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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

ITALY

FROM 6 TO 15 FEBRUARY 2018

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 an audit in Italy, carried out from 6 to 15 February 2018, as part of the Directorate-General for Health and Food Safety published work programme.

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 audit 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. Attention was also paid to examining the implementation of corrective actions promised in response to relevant recommendations made in the report of a previous European Commission audit to Italy in 2010.

It is concluded that the planning and implementation of the residue monitoring plan in Italy is generally effective though the fact that certain animals, sent from other Member States for direct slaughter in Italy are not eligible for sampling does weaken the plan. The laboratory network functions well though improvements in the performance of the national reference laboratory for residues of veterinary medicinal products are required.

Current EU rules governing equine identification have not yet been implemented and the control system based on previous EU rules demonstrates several weaknesses with regards to controls on equine identification requirements. Notwithstanding this, documented guidance on how to assess equine passport and food chain information in slaughterhouses decreases the risk that equidae, ineligible for human consumption, enter the food chain.

The system for the authorisation, distribution, use of veterinary medicinal products and official controls thereon, is generally in compliance with EU legislation.

The report contains recommendations to the Italian competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.

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ABBREVIATIONS & DEFINITIONS USED IN THIS REPORT

AIA	Italian association of horse breeders
ANA	National association of horse breeders
ASL	Local Health Unit
BDE	National database for *equidae*
BDN	National animal database
CC-alpha/CC-beta	Decision Limit / Detection Capability
DGAHVM	Directorate-General for Animal Health and Veterinary Medicines
DGFHFSN	Directorate-General for Food Hygiene, Food Safety and Nutrition
EU	European Union
EURL	European Union Reference Laboratory
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC
ISO	International Organisation for Standardisation
ISS	National Health Institute
IZS	Experimental Animal Health Research Institute
MRL	Maximum Residue Limit
NAS	Anti-adulteration and health unit
NRL	National Reference Laboratory
PT	Proficiency Test
RASFF	Rapid Alert System for Food and Feed
PCB	Polychlorinated Biphenyl
RVS	Regional veterinary services
UVAC	Italian Veterinary Offices for Community Procedures

1. INTRODUCTION

The audit took place in Italy from 6 to 15 February 2018 and was undertaken as part of the published work programme of the Directorate-General for Health and Food Safety.

An opening meeting was held on 6 February 2018 with the central competent authorities responsible for the monitoring of residues and contaminants in live animals and animal products and for the authorisation, distribution and control 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. Representatives from the central competent authority accompanied the audit team during the whole audit.

2. OBJECTIVES OF THE AUDIT

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 comprised Regulation (EC) No 882/2004 of the European Parliament and of the Council, Council Directive 96/23/EC and Directive 2001/82/EC of the European Parliament and of the Council.

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. In addition, attention was paid to examining the implementation of corrective actions promised in response to relevant recommendations made in the report of a previous audit in Italy in 2010.

The table below lists the sites visited and the meetings held in order to achieve the above objectives:

MEETINGS/VISITS		n	COMMENTS
COMPETENT AUTHORITIES	Central	2	Opening and closing meetings with the central competent authorities
	Regional	2	Meetings at the regional competent authorities in Lazio and Campania
LABORATORIES		2	Governmental National Reference Laboratory (NRL) for residues of veterinary medicinal products in Rome and Regional laboratory in Campania
FARMS		4	Dairy, equine, poultry (broiler and laying hens)
ESTABLISHMENTS		5	Slaughterhouse for equines and bovines, slaughterhouse for poultry, egg-packing centre, veterinary pharmacy, veterinary medicinal product wholesaler

3. LEGAL BASIS FOR THE AUDIT

The audit was carried out under the general provisions of EU legislation, and in particular Article 45 of Regulation (EC) No 882/2004 and Article 21 of Directive 96/23/EC.

4. BACKGROUND

The control of residues and contaminants and the use of veterinary medicinal products in Italy were most recently audited by the Commission in 2010 (DG(SANCO)/2010-8437 MR-Final – henceforth referred to as the 2010 audit). The report concluded that the planning and implementation of the national residues control plan was broadly in line with EU requirements. However, the effectiveness of residue controls was undermined by severe shortcomings in the performance of the laboratory network. It also concluded that official controls on the use of veterinary medicinal products are carried out, but not in a consistent way across regions. Furthermore, it found with regard to *equidae,* that non-eligible animals (without adequate documentation) originating in another Member State were accepted for slaughter and that their meat was placed on the market. In addition, such animals were excluded from testing under the national residue control plan, with the consequent risk that residue violations in these animals would not be detected.

5. FINDINGS AND CONCLUSIONS

Legal acts quoted in this report are provided in Annex I and refer, where applicable, to the last amended version. Relevant articles or sections of the legislation cited in Annex I are referred to in the individual findings in this section of the report.

5.1. Residue monitoring

5.1.1. Competent authorities

1. The competent authorities involved in the planning, implementation of the residue monitoring plan and follow-up of non-compliances are described in detail in the country profile for Italy.

5.1.2. Planning of residue monitoring

Legal Requirements

Articles 3, 5 and 7 of Directive 96/23/EC; Articles 3, 8 and 10 of Regulation (EC) No 882/2004; Commission Regulation (EU) No 37/2010; Regulation (EC) No 396/2005 of the European Parliament and of the Council; Commission Regulation (EC) No 1881/2006; Council Regulation (EEC) No 315/93; Article 4 of Commission Decision 2002/657/EC.

Findings

2. The planning process of the residue monitoring plan is initiated and finalised in a timely manner allowing its implementation as of January.
3. For planning, the competent authority took into account recommendations made by the European Commission and the European Reference Laboratories (EURLs) and the availability of analytical methods as well as, in line with Article 3(1)(a) of Regulation (EC) No 882/2004 certain risk factors such as previous non-compliant results and alerts and the use of veterinary medicinal products in food-producing animals.
4. The 2017 residue monitoring plan includes all of the required substance groups for all species and commodities as laid down in Annex II to Directive 96/23/EC. Thus **recommendation No 9** of the 2010 audit report has been addressed.

5. The number of samples calculated in the residue monitoring plan for all domestic species and commodities are largely based on national production and slaughter data. However, the residue monitoring plan, apart from porcines, does not take into consideration animals (bovines, ovines and caprines) sent from other EU Member States for slaughter for human consumption in Italy when calculating the required number of samples or when taken residue monitoring plan samples in slaughterhouses. The latter is for bovines, ovines and carprines not in line with the requirements of Annex IV of Directive 96/23/EC. Equines sent from other EU Member States for direct slaughter to Italy are not sampled under the Italian residue monitoring plan, which is no in line with requirements of point 2.2. of Commission Decision 98/179/EC, thus **recommendation No 7** of the 2010 audit report has not been addressed. In 2016, EU Members States sent 896,000 ovines/caprines, 40,000 bovines and 20,000 equines for direct slaughter to Italy according to the Italian Veterinary Offices for Community Procedures (UVAC) (see also finding 19).

6. Residue monitoring plan samples from farmed game were planned to be taken from farmed game birds and not from farmed *cervidae* like red or fellow deer, for which farms and primary processing establishments exist in Italy. This is not in line with point 2.3.3.1 of Commission Decision 98/179/EC which requires considering the species when selecting targeted samples from animal carcasses at primary processing establishments. 80% of samples from wild boar to be tested for heavy metals were planned to be taken in one region, while wild boar is also plentiful in other regions. Representatives of the Directorate-General for Food Hygiene, Food Safety and Nutrition (DGFHFSN) met by the audit team, stated their intention to amend the residue monitoring plan for wild and farmed game to rectify above mentioned shortcomings.

7. The planning spreads samples over the year or in key production periods for all species and commodities in line with the requirements laid down in point 2.1. of the Annex to Decision 98/179/EC.

Conclusion on the planning of residue monitoring

8. Notwithstanding certain shortcomings noted for not including all animals sent for direct slaughter to Italy from other Member States in the calculation of samples to be taken, not subjecting *equidae* sent from other Member States for direct slaughter to residue monitoring and sampling of farmed and wild game, the timely and largely comprehensive planning contributes to the effectiveness of controls on residues.

5.1.3. Implementation of the residue monitoring plan

Legal Requirements

Articles 3, 4, 10 and 12 of Directive 96/23/EC; Articles 3, 4, 6 and 8 of Regulation (EC) No 882/2004; Commission Decision 97/747/EC; Commission Decision 98/179/EC; Commission Directive 2002/63/EC; Commission Regulation (EU) No 589/2014; Commission Regulation (EC) No 333/2007; Commission Regulation (EC) No 401/2006; Article 69 of Directive 2001/82/EC; Annex I, Part A III, point 8(b) to Regulation (EC) No 852/2004 of the European Parliament and of the Council; Annex II, Section III, point 3(c) to Regulation (EC) No 853/2004 of the European Parliament and of the Council; Article 5 and Annex I, Section I, chapter IIA, point 1 of Regulation (EC) No 854/2004 of the European Parliament and of the Council; Commission Implementing Regulation (EU) 2015/262.

Findings

9. In line with the requirements of Article 8 of Regulation (EC) No 882/2004, staff had been provided with and followed detailed instructions on how to take targeted and suspect samples as required in point 2 of the Annex to Decision 98/179/EC.

10. The implementation of the residue monitoring plan can be monitored in a database which is fully accessible to national and regional authorities, and to the Local Health Units (ASL) for their own samples. The DGFHFSN verifies if sample were taken as planned and sends reminders to the regions, if adjustments are required. The regions supervise and re-allocate planned samples, if required. Thus **recommendation No 11** of the 2010 audit has been addressed. Planned residue monitoring plan sample targets for 2016 were met at national level except for wild game (75 instead of 100 samples) and they were met in the two regions visited by the audit team.

11. Sampling is carried out without prior warning and spread over the whole year by ASL veterinarians, which is in line with the requirements of point 2.1 of the Annex to Decision 98/179/EC. The slaughterhouse operator and the farmer owning the animal or products receive a copy of the sampling report, which indicates which animals/products have been sampled and for which residues the sample will be analysed. (see also finding 27).

12. Sampling plans were neither published in advance at national level, nor in the two regions visited, in accordance with the instructions governing the Italian residue monitoring plan. This is in line with the requirements of Article 3(2) of Regulation (EC) No 882/2004, thus **recommendation No 10** of the 2010 report has been addressed.

13. Samples are taken using standardised sampling materials purchased and distributed by each region and are adequately sealed in tamper-proof bags, frozen (for tissue samples) and transported in line with point 2.6 of the Annex to Decision 98/179/EC.

14. Representatives of the DGFHFSN met informed the audit team that the national audit system, implementing Article 4(6) of Regulation (EC) No 882/2004, did not yet cover the implementation of Directive 96/23/EC. However, an evaluation system is in place which enables the DGFHFSN to monitor each region with regards to the implementation rate of the residue monitoring plan, the percentages of questionnaires submitted in relation to non-compliances found or the percentage of sample analysis completed within the planned sample turn-around times (see also finding 33). The result of this evaluation has an influence on the provision of public funds to the regions or the official laboratories. They further stated that all regions have to have an internal audit plan in place and evidence was provided to the audit team that the majority of regions conducted audits with regards to the implementation of the residue monitoring plan. This is in line with the requirements laid down in Article 4(6) of Regulation (EC) No 882/2004.

15. Clear instructions exist enabling suspect samples to be taken during any inspection, if there is a suspicion of the presence of residues. This is in line with requirements of Article 24 of Directive 96/23/EC. In total around 10,000 suspect samples were taken in 2016 from almost all species and derived products destined for human consumption (see finding 29).

Conclusion on the implementation of the residue monitoring plan

16. The residue monitoring plan is generally implemented in accordance with planned arrangements.

5.1.4. Other residue monitoring programmes

Legal Requirements

Articles 9 and 11 of Directive 96/23/EC; Articles 8 and 10 of Regulation (EC) No 882/2004.

Findings

17. In addition to the national residue monitoring plan, there are several other residue control programmes in place which are planned by the Ministry of Health, the regions and ASL. The anti-adulteration and health unit (NAS) of the Carbanieri is also involved in residue controls. In addition to other residue monitoring programmes described in the 2010 audit report, the control programmes underlined below were in place:

18. Controls on animals sent for direct slaughter to Italy: The UVAC have decided to introduce an optional system of veterinary on-the-spot checks, based on Article 5 of Directive 90/425/CEE, which was transposed in Italian law by Decree 28/93. During these checks, which also take place at slaughterhouses, samples are taken from bovines, porcines, ovines, caprines and equines that were sent from other EU Member states for direct slaughter in Italy. Staff from UVAC informed the audit team that their sampling plan is based on their risk assessment considering *inter alia* information received from the DGFHFSN and the National Health Institute (ISS), but that it is fully independent from the national residue monitoring plan and does not intend to cover all substance groups as required in Annex I to Directive 96/23/EC for the national residue monitoring plan.

19. The audit team found that number of samples taken by UVAC from these animals are higher than required by Annex IV to Directive 96/23/EC, but that not all substance groups required by Annex I to Directive 96/23/EC are analysed for, as samples from:

    - bovines were not analysed for Group A1, Groups A4 to A6, Groups B2a to B2d and Groups B3a to B3d.
    - porcines were not analysed for Groups A1 and A2, Group A4, Group A6, Groups B2a to B2d and Groups B3a to B3d.
    - equines were not analysed for Groups A1 and A2, Groups A4 to A6, Groups B2a to B2d and Groups B3a, B3b and B3d.
    - Ovines and caprines were not analysed for Groups A1 to A6, Groups B2b to B2e and Groups B3a, B3b and B3d.

    Thus r**ecommendation No 7** of the 2010 audit report has not been addressed with regards to the inclusion of all animals sent from Member States for direct slaughter to Italy in the residue monitoring plan. (see also finding 5).

20. UVAC informed the audit team that it would be their responsibility, if non-compliances were found with regards to illegally used substances in such animals, to refer the matter to the Member State of origin and the Commission, as required by Article 15(3) of Directive 96/23/EC. Thus **recommendation No 7** of the 2010 audit report has been addressed with regards to the duty to inform other Member States and the Commission. The audit team was informed by staff from UVAC that illegal substances were not detected during 2016 and 2017.

21. Controls on residues of plant protection products: the Ministerial Decree of 23 December 1992 defines the annual control plans on residues of plant protection products in foodstuffs, implementing the requirements of Regulation (EC) No 396/2005. Results of this activity are published on the internet site of the Ministry of Health.

22. Fipronil: Representatives from the DGFHFSN informed the audit team that during the summer of 2017, three monitoring plans regarding the search for fipronil were implemented in Italy: 1) DGFHFSN: 11 August 2017: search for fipronil in eggs (in egg packing plants), egg products (in processing plants) and poultry meat and processed products on the market; 2) Directorate General for Animal Health and Veterinary Medicine (DGAHVM): 28 August 2017: search for fipronil and amitraz in eggs (on farms); 3) DGFHFSN: 15 September 2017: search for different acaricide active substances in poultry meat and fat (EU Plan). All data related to the above plans were submitted to EFSA by 30 November 2017, and they are under evaluation for the final report.

23. Mycotoxins: The national official control plan for mycotoxins (2016-2018), which is implemented by regional veterinary services (RVS) and their ASLs, takes samples from food and analyses them for mycotoxins covered by Commission Regulation (EC) No 1881/2006. The results of these activities are reported annually to the DGFHFSN.

Conclusion on other residue monitoring programmes

24. The analyses for residues and contaminants performed in the course of other residue monitoring programmes provide additional guarantees regarding food safety and their results are taken into account for the planning and implementing of the residue monitoring plan required by Directive 96/23/EC.

5.1.5. Follow-up of non-compliant results

Legal Requirements

Articles 13, 16, 17, 18, 19, 23, 24, 27 and 28 of Directive 96/23/EC; Article 54 of Regulation (EC) No 882/2004.

Findings

25. In line with Article 8(1) of Regulation (EC) No 882/2004, officials have been provided with instructions on how to carry out follow-up of non-compliant results.

26. The audit team evaluated two follow-up investigations of non-compliant samples taken in Lazio from 2015 and 2016 (tilmicosin in ovine and caprine milk) and (dexamethason in bovines liver) and one follow-up investigation of a non-compliant sample taken in Campania (monensin in porcine muscle), plus two Rapid Alert System for Food and Feed (RASFF) notifications (RASFF 2016.1327-Sulfadimethoxine in porcine meat and RASFF 2017.0260-cloxacillin in caprine milk). Measures taken by the competent authority were found to be in accordance with the requirements laid down in Articles 16 - 19 and 23 of Directive 96/23/EC. The reasons for the non-compliances were identified and administrative fines given to create a dissuasive effect, which is in line with Article 55 of Regulation (EC) No 882/2004.

27. Official laboratory results of residue monitoring plan samples which were non-compliant are sent by the head of the laboratory, simultaneously by e-mail to the

relevant competent authority and by registered letter to the owner of the animal or product the sample was taken from, in accordance with Article 18 of the Italian national decree No 327/1980.

28. The audit team found that in two follow-up investigations (dexamethasone in bovine liver and monensin in porcines - see finding 27) that official follow-up started without delay but visits at the farm where the non-compliance originated, took place later than 5 working days after the sending of the laboratory result, thus likely giving the owner prior warning that an on-the-spot investigation would be carried out. The competent authority stated that slaughterhouse operators and farmers owning an animal or product know already at the time of sampling for which substances the sample will be analysed (see finding 11). The audit team found at the farms visited that official control and follow-up visits were not announced in line with the procedures laid down in the Italian residue monitoring plan implementation guide, which state that "all precautions need to be taken to guarantee that surprise in controls is constant." The latter is in line with Article 12 of Directive 96/23/EC and Article 3(2) of Regulation (EC) No 882/2004. Thus **recommendation No 12** of the 2010 audit report has been addressed.

29. Non-compliances found during suspect sampling in bovines and porcines (see finding 15) related largely to the presence of antimicrobials, for bovine milk to antimicrobials and aflatoxin M1, and for honey to lead. An overview provided by the Italian competent authority indicated that carcasses of animals or affected products were retained and declared unfit for human consumption after the non-compliance was confirmed by confirmatory method analysis. This is in line with the requirements of Article 24 of Directive 96/23/EC.

Conclusion on follow-up of non-compliant results

30. A system of follow-up investigations is in place and the respective follow-up of non-compliant results has been implemented in an effective and largely timely manner.

5.1.6. Laboratories

Legal Requirements

Articles 4 and 12 of Regulation (EC) No 882/2004; Article 14 of Directive 96/23/EC; Articles 3, 4, 5 and 6 of Decision 2002/657/EC; Regulation (EU) No 589/2014; Regulation (EC) No 333/2007; Regulation (EC) No 401/2006.

Findings

31. The Italian laboratory network comprises five NRLs and 10 regional laboratories. Four NRLs belong to the National Health Institute (ISS) (residues of veterinary medicinal products, mycotoxins, heavy metals and pesticides) and one NRL (dioxins/Polychlorinated Biphenyls (PCBs)) plus the 10 regional laboratories belong to the Experimental Animal Health Research Institute (IZS). All the laboratories are accredited to ISO 17025 by the Italian accreditation body Accredia.

32. All analyses necessary for carrying out the national residue monitoring plan are performed by the IZS laboratories, no analyses are subcontracted. When necessary,

samples are sent by a receiving IZS laboratory to another IZS laboratory which has a validated/accredited method for the specific analyte and/or matrix required.

33. The national residue monitoring plan stipulates that the sample analysis turnaround time is 10 working days for Group A substances and 30 working days for Group B substances . The audit team noted that these turnaround times count from the moment the sample arrives at the laboratory which analyses the sample. In many cases IZS laboratories (IZSs) sent samples to another IZS laboratory for analysis (see also findings 32 and 45), which leads to the fact that the turnaround times from sampling to finalising the laboratory report are longer than 10 or 30 days.

34. According to the national legislation, samples taken to ensure the business operators' right for a supplementary expert opinion are to be analysed by the ISS. This is in line with Article 11(5)(6)(7) of Regulation (EC) No 882/2004 and Article 15(2) of Directive 96/23/EC. The audit team noted that for supplementary expert opinion samples, there is no obligation to adhere to the turnaround times established for routine samples in the residue monitoring plan. In the NRL visited, the audit team noted a sample which was under processing for more than 11 months, which may affect the analytes' stability and sample integrity, which is not in line with the requirements laid down by part 2.9 of the Annex to Decision 98/179/EC. This, in turn, may affect the sample's legal and analytical validity as outlined in Article 11(7) of Regulation (EC) No 882/2004.

35. The NRLs for dioxins/PCBs, mycotoxins, heavy metals and pesticides were not visited, but information was provided to the audit team showing that these NRLs largely meet their NRL's obligations as required by Article 33 of Regulation (EC) No 882/2004 and by Article 14 of Directive 96/23/EC.

5.1.6.1. The NRL for residues of veterinary medicinal products

36. The audit team found that the NRL regularly participates in the proficiency tests (PTs) organised by the relevant EURLs with good results and that laboratory facilities, equipment and staffing levels are adequate to meet its obligations under Article 33 of Regulation (EC) No 882/2004 and Article 14 of Directive 96/23/EC. The staff are appropriately trained. Thus this part of **recommendation No 1** of the 2010 audit report has been addressed.

37. The NRL has created and maintains a database which includes the information on, *inter alia*, CC-alphas and CC-betas of the methods applied by the IZSs. The information provided in the database is periodically evaluated and discussed within the IZS laboratory network, which was demonstrated in the form of minutes from two recent annual workshops between the NRL and the IZSs.

38. As regards the NRL task to ensure that the IZSs observe the limits established at the EU level, the audit team was informed that verbal discussions took place on this in 2014, but no evidence could be provided by the NRL that the IZSs took further action to achieve the relevant levels (see also finding 45). This is not in line with the requirements laid down in Article 14 of Directive 96/23/EC.

39. The audit team was informed by staff of the NRL that it did not arrange PTs (regarding chemical methods of analyses) for the IZSs, which is not in line with the requirements laid down in Article 33(2)(c) of Regulation (EC) No 882/2004 and in Article 14 of Directive 96/23/EC. Thus this part of **recommendation No 1** of the 2010 audit report has not been fully addressed.

40. The audit team observed the standard operating procedure for the validation of methods and found that it was in line with the relevant provisions of Commission

Decision 2002/657/EC. Staff of the NRL stated that a software-based validation protocol will in future be applied for all method validations. The envisaged validation protocol is based on the approach outlined in part 3.1.3 of the Annex I to Decision 2002/657/EC.

41. The audit team examined the validation files and reports for the analysis of chloramphenicol in muscles and found that the validation plan was adequate and included all relevant provisions laid down by Decision 2002/657/EC. The validation process was adequately presented in the validation report. However, quality assurance documentation for routine samples was not available, which is not in line with the requirements laid down in Article 5 of Decision 2002/657/EC.

42. The audit team also examined the validation files and reports for the analysis of tetracyclines (four parent drugs and three relevant epimers covered by Commission Regulation (EU) No 37/2010) in muscles and found that the validation plan was in general adequate and included all relevant provisions laid down by Decision 2002/657/EC. The validation process was adequately presented in the validation report.

    However, it was observed that during the validation of the method, the concentrations of the parent drug and its epimer had not been summed up for further calculation of the CC-alphas. This is not in line with the requirements laid down by Article 3 of Decision 2002/657/EC. In this way, the calculated CC-alphas (i.e. for the single substances) cannot be used for the assessment of the analytical results with the maximum residue limit (MRL) established by Regulation (EU) No 37/2010 for the sum of the parent drug and its epimer.

    The audit team further found that the method description did not contain any provisions on quality assurance, and that quality assurance documentation for routine samples was not available. This is not in line with the requirements laid down by Article 5 of Decision 2002/657/EC. In addition, the documentation provided for the tetracycline sample did not contain evidence of the inclusion of the reagent blank and compliant control sample in the order for injecting the extracts into the analytical instrument, which is not in line with the provisions laid down by part 2.3.1 of the Annex I to Decision 2002/657/EC.

5.1.6.2. The IZS Laboratory

43. The laboratory facilities, equipment and staffing levels are adequate to ensure the laboratory's performance is satisfactory and its analytical results reliable. The staff are appropriately trained.

44. The audit team examined five validation reports, method descriptions and test documentation, including control charts, for ten samples (two for each method examined) and found that the validations had been broadly undertaken in line with the requirements laid down in Decision 2002/657/EC and that the quality control measures of the methods and tests checked were in line with the requirements laid down in Article 5 of Decision 2002/657/EC. However, the audit team noted that not all relevant matrices (i.e. species and organs) had been included in the validations, even though those non-validated matrices are included in the residue monitoring plan (muscles of equines, rabbits and farmed game for the clenbuterol method; muscles of poultry, rabbits and farmed gamed for the antithyroid agents method). The laboratory staff met by the audit team explained that this is due to resource considerations for rarely used methods. Omitting certain species/matrices, included in the residue monitoring plan, from the validation procedure is not in line with the requirements laid down in part 3 of Annex I to Decision 2002/657/EC.

45. The audit team noted that CC-betas for Group A2 (antithyroid agents) and Group A5 (beta-agonists) established during the validations are higher than those recommended by the relevant EURL. No evidence could be provided that this had been questioned or discussed with the NRL for veterinary medicinal products. The audit team found that other IZS laboratories also had CC-betas which were higher than the respective EURL recommended concentrations for substances in Group A (see finding 38).

46. The audit team was provided with sample analysis turnaround time statistics. These showed that 80% of all samples analysed by the IZS laboratory were processed within the required turnaround time. However, 49% of the samples to be analysed for beta-lactam antimicrobials exceeded the 30 day turnaround time and were analysed within 70 days, and one sample within 165 days. Samples sent by the visited IZS to other IZS laboratories exceeded the 30 day deadline for 81.4% of all samples and 4.2% of samples had a turnaround time of 91 to 218 days. The long processing times may affect the analytes' stability and sample integrity (in particular for beta-lactam antimicrobials), which is not in line with the requirements laid down by part 2.9 of the Annex to Decision 98/179/EC. In addition, the delay with the samples' analysis may hinder the timely implementation of the follow-up measures required by Articles 15-19 of Directive 96/23/EC.

47. The laboratory regularly participates in relevant PTs. The results are largely satisfactory. The audit team examined two PTs where unsatisfactory z-scores were obtained. In the both cases these had been thoroughly investigated and corrective actions had been taken. Subsequent testing of similar samples, i.e. with the same substances and matrixes, was satisfactory.

Conclusion on laboratories

48. The competent authority can largely have confidence in the laboratory performance and the reliability of analytical results as all laboratories are accredited, methods are generally appropriately validated and staff well-trained. However, a few factors weaken the system, such as the long sample analysis turnaround times, the non-adequate validation for a few rare matrices/species combinations and the fact that the NRL for residues of veterinary medicinal products does not completely meet its NRL obligations and has deficiencies in its quality assurance procedures.

5.2. Veterinary medicinal products

5.2.1. Competent authorities

49. The central competent authority for veterinary medicinal products is the DGAHVM. It is responsible for the marketing authorisation, manufacturing, importation, monitoring and supervision of official controls at national level on the distribution and use of veterinary medicinal products, as described in detail in the country profile for Italy.

The RVS and their ASLs are responsible for the licensing of wholesalers and pharmacies.

The ASLs are responsible for inspecting wholesalers and pharmacies concerning the distribution of veterinary medicinal products as well as for controls on the use of veterinary medicinal products on farms. The planning, coordination and verification of these official controls is the responsibility of the RVS, which also reports the results to the DGAHVM.

Official controls on veterinary medicinal product manufacturing, distribution and use on farms are also conducted by the NAS.

5.2.2. Authorisation, distribution and use

Legal Requirements

Articles 5-15, 21-30, 35, 58-62, 65-71 and 83 of Directive 2001/82/EC; Articles 30-40 of Regulation (EC) No 726/2004 of the European Parliament and of the Council; Regulation (EC) No 470/2009 of the European Parliament and of the Council; Commission Regulation (EU) No 37/2010; Article 2 of Commission Directive 2006/130/EC; Council Directive 96/22/EC; Article 10 of Directive 96/23/EC; Annex I, Part A III, point 8(b) to Regulation (EC) No 852/2004; Annex II, Section III, point 3(c) to Regulation (EC) No 853/2004; Regulation (EU) 2015/262; Commission Regulation (EC) No 1950/2006; Regulation (EC) No 1831/2003 of the European Parliament and of the Council.

Findings

50. The requirements of Directive 2001/82/EC for the authorisation, manufacture, distribution, use and controls on veterinary medicinal products, as well as its subsequent legal amendments have been transposed into Italian law by Legislative Decree 193/2006 and its subsequent amendments.

51. A central register for all authorised veterinary medicinal products is in place and publicly accessible as required by Article 25 of Directive 2001/82/EC. It includes information about product characteristics such as the active pharmaceutical substance, the target species and the withdrawal period, which is an improvement on the central register information available during the 2010 audit.

52. Only wholesalers, pharmacies and para-pharmacies are able to sell veterinary medicinal products for food-producing animals and these require a veterinary prescription. The latter is in line with Article 67 of Directive 2001/82/EC. Representatives from the DGAHVM informed the audit team that Italy intends to implement as of September 2018 a compulsory electronic prescription system, guaranteeing full traceability for all veterinary medicinal products at any stage of distribution or use.

53. An authorisation to operate as a wholesaler, pharmacy or a para-pharmacy selling veterinary medicinal products requires that a qualified pharmacist is employed, which is in line with Articles 65 and 66 of Directive 2001/82/EC. The authorisation is without time-limit. The wholesaler and pharmacy visited by the audit team had been authorised and controlled in line with the nationally required frequency (see finding 59).

54. Batch numbers of incoming and outgoing veterinary medicinal products are required to be and were recorded in the wholesaler and the pharmacy visited by the audit team. This is in line with the requirements of Article 66(2) of Directive 2001/82/EC.

55. The audit team noted that the product information for relevant veterinary medicinal products had been updated pursuant to recent referrals to the European Medicines Agency, for example Commission Decision C(2010) 4684 of 1 July 2010 concerning products for food-producing species containing quinolones and/or fluoroquinolones and Commission Implementing Decision C(2012)182 of 13

January 2012 concerning veterinary medicinal products which contain the active substances cefquinome and ceftiofur.

Conclusion on the authorisation, distribution and use of veterinary medicinal products

56. The system for the authorisation, distribution and use of veterinary medicinal products is in line with EU requirements.

5.2.3. Official controls

Legal Requirements

Articles 5-15, 21-30, 35, 58-62, 65-71 and 83 of Directive 2001/82/EC; Articles 30-40 of Regulation (EC) No 726/2004 of the European Parliament and of the Council; Regulation (EC) No 470/2009 of the European Parliament and of the Council; Commission Regulation (EU) No 37/2010; Article 2 of Commission Directive 2006/130/EC; Council Directive 96/22/EC; Article 10 of Directive 96/23/EC; Annex I, Part A III, point 8(b) to Regulation (EC) No 852/2004; Annex II, Section III, point 3(c) to Regulation (EC) No 853/2004; Regulation (EU) 2015/262; Commission Regulation (EC) No 1950/2006; Regulation (EC) No 1831/2003 of the European Parliament and of the Council.

Findings

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

57. Staff from the DGAHVM advised the audit team that there are currently 362 wholesalers authorised for direct sale, 261 wholesalers not authorised for direct sale, as well as 11,525 pharmacies and 1,878 para-pharmacies authorised to sell veterinary medicinal products.

58. An Italian guideline for the preparation, conduct and management of controls on the distribution and use of veterinary medicinal products determines inspection frequencies, and includes detailed work instructions and nationally uniform checklists. These are to be used by RVS and ASL staff inspecting wholesalers, pharmacies, veterinarians and farms. This is in line with Article 8(1) of Regulation (EC) No 882/2004.

59. The required inspection frequency for wholesalers is once every year and varies for pharmacies from yearly to once every three years, based on clearly defined risk criteria. Evidence was provided by the competent authority met, that the aforementioned inspection frequencies for wholesalers and pharmacies had largely been met in 2016 at national level and were fully met in the two regions visited by the audit team. The assessment of the risk criteria and all controls to be conducted in wholesalers, pharmacies and veterinarians are included in nationally uniform checklists which require to control, among other things, the suitability of the premises, the presence of a pharmacist, the traceability of veterinary medicinal products and prescription requirements. These uniform checklists were used at the wholesaler in one region and at the pharmacy in another region visited by the audit team. Thus **recommendation No 13** of the 2010 audit report has been addressed.

60. Labelling information of veterinary medicinal products checked by the audit team at the wholesaler and pharmacy visited was in line with those of Article 58 of Directive 2001/82/EC.

5.2.3.2. Controls on farms and in slaughterhouses

61. National guidelines (see also finding 58) define the inspection frequency per type of farm. Farms which keep animals for food production and which have been granted permission to keep a stock of prescribed veterinary medicinal products, have to be inspected once every year. Other farms have to be inspected a minimum of every three years or more frequently based on pre-defined risk criteria. On-farm controls are based on uniform checklists. These include, among other things, checks of prescription requirements, the proper use of veterinary medicinal products or of medicated feed, the registration in the on-farm-treatment register by the farmer and the veterinarian, as well as compliance with veterinary medicinal product withdrawal periods in case animals are sent for slaughter. The checklists were used at the farms visited by the audit team.

62. The audit team found that in 2016, the Italian yearly inspection frequency target for porcine-, poultry-, equine- (including stables and race course holdings) and fish farms, which have permission to keep a stock of prescribed veterinary medicinal products, was largely not met. Similarly, the inspection frequency target of a minimum of once every three years was not met for porcine-, ovine/caprine-, equine- (including stables and race course holdings), fish farms and apiaries, which do not keep stocks of prescribed veterinary medicinal products. This is not in line with national inspection frequency targets.

63. At a visited laying hen farm with a connected egg packing centre, official controls, with regards to the use of veterinary medicinal products, took place every year using the national checklist (see also finding 58). The audit team verified the correctness of on-farm treatment records and found that in 2016, the farm veterinarian had not filled in the on-farm treatment registry, which is not in line with requirements of Article 10 of Directive 96/23/EC. This had also been observed during official controls and both the farmer and the veterinarian had to pay a fine. The fine was sufficiently high to have a dissuasive effect, which is in line with Article 55 of Regulation (EC) No 882/2004. After this incidence all on-farm treatments were correctly recorded both by the veterinarian and the farmer. The on-farm treatment register at the extensive horse and bovine farm visited by the audit team was in line with the requirements laid down in Article 10 of Directive 96/23/EC and Part A III, point 8(b) of the Annex I to Regulation (EC) No 852/2004. The on-farm treatment register at both farms also included a column in which left-over veterinary medicinal products were recorded, thus **recommendation No 14** of the 2010 report has been addressed.

64. Food-chain information forms used in the two slaughterhouses (one slaughtering bovines, ovines, caprines, porcines and equines and one slaughtering broilers) visited by the audit team were checked by the slaughterhouse operator if they complied with a national template and provided information as specified in Annex II, Section III of Commission Regulation (EC) No 853/2004. Supervisory checks of food-chain information provided were conducted by the official veterinarian of the slaughterhouses, thus **recommendation No 15** of the 2010 audit report has been addressed.

Conclusion on official controls

65. Notwithstanding the fact, that the nationally set inspection frequency was not met, official controls on the distribution chain and use of veterinary medicinal products were largely effective.

5.3. Identification of *equidae* and medicine record requirements

66. Staff from the Ministry of Health informed the audit team that the provisions of Commission Implementing Regulation (EU) 2015/262 have not yet been implemented, and that those of Commission Regulation (EC) No 504/2008 are still applied. This is not in line with the entry into force date of Regulation (EU) 2015/262, which was 1 January 2016.

67. The audit team was further informed that the overall responsibility for the system of equine identification and registration had been transferred as of 20 November 2017 from the Ministry of Agriculture, Food and Forestry Policy (MIPAAF) to the Ministry of Health by national law No 167. Staff from the Ministry of Health stated that the provisions of Regulation (EU) 2015/262 will be implemented as of May 2018, thus 180 days after the Law number 167 entered into force. They stated further that the 'Guidelines for the managing of *equidae* register' (ministerial decree, 29 December 2009), the related 'Operating manual' (ministerial decree No 20318, 26 September 2011) and newly issued equine passports, which are still based on requirements of Regulation (EC) No 504/2008, will be updated by May 2018 to those of Regulation (EU) 2015/262.

68. A representative of the Ministry of Health informed the audit team that Italy, to comply with the single equine identification database requirement of Article 39(1) of Regulation (EU) 2015/262, intends in future to require that all equine registration data are directly inserted into the existing national animal database (BDN). Staff from the DGFHFSN met by the audit team stated that their aim is to complete this task by the end of 2019.

69. Equine passports for Italian equines are issued by various passport issuing bodies and a list of those is publicly available, which is in line with the requirements of Article 4 of Regulation (EC) No 504/2008 or Article 6 of Regulation (EU) 2015/262. Seven passport issuing bodies of pedigree equines have their own database and are part of the National association of horse breeders (ANA), non-pedigree equines are registered in the database of the Italian association of horse breeders (AIA) and horses falling under the Italian terminology "*trotto*", "*jockey club*" and "*cavalli de sella*" are registered in the database of the MIPAAF. The equine passport issuing bodies register equine identification data in their equine passport database as required by Article 21 of Regulation (EC) No 504/2008 or Article 28(d) of Regulation (EU) 2015/262. Each of these databases upload new data daily to the national equine database (National database for *equidae* – BDE) which shall contains the data from all Italian databases for registered equines.

70. Slaughtered *equidae* are registered in the BDN which is connected to and notifies the death to the BDE. This is in line with the requirements laid down in Article 21(1)(n) of Regulation (EC) No 504/2008 or Article 38(1)(o) of Regulation (EU) 2015/262. Staff from the Ministry of Health informed the audit team that a circular letter, including a notification template and a list of all EU equine passport issuing bodies, was sent on 26 January 2018 to all regions and autonomous provinces, requesting that these shall communicate each quarter the death of foreign *equidae* to the issuing bodies in the Member State where the *equidae* were identified. This is in line with the requirements of Article 19(c) of Regulation (EC) No 504/2008 or Articles 34 and 36 of Regulation (EU) 2015/262. Thus **recommendation No 8** of the 2010 audit report has been partially addressed (see finding 73).

71. The MIPAAF has delegated the responsibility of supervision of the equine identification for all ANA passport issuing bodies and AIA registered equines to the representatives of the AIA. One representative of AIA met by the audit team stated

that he had access to all databases of ANA as well as to the AIA database in which he could see whether an equine was registered or not, alive or not and whether the equine was allowed for human consumption or not. A representative from the Ministry of Health informed the audit team that ASL staff responsible for controls at slaughterhouses and farms with regards to *equidae* have full access to the databases of all equine passport issuing bodies, the BDE and the BDN database. The audit team checked the validity of several living and slaughtered equines in the BDE database and found that these had been correctly reflected. In one case the information in the BDE stated the horse was stolen when accessed by the AIA official, while the publicly available data of the BDE stated that the equine was dead.

72. In 2012, the MIPPAF audited in three equine passport issuing bodies for the correct implementation of equine identification and registration requirements and found several deficiencies. The audit team was informed that no follow-up had been implemented to see if corrective action had been taken. This not in line with Article 5(3) of Regulation (EU) 2015/262. The audit team was further informed that since 2012, no other such audits at issuing bodies had been conducted by MIPAAF. This is not in line with the requirements laid down in Article 3(4) of Regulation (EU) 2015/262. Neither did the MIPAAF verify if issuing bodies:

    a) issue identification documents in line with requirements laid down in Article 7 of Regulation (EU) 2015/262 or have a system in place to verify that identification documents are unique, genuine and authentic and have a unique serial number. This is not in line with the requirements laid down in Article 8 of Regulation (EU) 2015/262;

    b) enter identification information of all equines for which they issued a passport into one of the databases in line with the requirements of Article 21 of Regulation (EC) No 504/2008 or Article 28(d) and Article 40 of Regulation (EU) 2015/262).

73. The audit team was informed by staff from the competent authorities that measures are not yet in place to notify deficiencies in the identification of foreign *equidae* to the competent authority of the Member State of dispatch as required by Article 38 of Regulation (EC) No 882/2004. Thus **recommendation No 8** of the 2010 audit report has not been fully addressed.

74. Five percent of all holdings with *equidae* shall be annually controlled to verify the correct application of the *equidae* identification and registration system, as outlined in point 31 of the operating manual for the management of the *equidae* register. The selection of these holdings is risk-based using clearly defined criteria. The above is in line with Article 3(4) of Regulation (EU) 2015/262. However, the audit team found, based on information provided by the MIPAAF, that out of the 19 regions and 2 autonomous provinces, 5 had met this target, 5 achieved between 4% and 5%, 1 between 3% and 4%, 3 between 2% and 3%, 3 between 1% and 2% and 4 less than 1% of the required controls. This is not in line with nationally established inspection frequencies targets.

75. A checklist has been developed, to check the relevant equine identification and registration requirements of Regulation (EC) No 504/2008 at holdings. This had been used during official controls on the horse farm visited by the audit team confirming compliance with equine passport and registration requirements. The audit team found at this farm, that the national requirements for the register of *equidae* and the equine passports requirements of Regulation (EC) No 504/2008 were fulfilled, but not yet of the equine passport content structure as foreseen by Annex 1 to Regulation (EU) 2015/262. The audit team randomly selected several

horses and confirmed that they had been provided with a microchip as indicated in the passport.

76. Checklists used for official controls do not provide for cross-checks between on-farm treatment records and section IX of the equine passports, with the aim to verify whether the animal's status (intended or not intended for slaughter for human consumption) is correctly recorded as required in Article 37 of Regulation (EU) 2015/262. Representatives from the DGAHVM and the DGFHFSN informed the audit team that they intend to amend the checklists to improve such controls.

77. Clear guidance is available of what needs to be checked at slaughterhouses with regards to food chain information, equine identification and information in section IX of the equine passport, to assess if equines can be slaughtered for human consumption. The audit team found at the slaughterhouse visited that this had been followed by the slaughterhouse operator and the official veterinarian present. The audit team checked the equine passports and food chain information for several foreign and national equines and found that those had been correctly assessed to be fit for slaughter for human consumption in line with Section II, point 2 of Annex II to Regulation (EC) No 853/2004. The slaughterhouse operator was also aware that he had to notify the official veterinarian in the event of animals that were not properly identified or relevant food chain information was missing as required by Section II, point 3 of the Annex II to Regulation (EC) No 853/2004. Thus **recommendations No 6 and No 16** of the 2010 audit report have been addressed.

Conclusion on identification of *equidae* and medicine record requirements

78. Current EU rules governing the equine passport system have not yet been implemented and the control system based on previous EU rules demonstrates several weaknesses with regards to controls on equine identification requirements. Notwithstanding this, documented guidance on how to assess equine passport and food chain information in slaughterhouses decreases the risk that equines, ineligible for human consumption, enter the food chain.

5.4. Follow-up of previous recommendations

The table below summarises the follow-up to the relevant recommendations made in report DG(SANCO)/2010-8437 MR-Final.

No	Recommendation	Findings
1	Ensure that the designated NRL at the National Health Institute (ISS) can fully meet its obligations under Articles 14 and 15 of Council Directive 96/23/EC, in particular that the NRL has expertise in substance groups for which it is responsible. Ensure that adequate laboratory facilities, equipment and staffing levels are made available in order to achieve this outcome.	Partially addressed. See findings: 35 to 39, 45 and recommendation 3 of this audit report.
2	Ensure that samples for a supplementary expert opinion (i.e. second opinion analysis) are carried out in line with the requirements of point 5 of	Addressed. See finding: 34

	Article 11 of Regulation (EC) No 882/2004.	
3	Ensure that only analytical methods validated in accordance with the requirements of Article 3 of Decision 2002/657/EC are used for analyses of samples for residues of veterinary medicinal products under the NRCP.	Partially addressed. See finding: 44 and recommendation 4 of this audit report.
4	Ensure that all methods used under the NRCP for monitoring residues of veterinary medicinal products are fit for purpose i.e. are capable of detecting residues at EU MRLs in line with the requirements of point 3 in the Annex III to Directive 96/23/ EC and point 2.2.(b) in the Annex to Decision 98/179/EC, and that confirmatory methods are in line with the definition laid down in point 10.1. of chapter 1 in the Annex I to Decision 2002/657/EC.	Addressed. See findings: 31, 32, 36, 40-42, 44, 47
5	Ensure that appropriate quality control measures are put in place in laboratories in line with Article 5 of Decision 2002/657/EC.	Addressed for IZS. See finding: 44 Not addressed for the NRL for residues of veterinary medicinal products. See findings: 41, 42 and recommendation 4 of this audit report.
6	Ensure that when *equidae* arriving at slaughterhouses are not properly identified in accordance with Regulation (EC) No 504/2008, appropriate measures are taken as required by Section II, point 3 of the Annex II to Regulation (EC) No 853/2004 and animals are not accepted for the food chain.	Addressed. See finding: 77
7	Ensure that foreign *equidae* are tested under the NRCP and, where testing reveals illegal treatment, the matter is referred to the Member State of origin or to the Commission if animals were imported from a third country, as required by Article 15(3) of Directive 96/23/EC.	Partially addressed. See finding: 5, 19, 20 and recommendation 1 of this report.
8	Ensure that on the slaughter or death of a foreign equine animal, an attestation is communicated to the issuing body in the Member State where animal was identified as required by Article 19(c) of Regulation (EC) No 504/2008 and that deficiencies in identification of foreign *equidae* are notified to the competent authority of the Member State of dispatch as required by Article 38 of Regulation (EC) No 882/2004.	Partially addressed. See findings: 70, 73 and recommendation 7 of this audit report.
9	Ensure that scope of testing carried out under the NRCP includes all relevant substances in line with the range of veterinary medicinal products on the	Addressed. See finding: 4

	market taking into account the requirements of Article 7 of Council Directive 96/23/EC.	
10	Ensure that food business operators are not informed in advance of the scope of testing under the NRCP (i.e. by not publishing the scope of testing and geographical distribution in advance) in order to ensure that the element of surprise in the checks is constantly maintained, in accordance with the requirements of the Annex III to Directive 96/23/EC.	Addressed. See finding: 11
11	Ensure that sampling and testing (including turnaround times) for residues is implemented in accordance with planned arrangements, if necessary taking appropriate corrective action to ensure this outcome as required by Article 8(3)b of Regulation (EC) 882/2004.	Partially addressed. See findings: 10, 33, 46 and recommendation 2 of this audit report.
12	Ensure that follow-up investigations are carried out without prior warning as required by Article 12 of Directive 96/23/EC and Article 3(2) of Regulation (EC) No 882/2004.	Addressed. See finding: 26-28
13	Ensure that all official controls on the use of veterinary medicinal products are carried out on a risk-basis, consistently and in accordance with documented procedures in line with the requirements of Articles 3(1), 4(4) and 8(1) of Regulation (EC) No 882/2004.	Addressed. See finding: 58
14	Ensure that all medicinal treatments (including with left-over veterinary medicinal products) given to food-producing animals are recorded in line with Article 10 of Directive 96/23/EC and Part A III, point 8(b) of the Annex I to Regulation (EC) No 852/2004.	Addressed. See finding: 63
15	Ensure that officials in charge of controls in slaughterhouses carry out inspection tasks related to the food chain information and take appropriate measures when necessary as required by Article 5 of Regulation (EC) No 854/2004.	Addressed. See finding: 64
16	Ensure that verification of official controls in relation to the use of veterinary medicinal products in food-producing animals, food chain information accompanying animals to slaughterhouses and identification of *equidae* at slaughter ensures the effectiveness and appropriateness of these controls as required by Article 4(2)a of Regulation (EC) 882/2004.	Addressed. See finding: 77

6. OVERALL CONCLUSION

It is concluded that the planning and implementation of the residue monitoring plan in Italy is generally effective though the fact that certain animals, sent from other Member States for direct slaughter in Italy are not eligible for sampling does weaken the plan. The laboratory

network functions well though improvements in the performance of the national reference laboratory for residues of veterinary medical products are required.

Current EU rules governing equine identification have not yet been implemented and the control system based on previous EU rules demonstrates several weaknesses with regards to controls on equine identification requirements. Notwithstanding this, documented guidance on how to assess equine passport and food chain information in slaughterhouses decreases the risk that equidae, ineligible for human consumption, enter the food chain.

The system for the authorisation, distribution, use of veterinary medicinal products and official controls thereon, is generally in compliance with EU legislation.

7. CLOSING MEETING

A closing meeting was held on 15 February 2018 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 providing some additional information, did not express disagreement and stated that they would take whatever actions were necessary in order to address the shortcomings identified.

8. RECOMMENDATIONS

The competent authorities are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below, within 25 working days of receipt of this audit report.

No	Recommendation
1	To ensure that cattle, sheep, goats and horses sent from other EU Member States to Italy for direct slaughter for human consumption, are eligible for sampling and testing under the national residue monitoring plan, as required by Annex IV of Directive 96/23/EC and point 2.2. of Decision 98/179/EC and that the criteria for the selection of targeted residue monitoring samples from farmed game also take into account the species as required by point 2.3.3.1 of the Annex to Decision 98/179/EC. *Recommendation based on conclusion: 8.* *Associated finding: 5 and 6.*
2	To ensure that sample analysis turnaround times established by the residue monitoring plan are met to ensure analyte stability and sample integrity in accordance with part 2.9 of the Annex to Decision 98/179/EC and to ensure the adequate implementation of measures required by Articles 15-19 of Directive 96/23/EC. *Recommendation based on conclusions: 48.* *Associated findings: 33 and 46.*
3	To ensure that the NRL for residues of veterinary medicinal products fully meets its obligations as an NRL in accordance with the requirements laid down by Article 33 of Regulation (EC) No 882/2004 and by Article 14 of Directive 96/23/EC. *Recommendation based on conclusions: 48.*

No	Recommendation
	Associated findings: 31, 37 to 39 and 45.
4	To ensure that the validation of analytical methods includes all relevant provisions laid down by Article 3 of Decision 2002/657/EC, especially as regards the inclusion of all species/matrices relevant for the national residue monitoring plan and that appropriate quality control measures are put in place for methods of analysis applicable for the purpose of supplementary expert opinion in line with Article 5 of Decision 2002/657/EC. *Recommendation based on conclusions: 48.* *Associated findings: 40, 41 43 and 44.*
5	To ensure that the provisions of Regulation (EU) 2015/262 are implemented. *Recommendation based on conclusion: 78.* *Associated findings: 66 - 68, 71, 74 and 75.*
6	To ensure that equine passport issuing bodies fulfil their obligations in line with the requirements laid down in Article 3(4) of Regulation (EU) 2015/262 and that when shortcomings with regards to equine identification and registration at such bodies are found, corrective actions are taken, as required by Article 5(3) of Regulation (EU) 2015/262. *Recommendation based on conclusion: 78.* *Associated findings: 72.*
7	To ensure that deficiencies in the identification of foreign *equidae* are notified to the competent authority of the Member State of dispatch as required by Article 38 of Regulation (EC) No 882/2004. *Recommendation based on conclusion: 78.* *Associated findings: 73.*

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

http://ec.europa.eu/food/audits-analysis/rep_details_en.cfm?rep_inspection_ref=2018-6343

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 315/93	OJ L 37, 13.2.1993, p. 1-3	Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food
Dir. 90/425/EEC	OJ L 224, 18.8.1990, p. 29-41	Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra- Community trade in certain live animals and products with a view to the completion of the internal market
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 beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
Dec. 97/747/EC	OJ L 303, 6.11.1997, p. 12-15	97/747/EC: Commission Decision of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products
Dec. 98/179/EC	OJ L 65, 5.3.1998, p. 31-34	98/179/EC: Commission Decision of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products
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

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
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
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
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
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
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

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. 401/2006	OJ L 70, 9.3.2006, p. 12-34	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs
Reg. 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
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
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. 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

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
Reg. 589/2014	OJ L 164, 3.6.2014, p. 18-40	Commission Regulation (EU) No 589/2014 of 2 June 2014 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 252/2012
Reg. 2015/262	OJ L 59, 3.3.2015, p. 1–53	Commission Implementing Regulation (EU) 2015/262 of 17 February 2015 laying down rules pursuant to Council Directives 90/427/EEC and 2009/156/EC as regards the methods for the identification of equidae (Equine Passport Regulation)