veterinary medicinal products as well as their distribution and use and official controls thereon, are generally in compliance with EU legislation.

The report makes a number of recommendations to the Croatian competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.
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<tr>
<td>CVI</td>
<td>Croatian Veterinary Institute</td>
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<td>EU</td>
<td>European Union</td>
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<td>EURL</td>
<td>European Union Reference Laboratory</td>
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<td>FVO</td>
<td>Food and Veterinary Office</td>
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<tr>
<td>HPLC –DAD/Fluor</td>
<td>High Performance Liquid Chromatography with Diode Array Detector / Fluorescence Detector</td>
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<td>ISO</td>
<td>International Organisation for Standardisation</td>
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<tr>
<td>LC-MS/MS</td>
<td>Liquid Chromatography-(Tandem) Mass Spectrometry</td>
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<td>LVO</td>
<td>Local Veterinary Office</td>
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<td>MoA</td>
<td>Ministry of Agriculture</td>
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<td>MRL</td>
<td>Maximum Residue Limit</td>
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<td>NRL</td>
<td>National Reference Laboratory</td>
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<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
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<td>RMP</td>
<td>Residue Monitoring Plan</td>
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<td>RVO</td>
<td>Regional Veterinary Office</td>
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<td>SOP</td>
<td>Standard Operating Procedure</td>
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<td>VFSD</td>
<td>Veterinary and Food Safety Directorate</td>
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<td>VIS</td>
<td>Veterinary Inspection Services</td>
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<td>VMPRMD</td>
<td>Veterinary Medicinal Products and Residue Monitoring Division</td>
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<td>VPHFSS</td>
<td>Veterinary Public Health and Food Safety Sector</td>
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1 INTRODUCTION

The audit took place in Croatia from 10 to 19 February 2015. The audit team comprised two auditors from the Food and Veterinary Office (FVO) and one expert from a European Union (EU) Member State. The audit was undertaken as part of the FVO's planned audit programme.

Representatives from the central competent authority accompanied the audit team during the whole audit. An opening meeting was held on 10 February 2015 with the competent authorities responsible for the monitoring of residues and contaminants in live animals and animal products and for the authorisation, as well as control of distribution and use 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 monitoring of residues of veterinary medicinal products, pesticides and contaminants in live animals and animal products and the effectiveness of official controls on the use of veterinary medicinal products in food-producing animals in the context of preventing, eliminating, or reducing to acceptable levels risks to humans and animals either directly or through the environment.

The principal audit criteria against which fulfilment of the above objective was assessed comprise:


The audit focused on the legal and administrative measures in place to implement the relevant European Union (EU) requirements and on the performance of the competent authorities in meeting these requirements. The table below lists the sites visited and meetings held in order to achieve the audit objective.

<table>
<thead>
<tr>
<th>MEETINGS/VISITS</th>
<th>n</th>
<th>COMMENTS</th>
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<tr>
<td>COMPETENT AUTHORITIES</td>
<td>Central</td>
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<tr>
<td></td>
<td>Regional</td>
<td>2</td>
</tr>
<tr>
<td>LABORATORIES</td>
<td>4</td>
<td>Governmental laboratories, the Croatian Veterinary Institute, two laboratories in Zagreb and two local laboratories in Križevci and in Rijeka</td>
</tr>
<tr>
<td>FARMS</td>
<td>2</td>
<td>One cattle and one pig farm</td>
</tr>
<tr>
<td>ESTABLISHMENTS</td>
<td>3</td>
<td>One slaughterhouse for cattle and pigs, one wholesaler and one pharmacy for veterinary medicinal products</td>
</tr>
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</table>

3 LEGAL BASIS

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

- Article 45 of Regulation (EC) No 882/2004;

A full list of the legal instruments referred to in this audit report is provided in Annex 1 and refers, where applicable, to the last amended version.

4 BACKGROUND

This was the first FVO audit to evaluate the monitoring of residues of veterinary medicinal products, pesticides and contaminants in live animals and animal products and the effectiveness of official controls on the use of veterinary medicinal products since the accession of Croatia to the EU. Prior to accession, the FVO carried out audits in the framework of the accession preparations of Croatia, in order to assist and monitor progress with the adoption of the relevant EU requirements.

5 FINDINGS AND CONCLUSIONS

5.1 RESIDUE MONITORING

5.1.1 Competent authorities

1. The Veterinary and Food Safety Directorate (VFSD) within the Ministry of Agriculture (MoA) is the central competent authority for drafting and implementing the national residue monitoring plan (RMP).

2. Within VFSD, staff of the Veterinary Medicinal Products and Residue Monitoring Division (VMPRMD, part of the Veterinary Medicinal Products, Feed and Animal By-products Service, which in turn is part of the Veterinary Public Health and Food Safety Sector, VPHFSS) is responsible for drafting legislation, elaborating the RMP, supervising the implementation of the RMP and reporting on laboratory results.

3. Also within VFSD, the Veterinary Inspection Services (VIS) - part of the Veterinary Inspection Sector - is responsible for carrying out sampling under the RMP and - exclusively – for follow-up measures in case of non-compliant laboratory results. Within VIS there are 13 regional veterinary offices (RVOs) and 65 local/branch veterinary offices (LVOs) in which a total of 198 veterinary inspectors are employed. In each RVO, one coordinator for residue monitoring - functioning as the contact person for the VMPRMD - has the responsibility for supervising the implementation of the RMP at regional level.

4. VFSD can contract an “authorised veterinary organisation” as a “control body” for certain official controls. Beforehand, such organisations must be accredited by the Croatian Accreditation Agency to EN/ISO/IEC 17020. Control bodies' tasks include residue monitoring sampling under the supervision of the veterinary inspectors of the VIS. Only specific appointed veterinarians in the control body are permitted to take samples and cannot provide veterinary services to farmers at the same time. At the time of the audit, the VFSD had contracted 57 control bodies.
5.1.2 Planning

Legal Requirements


Findings

5. In line with Article 4 of Directive 96/23/EC, the VMPRMD drafted the 2014 RMP, taking into account the requirements of Articles 4, 5 and 7 of this Directive.

6. The planning process of the 2014 RMP included the relevant bodies (VMPRMD, the coordinators of the RVOs and the Croatian Veterinary Institute, (CVI)). This is in line with Article 14 of Council Directive 96/23/EC and Article 4(3) of Regulation (EC) No 882/2004. For the planning of the 2015 RMP, VFSD scheduled a meeting of the relevant bodies on 6 March 2015.

7. In line with Article 3(1)(a) of Regulation (EC) No 882/2004, the VMPRMD had taken risk factors into account for the planning of the 2015 RMP. The risk factors applied included previous non-compliant results (e.g. the number of samples for group A3 was planned to be increased from 54 samples in 2014 to 72 samples in 2015) and updated information on analytical methods by the CVI. At the time of the audit, the wholesalers’ annual reports of sales data for veterinary medicinal products were not fully available, but were due to be completed within the following two weeks.

8. For planning the 2015 RMP, the VMPRMD had taken into account the outcome of the EU Reference Laboratories’ (EURLs) and the FVO’s evaluations of the 2014 RMP.

Conclusions on planning

9. The competent authority can have confidence in the effectiveness of its planning process for residue monitoring as relevant risks factors are taken into account.

5.1.3 Implementation

Legal Requirements

Findings

10. In 2014, RMP sampling started in the second half of March, as the planning process was not finalised earlier. In 2015, VMPRMD had forwarded the first set of sampling requests to the regional coordinators in the week preceding the FVO audit. VSFD was aware of the fact that the RMP planning process needs to be finalised as soon as possible in order to fulfil the requirement in point 2.1 of the Annex to Decision 98/179/EC regarding the distribution of sampling over the whole year.

11. In relation to the 2014 RMP, the VMPRMD coordinated and supervised its implementation at regional level as required by Article 4(2) of Directive 96/23/EC. Every four months, the VMPRMD sent pre-defined sampling requests to the coordinators of the 13 RVOs and recorded in an electronic spreadsheet if the samples had been taken and if the respective laboratory results had been received.

12. In line with Article 8(1) of Regulation (EC) No 882/2004, a detailed “Instruction on sampling under the national RMP and follow-up of non-conforming results” was in place, its last revision dated November 2012. This instruction covered all commodities, contained information on the (targeting/risk) criteria for sample selection, or requirements for packaging and temperature during transport.

13. In line with the requirements of Article 4 of Regulation (EC) No 882/2004, VSFD had organised a specific training on residue sampling in 2012. In 2013 and 2014, a total of 11 staff members attended training on residue controls (Better Training for Safer Food) funded by the European Commission.

14. With regard to on-farm sampling carried out by control bodies, the VIS had not to date verified whether such sampling was unforeseen and unexpected (without prior notice being given to the farmer) as required by point 2.1 of the Annex to Decision 98/179/EC.

15. For the 2015 RMP, the VMPRMD intends to implement targeted sampling, a requirement in Article 24 of Directive 96/23/EC, by means of re-sampling animals from farms where non-compliant results were found in 2014. It is foreseen that the same procedure of re-sampling applies to farms with confirmed non-compliant results for inhibitory substances found under the additional official monitoring programme for raw milk or the meat inspection programme – see section 5.1.4. (see also finding 23). So far, the VFSD has not implemented a procedure to verify if such targeted sampling has been implemented by the respective control bodies for sampling at slaughterhouses.

16. In 2014, the CVI rejected 64 samples as being unsuitable for analysis. The respective records on rejected samples documented the reasons for rejection and the audit team could verify that replacement samples had been requested and taken.

17. In line with point 2.6. of the Annex to Decision 98/179/EC, the use of adequate tamper-proof bags ensures the integrity of samples during transport to the laboratories.

18. At the slaughterhouse visited, a control body was responsible for sampling under the RMP. The veterinarians, responsible for sampling, had been informed during a training session about the updated instruction of VFSD on sampling (see finding 12). Based on the five sampling reports selected at random and examined by the audit team it was seen that documents on food chain information had only been signed by an authorised veterinarian appointed for sampling, as required by national rules (see also finding 4 and 19).
19. At the slaughterhouse visited the requirement of Annex II, Section III, point 3(c) to Regulation (EC) No 853/2004 was fulfilled by means of two types of documents containing food chain information:

- a nationally required veterinary health certificate, which obliges the farmer to confirm that if veterinary medicinal products have been administered, the requisite withdrawal period has been observed and the animal has not been treated with prohibited substances (hormones). This certificate has to be countersigned by the authorised veterinarian providing veterinary services;
- a slaughterhouse specific document, attesting that records on veterinary medicinal products are kept.

20. In 2013, the independent internal audit department of the MoA carried out an internal audit in three LVOs/RVOs related to the implementation of the 2012 and 2013 RMPs. The internal audit department concluded that the outcome of this audit was satisfactory and made three suggestions for improvement which were followed up. The current three year internal audit planning schedule does not include another audit on residue monitoring.

Conclusions on implementation

21. With the exception of the absence of residue monitoring in the first two months of the year and the lack of verification on how control bodies implement suspect or targeted sampling, the residue monitoring plan is implemented effectively.

5.1.4 Other residue monitoring programmes

Legal Requirements


Findings

22. In 2014, the VPHFSS implemented an official feed monitoring programme which - among other substances – included the analyses of residues of mycotoxins, heavy metals, pesticides and coccidiostats. The RVOs reported the results to the Veterinary Medicinal Products, Feed and Animal By-products Services on a monthly basis.

23. In line with a national Ordinance on controls of raw milk intended for public consumption and implementing instructions (OG 110/10), one sample is taken every month from each bovine and sheep/goat dairy holding and analysed for inhibitors at the accredited Central Laboratory for Milk Control. This laboratory publishes its results on its webpage. The LVOs must check the webpage daily and have to take follow-up samples on the respective farms within 24 hours. In the event of a non-compliant result of such a sample, the respective farm would be subject to suspect sampling under the next year’s RMP (see also finding 15).

24. In 2014, the CVI analysed around 2500 establishment own-check milk samples for group B1, B3a, B3c and B3d (mycotoxins) and around 500 meat samples for group A6, B1, B3a, and B3c. All results were compliant.
Conclusions on other residue monitoring programmes

25. Other programmes and own-checks contribute to ensuring food safety. The fact that these data are taken into account for suspect sampling increases the effectiveness of the RMP.

5.1.5 Follow-up of non-compliant results

Legal Requirements


Findings

26. The CVI has to immediately inform the VMPRMD and the respective regional coordinator on non-compliant results. In case of non-compliant results obtained in samples from slaughtered animals, the coordinator requests the veterinary inspector responsible for the slaughterhouse to identify the farm of origin. This information is forwarded (via the coordinator/s) to the veterinary inspector responsible for the farm of origin, who does the follow-up investigation. The audit team could verify in the follow-up files examined that investigations had been undertaken in a timely manner.

27. In line with Article 8(1) of Regulation (EC) No 882/2004, the “Instruction on sampling under the national RMP and follow-up of non-conforming results” (see finding 12) contained detailed procedures for investigation on farms. In line with the relevant Articles of Directive 96/23/EC and Regulation (EC) No 882/2004, national legislation provides for the empowerment of the competent authorities to investigate, take measures and impose sanctions where appropriate.

28. Under the 2014 RMP, within Group A, the LVOs followed up 8 non-compliant results for hormones in bovine samples and 109 non-compliant results for mycotoxins (67 in bovine and 42 in porcine samples). Within Group B, 40 non-compliant results (the majority of which were for mycotoxins (13) and heavy metals (13) in various commodities), were investigated.

29. Follow-up activities of non-compliant results for Group A and Group B substances comprised the activities required by Articles 16 to 19 of Directive 96/23/EC: investigation on farm, detention of animals, re-sampling, costs borne by the farmer and launch of a court case. The "Instruction" (mentioned in finding 27) did not describe how veterinary inspectors or control bodies responsible for sampling at slaughterhouses receive information on farms which would be subject to suspect sampling (see finding 15).

30. Based on the records/information provided for the follow-up of non-compliant results, the audit team noted that investigation of on-farm treatment records was limited to verifying whether records were kept and treatments were recorded. Based on the RVO’s/LVO’s records for follow-up, the on farm investigations did not include to verifying whether the information contained in the treatment records was complete (e.g. two non-compliant results for toltrazuril) or would allow the farmer to properly respect withdrawal periods.
31. In 2013 and 2014, there had been no notifications in the RASFF system for residues of veterinary medicinal products detected in food of animal origin produced in Croatia.

**Conclusions on follow-up of non-compliant results**

32. In general, the follow-up of non-compliant results is done in a timely and effective manner in particular with regard to the application of preventive/restrictive measures on farms. A complete root cause analysis of all non-compliant results is to some extent compromised by limitations in the verification of the completeness and correctness of treatment records kept on farms.

5.1.6 **Laboratories**

**Legal Requirements**


**Findings**

33. The CVI has been designated by the MoA as being responsible for all laboratory tasks under Directive 96/23/EC.

34. The Croatian laboratory system for residue analyses under the RMP comprises five laboratories of the CVI, two laboratories in Zagreb (NRL-1 and NRL-2), and three other laboratories located in three of the five regional Institutes of the CVI (NRL-3 in Split, NRL-4 in Rijeka and NRL-5 in Križevci).

35. In line with Article 14 of Directive 96/23/EC, NRL-1 functions as the National Reference Laboratory (NRL) in addition to carrying out routine analytical testing.

36. In line with Article 12(2)(a) of Regulation (EC) No 882/2004, the CVI’s laboratories are accredited by the Croatian Accreditation Agency (a member of the European Accreditation and of the International Laboratory Accreditation Co-operation) in accordance with the standard EN ISO/IEC 17025.

37. In total, 18 chemists and 14 technicians of the CVI are responsible for analyses under the RMP. For all of the staff records evaluated in the three CVI laboratories visited, the audit team noted that staff were appropriately trained for the respective analytical methods (in line with Article 4(2)(c) of Regulation (EC) No 882/2004), and had participated in national/international conferences or in EURL workshops.

38. All laboratories visited used methods which had been validated in line with the requirements of Decision 2002/657/EC and had suitable equipment (e.g. HPLC-DAD-FLD instruments for screening methods and LC-MS/MS instruments for confirmatory methods or, in future, combined screening and confirmatory methods).

39. All laboratories visited followed the centralised procedure for sample reception and handling, including rejection and reporting of samples not fit for analysis.

40. Since the accession of Croatia to the EU, CVI has subcontracted some testing to several accredited laboratories in other Member States and to one national institute in respect of
substances for which the CVI does not have validated and accredited methods available (Article 11 of Regulation (EC) No 882/2004 and Article 3 of Decision 2002/657/EC). For the 2015 RMP, the CVI plans to subcontract seven accredited laboratories in five Member States.

5.1.6.1 Laboratory for Residue Control in Zagreb (NRL-1) and Laboratory for Analytical Chemistry in Zagreb (NRL-2)

41. In line with the requirements of Articles 14 and 15 of Directive 96/23/EC, the NRL-1 – in its function as NRL – supports the VMPRMD in the planning of the RMP (see finding 6), provides assistance to and coordinates the activities of the other laboratories, organises inter-laboratory testing within the laboratory network and participates in proficiency tests and workshops organised by the EURLs or by other proficiency test organisers.

42. NRL-1 receives all samples under the RMP, records them in an electronic database (LIMS) and if necessary forwards the samples to the other (subcontracted) laboratories. In general such transfers were carried out quickly though for one sample selected at random the audit team noted that it took more than five days to deliver the sample from NRL-1 to NRL-4. NRL-1 is also responsible for reporting the analytical results of the samples to the VMPRMD and, in case of non-compliant results, to the 13 regional coordinators.

43. The audit team evaluated the validation files for the streptomycin/dihydrostreptomycin ELISA method in muscle and in milk (NRL-1) and the method for beta-agonists in muscle, liver and urine by LC-MS/MS (NRL-2). The validation for both methods was in line with the requirements of Decision 2002/657/EC.

44. Since 2012, NRL-1 has participated in 34 proficiency tests, 32 of them with satisfactory results. The results were unsatisfactory for one chloramphenicol and for one coccidiostat (nicarbazin) analysis. The audit team examined the proficiency test for chloramphenicol and noted that the laboratory had performed a root cause analysis and that corrective measures were in the process of being undertaken (problems identified for muscle and egg matrices were already satisfactorily resolved and the problem with urine was under further investigation).

5.1.6.2 Laboratory for Analytical Chemistry and Residues in Rijeka (NRL-4)

45. NRL-4 is responsible for analysis of nitroimidazoles in the plasma, water, milk, eggs and fish muscle by HPLC-DAD. The laboratory had successfully participated in a proficiency test for nitroimidazoles in eggs in 2013, and in 2014, in an inter-laboratory comparison for nitroimidazoles in water and in plasma.

46. The audit team examined the SOP and the validation report of the analytical method for plasma and water. The validation was in line with the requirements of Decision 2002/657/EC. The quantification of nitroimidazoles in the different matrices was in conformity with point 2.1.2.1 of the Annex to this Decision and a recovery correction was always undertaken for quantification (though this is a screening method). However, it was seen that the spiking level used for recovery (5 µg/kg) was higher than the concentration range established during initial validation (1-3 µg/kg) and may adversely influence the accuracy of quantification. Additionally, whilst validation of the method
had been carried out at a column temperature of 40°C, in practice the method is run at two other temperatures (to help remove matrix interferences).

47. The handling of pure standards (weighing and further preparation of stock/intermediate/spiking standard solutions) was not properly separated from the handling of samples in order to avoid potential cross-contamination of standards and official samples. The records of pure standards expiry dates and vial discard dates were not sufficiently detailed to demonstrate that standards used were in date.

5.1.6.3 Laboratory for Analytical Chemistry and Residues in Krževci (NRL-5)

48. NRL-5 is responsible for analysis of benzimidazoles in milk and fish muscle. In 2014, the laboratory had participated in an EURL proficiency test for benzimidazoles and, although the test is not yet completed by the EURL, stated that six of the seven results out of seven materials tested were satisfactory.

49. The audit team examined the SOP and the validation report of the analytical method for milk. Whilst the validation was broadly in line with the requirements of Decision 2002/657//EC, the quantification of benzimidazoles in milk was not in conformity with point 2.1.2.1 of the Annex to this Decision as recovery correction was not implemented.

Conclusions on laboratories

50. Despite some shortcomings in the implementation of some analytical methods (e.g. the lack of application of analytical recovery for benzimidazoles and recording of the use of analytical standards), the competent authority can have confidence in the laboratory performance and the reliability of analytical results as all of the laboratories in the network are accredited to ISO 17025 and methods are adequately validated and staff are appropriately trained.

5.2 VETERINARY MEDICINAL PRODUCTS

5.2.1 Competent authorities involved

51. The VPHFSS is responsible for issuing marketing authorisations for veterinary medicinal products and the LVOs within VIS are responsible for official controls on the distribution and use of veterinary medicinal products.

5.2.2 Authorisation, distribution and use

Legal Requirements


Findings


53. In line with Article 65 of Directive 2001/82/EC, only registered wholesalers can distribute veterinary medicinal products to approved veterinary organisations (the latter comprising veterinary pharmacies, veterinary clinics or veterinarians providing veterinary services). The VPHFSS publishes the actual list of approved veterinary organisations as well as the list of veterinary medicinal products with a national marketing authorisation on its webpage.

54. In line with Article 66 of Directive 2001/82/EC, only authorised veterinarians of a veterinary pharmacy can sell veterinary medicinal products to veterinarians or farmers based on a veterinary prescription as required in Article 67 of this Directive.

55. In line with Article 2 of Directive 2006/130/EC, the VPHFSS has drawn up a list of veterinary medicinal products which are exempted from the prescription requirement of Article 67 of Directive 2001/82/EC. The VPHFSS has not yet notified this list to the European Commission as required by Article 3(1) of Directive 2006/130/EC.

56. The audit team noted that for 3 of the 15 veterinary medicinal products for food-producing animals, selected at random, there was mismatching information with regard to the information on withdrawal periods. In the veterinary pharmacy visited, the information on the label or package leaflet of one product examined did not match with the information contained in the VPHFSS’s list of authorised veterinary medicinal products for this product due to a typing error in the VPHFSS’s list. For two other products, the information on the VPHFSS’s list did not match with the information contained in the electronic database used on the pig farm visited for recording treatments or with the information on the labels and leaflet of these products found in stock at the wholesaler visited. The audit team verified that the VPHFSS had issued a previous marketing authorisation for the two products in stock in 2009, and that the renewed marketing authorisation in 2015 resulted - on the request of the marketing authorisation holder - in a prolonged withdrawal period allocated to the newly authorised products.

57. In February 2015, the VPHFSS stated that for all nationally authorised veterinary medicinal products, containing quinolones or fluoroquinolones, it had verified whether the respective summary of product characteristics and package leaflets contained the “special precautions for use” and the “special warnings” as required in Annex II to Commission Decision of 01-07-2010. The VPHFSS identified that for four products the requirements of this Decision were not yet respected. In addition, the audit team noted at the wholesaler visited, that for another of these products the package leaflet contained only part of the required information (susceptibility testing was not included).

Conclusions on authorisation, distribution and use

58. Notwithstanding the observations made by the audit team concerning discrepancies in...
the information held for some veterinary medicinal products and the fact that the Commission services had not been notified about the list of products exempted from veterinary prescription, the marketing authorisation of veterinary medicinal products as well as their distribution and use are in compliance with EU legislation.

5.2.3 Official controls on veterinary medicinal products

Legal Requirements


Findings

59. In line with Article 4 of Regulation (EC) No 882/2004, in February and December 2014, the VIS provided training related to official controls on the distribution and use of veterinary medicinal products, attended by 19 and 26 veterinary inspectors respectively. The VIS had evaluated the effectiveness of the training (an increase in the proportion of correct answers to a questionnaire from 55% before training to 88% after completion of the training).

60. In line with Article 8(1) of Regulation (EC) No 882/2004, the VIS had provided a checklist for official controls on the distribution and use of veterinary medicinal products to its veterinary inspectors. In addition, in 2015, the VIS published updated instructions on how to carry out official controls on the use of veterinary medicinal products on farms.

61. For 2015, the independent internal audit department of the MoA has scheduled an internal audit of controls on the distribution and use of veterinary medicinal products (see also finding 20).

5.2.3.1 Controls at wholesale level, retail level and on veterinary practitioners

62. At the wholesaler visited, the audit team noted that in 2014, the responsible veterinary inspector had carried out the two nationally required official controls, had recorded the results of the controls by properly completing both checklists (developed by the VIS) and had completed both checklists properly, recording one noncompliance, issued the respective administrative note and followed up the rectification of this noncompliance.

63. In one of the LVOs, the veterinary inspector had adequately recorded the results of an official control of a veterinary pharmacy. In the other LVO, in 2014, the veterinary inspector inspected four out of ten veterinary pharmacies (once instead of the nationally prescribed twice a year - the Head of the RVO stated that this is due to lack of staff).

64. With regard to the last official control of the veterinary pharmacy visited, the veterinary inspector had recorded everything as compliant in the checklist, even for questions which required a statement on which of two options was implemented by the pharmacy. Whilst the audit team identified several discrepancies in the pharmacy’s electronic database for the annual audit of reconciliations between incoming and outgoing products and products held in stock, the veterinary inspector stated that ten different products in this regard had been evaluated during the last official control and the results were recorded as compliant in the checklist.
5.2.3.2 Controls on farms and in slaughterhouses

65. According to the information of the VFSD, the LVOs regularly carry out official controls on farms, e.g. in 2014, around 10% of the fattening pig farms were controlled. The VIS checklist of controls on farms includes the verification of compliance with the requirement of Article 10 of Directive 96/23/EC as one point of the checklist relates to the use of veterinary medicinal products on farms and the required record-keeping of treatments of food-producing animals.

66. The pig farm visited kept an electronic database to record treatments of pigs with veterinary medicinal products, in line with Article 10 of Directive 96/23/EC. The farmer also recorded treatment manually on a record sheet kept at the individual pen of treated pigs. At the cattle/dairy farm visited, the veterinarian of the farm had filled in all of the required data for treatments in the record book which was kept on farm.

67. The VFSD stated that with regard to the monitoring of the prudent use of antimicrobials, the prescribing pattern of individual veterinarians should be in accordance with good veterinary practice and stated that articles (on this) are published on the website of the MoA. Veterinary prescribing is also regulated by the quality management systems of the authorised veterinary organisations and veterinarians are subject to the supervision of the Croatian Veterinary Chamber.

68. The slaughterhouse visited received the food chain information, as required in Annex II, Section III, point 3(c) to Regulation (EC) No 853/2004. Due to the way in which the template for food chain information as well as the nationally required veterinary certificate are designed (the farmer and the veterinarian both sign that withdrawal periods have been respected), slaughterhouse veterinarians cannot use this information as a risk factor in selecting animals for sampling under the residue monitoring plan.

Conclusions on official controls on veterinary medicinal products

69. Notwithstanding some shortcomings identified in the official controls carried out in one of the three veterinary offices visited, in general the system of official controls on the distribution chain and use of veterinary medicinal products is effective.

6 Overall Conclusion

Notwithstanding the absence of residue monitoring in the first two months of the year, the competent authority can have confidence in the effectiveness of the planning process and the implementation of its residue monitoring plan as well as in the follow-up of non-compliant results. Whilst there are a few shortcomings in the implementation of some analytical methods, the competent authority can trust in the laboratory performance and the reliability of analytical results, as all of the laboratories in the network are accredited to ISO 17025, laboratory methods are adequately validated and staff are sufficiently trained. With the exception of the outstanding notification of the list of products exempted from a veterinary prescription, the national marketing authorisation of veterinary medicinal products as well as their distribution and use and official controls thereon, are generally in compliance with EU legislation.
7 **CLOSING MEETING**

A closing meeting was held on 19 February 2015 with representatives of the central competent authority. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities did not express disagreement and stated that they would take whatever actions were necessary in order to address the areas for improvement identified during this audit.

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 this audit report.

<table>
<thead>
<tr>
<th>No.</th>
<th>Recommendation</th>
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<tbody>
<tr>
<td>1.</td>
<td>To ensure that sampling under the residue monitoring plan is distributed over the whole year as required by point 2.1 of the Annex to Decision 98/179/EC. Recommendation based on conclusion 21. Associated finding 10.</td>
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<td>2.</td>
<td>To ensure that, where appropriate, analytical recovery is applied consistently for the calculation of results in line with point 2.1.2.1. of the Annex to Decision 2002/657/EC. Recommendation based on conclusion 50. Associated finding 49.</td>
</tr>
<tr>
<td>3.</td>
<td>To ensure that handling and processing of test and calibration items do not interfere with the legal and analytical validity of samples (as required by Article 11(7) of Regulation (EC) No 882/2004). Recommendation based on conclusion 50. Associated finding 47.</td>
</tr>
<tr>
<td>4.</td>
<td>To notify to the Commission, in line with Article 3(1) of Directive 2006/130/EC, the list of veterinary medicinal products which are exempted from the prescription requirement of Article 67 of Directive 2001/82/EC. Recommendation based on conclusion 58. Associated finding 55.</td>
</tr>
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## ANNEX 1 – LEGAL REFERENCES

<table>
<thead>
<tr>
<th>Legal Reference</th>
<th>Official Journal</th>
<th>Title</th>
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<tbody>
<tr>
<td><strong>Audits by the Commission Services</strong></td>
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<td><strong>Food Law</strong></td>
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<td><strong>Veterinary medicinal products</strong></td>
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<tr>
<td>Regulation</td>
<td>Page/Reference</td>
<td>Description</td>
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<td><strong>Medicated feedingstuffs and additives</strong></td>
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<th><strong>Monitoring of residues and contaminants in food of animal origin</strong></th>
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<tr>
<td>Directive/Regulation</td>
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