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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

TUNISIA

FROM 13 TO 22 MAY 2014

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 Tunisia, carried out from 13th to 22nd May 2014, as part of the published programme of FVO audits.

The objective of the audit was to evaluate the performance of competent authorities and other officially authorised entities in their implementation of official controls concerning residues and contaminants in live animals and animal products, in order to assess whether these controls offer adequate assurance that the products and animals concerned, eligible for export to the European Union (EU) do not contain residues of veterinary medicinal products, pesticides and contaminants at concentrations in excess of EU maximum limits. Since the authorisation, distribution and use of veterinary medicinal products and feed additives have an impact on the monitoring of residues, the national rules governing the control systems in these areas were also part of the audit.

In general the residue monitoring plan meets the requirements of Directive 96/23/EC in relation to the number of samples to be taken and the substance groups to be analysed with some exceptions (e.g. no coccidiostats tested for in turkey and the absence of any sampling during several months of the year). However, the plan on paper does not reflect the reality as several sub-groups in poultry are not actually being tested for as the Tunisian laboratories have no analytical methods in place. Collectively these shortcomings undermine the guarantees provided by the residue monitoring plan, particularly for poultry (though it should be stressed that there are no exports of poultry to the EU).

With regard to the follow-up of non-compliant results, whilst there are clear procedures in place and follow-up investigations have been carried out promptly and are well-documented, the long turnaround times from sampling to reporting of results militate against the effectiveness of the whole process. Whilst there are certain positive aspects concerning laboratory performance such as the involvement of accredited EU laboratories in aquaculture testing and satisfactory results in proficiency tests, major shortcomings in the Tunisian laboratory network concern quality control (which is still at an early stage of development for the majority of the Tunisian laboratories) and a lack of appropriately validated analytical methods. Consequently, the competent authorities cannot have confidence in the performance of the Tunisian laboratories in many cases.

With regard to veterinary medicinal products, in general, rules governing their authorisation, distribution and use in food-producing animals are equivalent to EU requirements. Whilst the system for official controls on the distribution and use of veterinary medicinal products does not cover all of the points of the distribution chain, at farm level, the work of the veterinary services and their frequent and/or continuous presence at aquaculture and poultry farms provides assurances that veterinary medicinal products are used in accordance with label requirements.

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

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Abbreviations and definitions used in this report

Abbreviation	Explanation
APA	*Arrondissements de Production Animale*
CNSTN	*Centre National des Sciences et Technologies Nucléaires*
CRM	Certified Reference Material
CRDA	*Commissariat Régional au Développement Agricole*
DG(SANCO)	Health and Consumers Directorate-General
DGPA	*Direction Générale de la Production Agricole*
DGSV	*Direction Générale des Services Vétérinaires*
DIP	*Direction de l 'Inspection Pharmaceutique*
EEC	European Economic Community
EC	European Community
EU	European Union
FVO	Food and Veterinary Office
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC:
INRAP	*Institut National de Recherche et d'Analyses Physicochimique*
ISO	International Organisation for Standardisation
IRTV	*Institut de la Recherche Vétérinaire de Tunisie*
LCAE	*Laboratoire Central d'Analyse et d'Essais*
ML	Maximum Level
MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
PCB	Polychlorinated Biphenyls
PCT	*Pharmacie Central de Tunisie*
RASFF	Rapid Alert System for Food and Feed
RMP	Residues Monitoring Plan

1 Introduction

The audit took place in Tunisia from 13th to 22nd May 2014. The audit team comprised two auditors from the Food and Veterinary Office (FVO). The audit was undertaken as part of the FVO's planned audit programme.

An opening meeting was held on 13th May 2014 in two sessions with the central competent authorities responsible for (a) the monitoring of residues and contaminants in live animals and animal products (*Ministère de l'Agriculture des Ressources Hydrauliques et de la Pêche – Direction Générale des Services Vétérinaires* – DGSV) and (b) the authorisation of veterinary medicinal products (*Ministère de la Santé*). At this meeting, the objectives of, and itinerary for, the audit were confirmed and the control systems were described by the authorities. Representatives from DGSV accompanied the audit team during the whole audit.

2 Objectives

The objective of the audit was to evaluate the performance of competent authorities and other officially authorised entities in their implementation of official controls concerning residues and contaminants in live animals and animal products, in order to assess whether these controls offer adequate assurance that the products and animals concerned, eligible for export to the European Union (EU) do not contain residues of veterinary medicinal products, pesticides and contaminants at concentrations in excess of EU maximum limits. Since the authorisation, distribution and use of veterinary medicinal products and feed additives have an impact on the monitoring of residues, the national rules governing the control systems in these areas were also part of the audit.

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

- Regulation (EC) No 882/2004 of the European Parliament and of the Council;
- Council Directive 96/23/EC;
- Directive 2001/82/EC of the European Parliament and of the Council;
- Regulation (EC) No 183/2005 of the European Parliament and of the Council.

Further particulars are listed in each of the 'legal requirements' sections below with details provided in Annex 2.

The table below lists sites visited and meetings held in order to achieve the audit objective.

Meetings/Visits		**N**	**Comments**
Competent authorities	Central	2	Opening and closing meetings with *Ministère de l'Agriculture, des Ressources Hydrauliques - Direction Générale des Services Vétérinaires* - (Opening meeting with *Ministère de la Santé*).
	Regional	2	Meetings at the Regional Competent Authority in the *Arrondissement de Production Animale* (APA) of *Commissariat Régional au Développement Agricole* (CRDA)- *Gouvernorats* of Ben Arous and Sfax.
Laboratories		4	Governmental laboratories: *Centre National de Sciences et*

		Technologies Nucléaires – CNSTN; *Institut National de Recherche et d'Analyses Physicochimique* – INRAP; *Laboratoire Central d'Analyses et d'Essais* – LCAE; *Institut de la Recherche Vétérinaire de Tunisie*– IRVT.
Farms	4	One broiler farm, one laying hen farm, one finfish farm inland, one finfish farm offshore.
Establishments	3	One poultry slaughterhouse and two establishments processing finfish.
Other Sites	4	One wholesaler and two pharmacies of veterinary medicinal products and one feed mill producing medicated feeding stuffs.

3 Legal Basis

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

- Article 21 of Directive 96/23/EC;
- Article 46 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

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

Commission Decision 2011/163/EU indicates that Tunisia's residue monitoring plan (RMP) is approved in accordance with Council Directive 96/23/EC for aquaculture, poultry and wild game. Although not listed in the Annex to Decision 2011/163/EU, the RPM for eggs has been included in the audit scope following its submission by the Tunisian competent authority.

4.2 Summary of previous FVO audit reports

There have been no FVO audits on official controls on residues and contaminants and the use of veterinary medicinal products in Tunisia.

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

There have been no notifications from 1st January 2011 to date for the commodities included in the audit scope.

4.4 Production and Trade Information

Tunisia exports aquaculture finfish (sea-bream and sea-bass) and wild game (sparrows and wild quails) to the EU.

Production data for 2013 were supplied by the DGSV as follows:
Finfish: 4,500 tonnes of which 400 tonnes exported to the EU.

Wild game: 20 tonnes, almost all exported to the EU.
Poultry: 123,837 tonnes, none exported to the EU (No approved establishments).
Eggs: 95,390 tonnes, none exported to the EU (No approved RMP).

5 Findings And Conclusions

5.1 Residue monitoring

5.1.1 Competent authorities involved

1. The DGSV is the competent authority for the monitoring of residues and contaminants in live animals and animal products in the framework of Directive 96/23/EC. Article 1, 6th indent of law 2005-95 concerning livestock and animal products, and Article 30, 9th indent of *Décret* 2001-420 on the organisation of the *Ministère de l'Agriculture* represent the legal basis for this attribution.
2. DGSV is responsible for drawing up the RMP, coordinating the activities of the central and regional departments responsible for its implementation, collecting the data needed and the results obtained, and sending these to the Commission in line with the requirements of Article 4 of Directive 96/23/EC.
3. The implementation of the plan at local level in the 24 *Gouvernorats* of Tunisia is attributed to the *Commissariat Régional de Développement Agricole* (CDRA) and its *Arrondissements de Production Animale* (APA), which are established in each *Governourat*. The regional veterinary officers of the APA involved in the implementation of the RMP belong from the administrative point of view to the CRDA and functionally to the DGSV. The budget for the laboratory tests is taken from DGSV, the budget for sampling and delivering to laboratories is taken from CDRA. Both national and foreign laboratories are involved in the RMP.

5.1.2 Planning of residue monitoring plan

Legal Requirements

Directive 96/23/EC; Council Directive 96/22/EC; Commission Decision 97/747/EC; Regulation (EC) No 178/2002 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; Regulation (EC) No 396/2005 of the European Parliament and of the Council; Commission Regulation (EC) No 1881/2006; Commission Decision 2002/657/EC; Commission Decision 2011/163/EU. (See Annex 2).

Findings and observations

4. The 2014 plan addresses on the whole all of the information required by Article 7 of Directive 96/23/EC.
5. A new general plan for surveillance and control for the research of residues in food stuff (*Note de Service* 908), was established on 18th April 2014 and repealed the *Note de Service* 200/773 of 17th March 2008 which constituted the general plan in the previous 6 years. In the course of the audit, DGSV provided (updated) commodity-specific plans (*Notes de Service* 200/1056, 1057, 1059, and 1060) dated 2nd May 2014 to the audit team.
6. The audit team noted that the number of samples scheduled is higher than the minimum requirement for aquaculture, poultry and eggs as set out in Chapters 2 and 3 of Annex IV of

Directive 96/23/EC, and in Chapter 2(1) of the Annex to Decision 97/747/EC respectively. For wild game, the number planned matches the minimum number set out in Chapter 3(3) of the Annex to Decision 97/747/EC.

7. Although the 2014 RMP includes all of the substance sub-groups as defined in Annex II to Directive 96/23/EC with the attribution of the analysis to laboratories of the Tunisian network, some substance sub-groups have not been included in the commodity-specific plans without any rationale being provided. Mycotoxins (B3d) have not been included in the specific plan for finfish; anthelminthics (B2a), non-steroidal anti-inflammatory drugs (B2e) and mycotoxins (B3d) have not been included in the specific plan for poultry. In addition, anticoccidials (B2b) have not been included in the plan for turkey (and eggs).

8. During the visits to the laboratories of the Tunisian network the audit team noted that these laboratories do not have methods in place and have not been involved in recent years in testing of the aforementioned substance sub-groups/matrices including B2b for poultry (see also observation 37) . In addition, the audit team was informed that according to the *Note de Service* 908 the laboratory indicated for B2a analysis will be no longer used from 2014 on. The discrepancies described above make the plan not fully in line with the requirement of Article 7, 3rd and 5th indent of the Directive 96/23/EC.

9. Whilst there is no formalised procedure for the establishment of the range of substances to be tested, the relevant personnel in charge of each commodity at central level are consulted for their input.

10. For the 2014 RPM, an increased number of samples for some prohibited substances, namely chloramphenicol and nitroimidazoles (A6), has been scheduled following an official note of the *Ministère de l'Intérieur* concerning an alleged illegal trade of those substances across the country boundaries and non-compliant results found for those substances under the 2013 plan for poultry and eggs. Also the number of samples of aquaculture finfish has been increased in consideration of data published in Tunisian scientific literature concerning a reported increased use of antibiotics (B1) in this commodity.

11. The commodity specific plans distribute and specify the number of samples to be taken according to regional production data; they are set up centrally and subsequently sent to the responsible officer at the regional level. In turn the responsible officers set up the regional plans distributing the sampling over the rest of the year in the farms/establishments under their territorial competence.

12. The *Note de Service* 908 describes the objectives, the responsibilities and the procedures for sampling, packaging, labelling, storage and transport of samples to the laboratories; management of non-compliant results and the follow-up actions.

13. A list of Maximum Residue Limits (MRLs), Maximum Levels (MLs) and Minimum Required Performance Limits (MRPLs) for laboratories' reference are included in the *Note de Service* 742/200 last amended in 2010. Although most of the limits included are in line with EU legislation, a few are not updated and sometimes above the current EU limits. Concerning this issue, the DGSV presented the audit team with a draft *Note de Service* which is going to repeal the aforementioned one. In this draft, the relevant EU legislation is quoted directly as the reference for MRLs, MLs and MRPLs.

Conclusions on planning of residue monitoring

14. The RMP generally meets the requirement of Directive 96/23/EC. However, analysis for anticoccidials (B2b) have not been included in turkey and concerning sub-groups B2a,

B2b, B2e and B3d for poultry, although Tunisian laboratories are indicated in the RMP as carrying out these analyses, these laboratories were found not to have methods in place. Collectively these shortcomings undermine the guarantees provided by the RMP, particularly on poultry (though it should be stressed that there are no exports of poultry to the EU).

5.1.3 Implementation of the residue monitoring plan

Legal Requirements

Directive 96/23/EC; Decision 97/747/EC; Commission Decision 98/179/EC; Commission Directive 2002/63/EC; Commission Regulation (EU) No 252/2012; Commission Regulation (EC) No 333/2007; Commission Regulation (EC) No 401/2006. (See Annex 2).

Findings and observations

15. According to the *Note de Service* 908, the plan is designed to run from January to December, however the planning process actually starts every year at the end of March together with the dispatch of the results of the year before to the Commission services. Therefore, the timing of the planning is at the moment not adequate in order to ensure that sampling is carried out at variable intervals spread out over the whole year according to the requirements of point 2.1 of the Annex to Decision 98/179/EC.

16. The regional authorities visited confirmed that the latest two RMPs were received in April 2013 and in May 2014 respectively. According to DGSV, the regional authorities have the power to initiate sampling on their own initiative on the base of the previous year's figures, and then adjusting it once the new plan is received. However, according to the regional authorities visited, the administrative system of CDRA, which is responsible for the budget of sampling and delivering to the laboratories, is not flexible enough to allow this to happen in practice. Only follow-up samples of non-compliant results of the previous year's plan are actually taken in the first four months of the year.

17. *Note de Service* 908 establishes a register of sampling for the regional level; and a set of indicators for the monitoring of the plan, e.g. implementation status every three months and monitoring of the turnaround time from laboratories every month.

18. Sampling is carried out without prior warning and at no fixed time during the day or the week. Samples are collected in plastic containers and are officially sealed. The personnel performing sampling are always veterinary officers. All samples are taken and delivered to laboratories by officials. This is in line with the provisions of Annex III (1) of Directive 96/23/EC and point 2.1, 2.6 and 2.9 of the Annex to Decision 98/179/EC. A sampling report is produced after each sampling; it includes the information required by point 2.7 of Annex to Decision 98/179/EC.

19. All of the responsible people at regional level have received training by DGSV. A compact disc with, *inter alia*, a video illustrating the sampling procedure and practicalities has been distributed to all of the regional offices for training of newly appointed staff. This can be considered in line with the provisions of Article 6 (a) of Regulation (EC) No 882/2004.

20. According to the records reviewed at central level and at the regional offices visited, the realisation of the 2013 plan ranged from approximately 80% for broiler and turkey to 100% for finfish and eggs. Budget constraints at CDRA level did not allow to reach the 100% for all the commodities and in addition a number of further samples had not been analysed by

the laboratories due to lack of reagents. However, the minimum required by EU legislation was achieved also for poultry in consideration of the high number of samples scheduled.

21. At regional level the number of samples is distributed randomly and proportionally amongst the farms in a way that each farm is sampled at least once. When the number of farms exceed the number of samples the regional office ensures that in the following year the remaining farms are sampled. When the number of samples is more than the number of farms, one sample is attributed to each farm and the second sample is attributed proportionally at random. Further samples are however attributed with priority to the farms where non-compliant results have been recorded in the previous year's RMP.

22. Samples were generally delivered promptly to the designated laboratories for testing. However, sometimes the delivery took up to a month, due to no transport being available to deliver the sample to the laboratory in Tunis, for example. The audit team noted that this initial delay could have an impact on efficacy of follow up investigations in the event of a non-compliant result.

Conclusions on implementation of residue monitoring

23. The RMP is generally implemented as planned, with at least the minimum number of samples required by EU legislation being taken. However, the scheduling of sampling is not fully in line with EU requirements and weakens the effectiveness of residue controls due to the absence of sampling during several months of the year.

5.1.4 Other residues monitoring programmes

Legal Requirements

Directive 96/23/EC. (See Annex 2).

Findings and observations

24. At central level there are no residue monitoring programmes other than the RMP.

25. The own-checks of one of the aquaculture establishments visited included heavy metals (B3c) and polychlorinated biphenyls (PCBs) (B3a). All results are regularly sent to the DGSV; there have been no positive results so far.

Conclusions on other residue monitoring programmes

26. The own-checks performed in the aquaculture establishment visited underpin the guarantees on the residues status of aquaculture (finfish) products exported to the EU.

5.1.5 Follow-up of non-compliant results

Legal Requirements

Directive 96/23/EC. (See Annex 2).

Findings and observations

27. Articles 21-25 of law 92-117 of 7 December 1992 on consumer health represent the legal basis which entitles DGSV to carry out follow-up investigations of non-compliant results and to impose sanctions where appropriate. Regional offices at APA level are in charge of it.

28. *Note de Service* 908 sets out written instructions for staff on performing follow-up investigations in case of non-compliant results being detected including the taking of follow-up samples, restrictions to be placed on the animals/products of farm/s or establishment/s involved, and when appropriate to the farm/s or establishment/s of the same owner.

29. During the course of the 2013 RMP, 44 non-compliant samples were detected. Eight for chloramphenicol in eggs and poultry meat, 36 for nitroimidazoles (ronidazole and metronidazole in eggs, poultry meat and (one) in finfish meat). Chloramphenicol and nitroimidazoles (A6) are prohibited substances both in the EU and in Tunisia.

30. According to the DGSV following the high number of non-compliant results under the 2013 plan for chloramphenicol and nitroimidazoles different ministries (*Santé, Intérieur, Commerce* and *Économie*) have been alerted and asked to investigate in their respective domain of competence. Meetings with representatives of the veterinary profession have been organised and a multidisciplinary committee with the aforementioned ministries has been proposed to be set up. Moreover DGSV has proposed a communication plan via television, radio and newspaper advertisements in the 2nd half of 2014 addressed to private veterinarians, farmers and consumers in order to make them aware of the consequences of the illegal use of prohibited substances and of the danger linked to the consumption of animal products bought from non-controlled traders.

31. The audit team noted that in case of non-compliant results under the 2013 RMP, on-the-spot investigations were performed at the farm of origin; the farms were put under targeted control (their name and location are flagged up in the commodity specific plans in the following year); new controls broadening the nature of sampling (water, feed, etc.) were established. This is in line with the provisions of Article 16 of Directive 96/23/EC.

32. Twenty non-compliant results were reviewed by the audit team in the two regional offices visited; 5 for chloramphenicol and 15 for nitroimidazoles in poultry and eggs. The audit team noted that all of the 14 non-compliant samples for nitroimidazoles in eggs were tested by the laboratory in charge on the same day.

33. The regional authorities carried out comprehensive, well-documented investigations. The investigations were in general carried out promptly within a few days of the results being received by the DGSV, but because of the delay in obtaining the initial result from the laboratory, considerable time had elapsed since the original sample had been taken. The farms of origin were inspected unannounced and the distribution of veterinary medicinal products to the farm was investigated. Follow-up samples were taken as soon as possible. In none of the follow-up investigations was the source of the prohibited substance identified.

34. DGSV and the laboratories have agreed a turnaround of 15 days to complete the tests, however, in 18 out of the 20 follow-up cases the turnaround time was over two months and only in two cases was it within the 15 days agreed. In addition, from some of the files reviewed, the laboratories took a further 15-20 days to communicate the results to DGSV.

Conclusions on follow-up of non-compliant results

35. Whilst there are procedures for follow-up of non-compliant results and follow-up investigations have been done promptly and are generally well-documented, the long turnaround times by the laboratory and sometimes initial delays in delivering samples to

the laboratory, militate against the effectiveness of the whole process particularly in relation to identifying the source of illegal substances.

5.2 LABORATORIES

Legal Requirements

Directive 96/23/EC; Decision 98/179/EC; Decision 2002/657/EC; Regulation (EU) No 252/2012; Regulation (EC) No 333/2007; Regulation (EC) No 401/2006. (See Annex 2).

5.2.1 General description

Findings and observations

36. Residue analyses under the RMP are contracted to the following six laboratories:

    a) *Institut National de Recherche et d'Analyses Physicochimique* – INRAP, under the *Ministère de l'Enseignement Supérieur et de la Recherche* - for testing stilbenes (A1), steroids (A3), zeranol (A4), beta-agonists (A5), chloramphenicol, marker residues for nitrofurans, nitroimidazoles (A6), carbamates (B2c) and dyes (B3e);

    b) *Laboratoire Central d'Analyse et d'Essais* – LCAE, under the *Ministère de l'Industrie* - for testing PCBs (B3a) and chemical elements (B3d);

    c) *Institut de la Recherche Vétérinaire de Tunisie* – IRVT, under the *Ministère de l'Agriculture* - for testing antibacterial substances (B1) under the 2014 RMP;

    d) *Centre National des Sciences et Technologies Nucléaires* – CNSTN, under the *Ministère de l'Enseignement Supérieur et de la Recherche* - for testing antibacterial substances (B1) under the 2013 RMP;

    e) Two EU laboratories for analysis of substance groups A1, A3, A6, B1, B2a and B3e in aquaculture finfish.

37. Although in the 2014 RMP all the sub-groups are covered by a Tunisian (or an EU laboratory) and in particular anthelmintics (B2a) in poultry by CNSTN, non-steroidal anti-inflammatory drugs (B2e) and mycotoxins (B3d) in poultry by LCAE and coccidiostats (B2b) in poultry (and eggs) by INRAP, the audit team noted that there are no methods in place in these Tunisian laboratories for testing those substances/matrices (see also finding 8). Only aquaculture samples are tested for those sub-groups in the EU laboratories.

38. Only the two foreign laboratories and LCAE are accredited according to the International Organisation for Standardisation (ISO) standard 17025 and the audit team confirmed that the analytical methods in use in the EU laboratories are within the respective laboratories' scope of accreditation. LCAE is accredited by Tunisian Accreditation Council with only the method for mercury in fish included in its scope of accreditation. In INRAP, accreditation has been suspended since 2012, while in CNSTN and INRV the quality management system according to ISO standard 17025 was being developed and there were no deadlines established for its full implementation.

39. There are no formal contracts with the EU laboratories and the DGSV has neither a procedure for selecting/assessing the performance of foreign laboratories nor contracts in place for chemical confirmation of potentially non-compliant samples screened for

antibacterial substances. However, informal communication with EU laboratories is maintained and samples had been analysed promptly.

40. Valid contracts are in place with three national laboratories: INRAP, LCAE and IRVT. Those contracts include, *inter alia*, the statement of the contracted laboratory that it applies the reference analytical methods and techniques established by EU legislation or equivalent and validated methods, and that it has in place a quality control mechanism for analyses conducted within official controls.

41. The audit team visited four laboratories: INRAP, LCAE, INRV and CNSTN. All laboratories were located in adequate premises and were equipped with appropriate analytical instrumentation. Documents and records were well maintained and traceable except for the number of samples received for residue analysis in INRAP.

5.2.2 Institute National de Recherche et d'Analyses Physicochimique (INRAP)

42. There was no instruction in place specifying criteria for sample reception.

43. Methods for chloramphenicol, nitroimidazoles and beta-agonists were validated in 2012 by students (not by the laboratory staff) and followed the principles of *Association Française de Normalisation* standard NF V03-110 1998. This approach does not cover recovery assessment and therefore could not be considered equivalent to the requirements laid down in Commission Decision 2002/657/EC.

44. Regarding the method for chloramphenicol (a Liquid Chromatography – (Tandem) Mass Spectrometry), the internal standard was purchased in March 2014 and only certain elements of method validation had been performed. The internal standard was not used for routine chloramphenicol testing. The Standard Operating Procedure for chloramphenicol analysis with the use of the internal standard was at the draft stage.

45. A five point matrix-matched calibration curve starting at 0.3 µg/l which equals to the MRPL is run in every assay series.

46. The laboratory has no established procedures for quality control. Control materials or Certified Reference Materials (CRMs) were not available. The only CRM for chloramphenicol in muscle was ordered in October 2013 but had not yet been received. The positive control sample concentration of 10 µg/l is far above the MRPL (therefore not appropriate) and it is not included in every assay series.

47. Up to the time of the audit the laboratory has participated in proficiency tests for chloramphenicol in milk. Results were satisfactory.

5.2.3 Laboratoire Central d'Analyse et d'Essais Central (LCAE)

48. There was a comprehensive instruction in place for sample reception. However, sample reception criteria were assessed only visually and no records were maintained.

49. A Gas Chromatography – Electron Capture Detection method for PCBs and Graphite Furnace-Atomic Absorption Spectrometry method for cadmium were examined by the audit team. The method for PCBs analysis was partially validated while the one for cadmium was not validated.

50. Certain CRMs were available, especially for heavy metals, a list of which was maintained. However, one expired CRM was in use without verification and it was the laboratory policy

to use, instead of uncertainty provided in the CRM certificate, the arbitrarily assigned 30% of certified value to assess the analytical results for cadmium in CRM, thus allowing for higher analytical error.

51. For cadmium CRMs are periodically used for quality control purposes but control charts are not maintained.

52. For PCBs control samples spiked with each PCB at 40ng/g and 70-110% interval was used for recovery control. The spiking level is higher than the ML as laid down in Regulation (EC) No 1881/2006 but is limited by the low sensitivity of the electron capture detector. Control charts are not maintained.

53. A double standard deviation is used to express the measurement uncertainty and not the expanded measurement uncertainty as required by Article 4 of Regulation (EU) No 252/2012 and Annex IV to that Regulation.

54. The laboratory has regularly participated in proficiency tests for PCBs and heavy metals with satisfactory results.

5.2.4 Institute de la Recherche Vétérinaire de Tunisie (IRVT)

55. Sample reception instructions and equipment were in place, operational and adhered to. However, only one sample (of poultry meat) had been received up to the time of the audit.

56. For screening antimicrobials under the RMP the use of a commercially available microbial growth inhibition-based testing kit is provided for.

57. The laboratory staff comprised 1 veterinarian and 4 technicians. Laboratory personnel were not aware of the analytical capability of the testing kit ordered, the need to establish method performance parameters, quality control requirements and there were no measures in place to control false negative results.

58. At the time of the audit the laboratory was not technically prepared to carry out any analyses for antimicrobials. Four packages of testing kits had been ordered and were expected to be received in June 2014. These quantities are not sufficient to ensure the continuity of routine testing after performing method performance verification. No analytical standards had been ordered for quality control purposes.

5.2.5 Centre National des Sciences et Technologies Nucléaires (CNSTN)

59. In 2010 the performance of a screening method for antimicrobials was examined in the laboratory for three different concentration levels of penicillin G ranging from 2.5 to 10.0 µg/kg in poultry, fish and egg matrices separately. Negative and penicillin G positive controls were run in every assay series and the serial number of the testing kit was recorded. However, as these controls cover only penicillin G, the laboratory has no control on method performance with regard to other chemical groups of antibiotics.

60. The audit team noted a substantial discrepancy between the spectrum of method detection capability provided by the testing kit supplier and the one presented in the laboratory test report.

61. In case of non-compliant results the laboratory has a policy to repeat the test with a different package of the same testing kit.

62. In 2010, the laboratory successfully participated in inter-laboratory comparisons for antimicrobials organised by one of the European Union Reference Laboratories.

Conclusions on laboratories

63. Whilst there are certain positive aspects concerning laboratory performance such as involvement of accredited EU laboratories in aquaculture testing and satisfactory results in proficiency tests, major shortcomings include the lack of accredited quality control systems (which are still at an early stage of development for the majority of the Tunisian laboratories), a lack of fully validated analytical methods and a lack of quality controls on method performance. Given those deficiencies the Tunisian competent authorities cannot have confidence in laboratory results except those for aquaculture finfish tested in the two EU laboratories.

5.3 Veterinary medicinal products and medicated feedingstuffs

5.3.1 Authorisation, distribution and use of veterinary medicinal products

Legal Requirements

Directive 96/23/EC; Directive 96/22/EC; Directive 2001/82/EC; Regulation (EC) No 726/2004; Regulation (EC) No 470/2009, Regulation (EU) No 37/2010; Commission Directive 2006/130/EC; Council Directive 90/167/EEC; Regulation (EC) No 183/2005. (See Annex 2).

Findings and observations

64. The legal base for the medicinal sector is the law 78-23 of 8 March 1978 as amended by the law 2000-40 of 5 April 2000. The competent authority is the *Ministère de la Santé – Direction de la Pharmacie et du Médicament* which is responsible for the granting of marketing authorisations. The *Arrêté du Ministère de l'Agriculture et du Ministère de la Santé* of 19 September 2013 is the implementing regulation for the marketing authorisation of veterinary medicinal products.

65. When considering pharmacological products (i.e. excluding vaccines) all the ones authorised in Tunisia are copies or generics of veterinary medicinal products authorised in at least one EU country. Withdrawal periods for food-producing animals are therefore set according to the EU MRLs.

66. All veterinary medicinal products which are classed as A (toxic), B (narcotic), C (harmful) under national legislation are prescription-only medicines. According to the DGSV class A and C include all veterinary medicinal products with an MRL.

67. Veterinary medicinal products can be dispensed to the public (farmers or animal owners) only by the pharmacies or by those veterinarians authorised to keep an own stock. Pharmacies can dispense veterinary medicinal products only under a veterinary prescription. This is in line with provisions laid down in Article 67 (a) of Directive 2001/82/EC.

68. The *Arrêté of the Ministère de l'Agriculture et du Ministère de la Santé* of 27 December 2006 authorised cocciodiostats as feed additives with withdrawal periods varying from 3 to 9 days at the prescribed concentrations. The list mirrors the one in force in EU with the exception of ethopabate, meticlorpindol, methylbenzoquate, aprinocide and nifursol, which are no longer authorised in the EU.

69. *Note de service* 743/200 of 28 March 2006 has established a list of prohibited substances for use on food producing animals which generally mirrors the provisions of Directive 96/22/EC and of Table 2 of the Annex to Regulation (EU) No 37/2010. During the whole visit the audit team found no evidence that substances which are banned in EU are authorised for use in food-producing animals.

70. The *Arrêté du Ministère de l'Agriculture* of 17 June 1982 and the *Note de Service* 1204 of 14 May 2014 set out the requirement for treatment records in poultry and aquaculture farms respectively. Treatment records were kept in all the farms visited (broiler, laying hens, and inland finfish).

71. A food chain information form for poultry has been established by the DGSV. It includes all the treatment for the whole production cycle. This is in line with the provision in Annex II, Section III point 3(c) of Regulation (EC) No 853/2004. Examples of this form have been reviewed at the broiler slaughterhouse visited.

72. There is no legislation in place for medicated feedstuffs. Feed mills are authorised by the *Direction Général de la Production Agricole* (DGPA) with no special provision for feed mills dealing with medicated premixes. This differs from the provisions established in the EU and specifically in Directive 90/167/EEC.

73. The feed mill visited produces medicated feed with antibiotics, and feed containing coccidiostats. The feed mill supplied medicated feed to farms only following veterinary prescription. This is in line with the provision of Article 8(1) of Directive 90/167/EEC.

74. The feed mill visited performs a regular test at least monthly to ensure that homogeneity is guaranteed. This can be considered in line with the provision laid down in Art 4(1) e of Directive 90/167/EEC.

Conclusions on authorisation, distribution and use of veterinary medicinal products

75. In general, rules governing the authorisation, distribution and use of veterinary medicinal products in food-producing animals are equivalent to the EU requirements.

5.3.2 Official controls on the distribution and use of veterinary medicinal products

Legal Requirements

Directive 96/23/EC; Directive 2001/82/EC; Directive 90/167/EEC. (See Annex 2).

Findings and observations

76. The law 91-63 of 29 July 1991 appointed the *Direction de l' Inspection Pharmaceutique* (DIP) as the responsible body for the control of the application of the legislation concerning import, manufacturing and distribution of veterinary medicinal products.

77. According to the DIP there are 53 wholesalers in Tunisia and 1,937 pharmacies, in addition to the *Pharmacie Central de Tunisie* (PCT) and its 5 detached deposits. Inspections are planned every two years through the supply chain at level of local manufacturer, wholesalers and pharmacies. Private veterinary practitioners and farms are not subject to official controls either by DGSV or DIP on the distribution and use of veterinary medicinal products.

78. According to the figures provided for the year 2013, 20 inspections were planned for wholesalers and 193 for pharmacies, which is not sufficient to reach the whole target in two

years' time. Ten wholesalers and 65 pharmacies were actually inspected in 2013 with no nonconformities raised. The DIP explained that the shortfall was due to the current shortage in personnel.

79. Although DGSV claims that it does not have any legal attribution and responsibility for carrying out controls with regard to the correct use of veterinary medicinal products and records, the veterinary services supplement these controls on poultry and laying egg farms on an informal basis during their animal health activities. In aquaculture, the constant presence of a veterinary officer at farms is necessary for issuing the export certificates and checks are regularly performed as well in these establishments (though the results are not documented).

80. DGPA is in charge of authorisation and controls on feed mills, however according to the feed mill visited such controls have never included the use of medicated premixes.

81. The DIP has set out different checklists for the inspections of manufacturers, wholesalers and pharmacies. DIP's checklists focus on personnel training, condition of storage, management of prescriptions and records, preparation of magistral formulas, delivery of narcotic and psychotropic products, management of expired products or products withdrawn from the market. Inspections also covered label checks but do not include a cross-check of the correctness of e.g. target species, indications, contraindications, and withdrawal periods with the authorised product literature.

82. All the veterinary medicinal products which the audit team came across during the audit in pharmacies, wholesalers and farms were cross-checked and found to be included on the PCT website at the following link: http://www.phct.com.tn/index.php?option=com_searchproduct&view=searchproduct&Itemid=14&lang=en&ctg=V. They bear marketing authorisations numbers, batch numbers, expiry dates and withdrawal periods on the labelling. As this information is not included in any official public source there was no way for the audit team to verify their correctness.

83. A veterinarian inspector officer is present every other day in the slaughterhouse visited. Each consignment of poultry comes together with a health certificate which includes a statement about "no objection from the legal and safety point of view" to slaughter the animals covered by the certificate. This certificate is linked to the farm records where all the treatment needs to be transcribed (including medicated feed). This information is received and checked by the food business operator and forwarded to the official veterinarian before the slaughter operation begins or the day after when the official veterinarian is not present. This is in line with the provision of Article 9(2)(a) of Directive 96/23/EC.

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

84. Whilst there is a system in place for official controls on the distribution and use of veterinary medicinal products, this does not cover all of the points of the distribution chain.

However at the level of farms, the veterinary services supplements controls with a frequent and/or continuous presence at aquaculture and poultry farms. Moreover, national requirements in relation to the maintenance of medicinal treatment records on farms provide assurances that animals are not inadvertently sent for slaughter/human consumption within withdrawal periods.

6 Overall Conclusions

In general the residue monitoring plan meets the requirements of Directive 96/23/EC in relation to the number of samples to be taken and the substance groups to be analysed with some exceptions (e.g. no coccidiostats tested for in turkey and the absence of any sampling during several months of the year). However, the plan on paper does not reflect the reality as several sub-groups in poultry are not actually being tested for as the Tunisian laboratories have no analytical methods in place. Collectively these shortcomings undermine the guarantees provided by the residue monitoring plan, particularly for poultry (though it should be stressed that there are no exports of poultry to the EU).

With regard to the follow-up of non-compliant results, whilst there are clear procedures in place and follow-up investigations have been carried out promptly and are well-documented, the long turnaround times from sampling to reporting of results militate against the effectiveness of the whole process. Whilst there are certain positive aspects concerning laboratory performance such as the involvement of accredited EU laboratories in aquaculture testing and satisfactory results in proficiency tests, major shortcomings in the Tunisian laboratory network concern quality control (which is still at an early stage of development for the majority of the Tunisian laboratories) and a lack of appropriately validated analytical methods. Consequently, the competent authorities cannot have confidence in the performance of the Tunisian laboratories in many cases.

With regard to veterinary medicinal products, in general, rules governing their authorisation, distribution and use in food-producing animals are equivalent to EU requirements. Whilst the system for official controls on the distribution and use of veterinary medicinal products does not cover all of the points of the distribution chain, at farm level, the work of the veterinary services and their frequent and/or continuous presence at aquaculture and poultry farms provides assurances that veterinary medicinal products are used in accordance with label requirements.

7 Closing Meeting

A closing meeting was held on 22nd May 2014 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 needed within their possibilities in order to address the recommendations included in the report.

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.

N°.	Recommendation
1.	Planning: Ensure that the RMP includes all relevant and correct information in particular with regard to laboratories responsible for analysis in line with provision of Article 7, 3rd and 5th indent of Directive 96/23/EC. Conclusions upon which this recommendation is made: 14.Associated findings and observations: 7, 8, 37.
2.	Implementation: Ensure that sampling is carried out at variable intervals spread out over the whole year in order to provide guarantees at least equivalent to the requirements of the Annex to Decision 98/179/EC. Conclusions upon which this recommendation is made: 23. Associated findings and observations: 15,16.
3.	Laboratories: Ensure that all the laboratories contracted and approved for testing samples under the RMP are accredited in order to provide guarantees with the effect equivalent to that foreseen by Article 1 and Point 1.2 of the Annex to Decision 98/179/EC. Conclusions upon which this recommendation is made: 63. Associated findings and observations: 38.
4.	Laboratories: Ensure that all analytical methods used for the RMP are validated to a standard equivalent to Article 3 of Decision 2002/657/EC (residues of veterinary medicines) and Regulation (EC) No 333/2007 (chemical elements) and are demonstrably 'fit for purpose' taking into account requirements described in part 2 of Annex I and Article 4 of this Decision. Conclusions upon which this recommendation is made: 63. Associated findings and observations: 43, 44, 49, 57, 59.
5.	Laboratories: Ensure that all the laboratories contracted and approved for testing samples under the RMP have quality control procedures in place in accordance with Article 5 of Decision 2002/657/EC. Conclusions upon which this recommendation is made: 63. Associated findings and observations: 46, 52, 57, 59.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2014-7035

Annex 1 - Legal References

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

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

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

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

Legal Reference	Official Journal	Title
Reg. 1883/2006	OJ L 364, 20.12.2006, p. 32-43	Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs
Sampling methods for pesticides in foodstuffs		
Dir. 2002/63/EC	OJ L 187, 16.7.2002, p. 30-43	Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC

Residue monitoring:

Planning of the residue monitoring plan

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

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

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

In accordance with Article 29 of Council Directive 96/23/EC, Commission approval of every third country's residue monitoring plan is necessary if that country is to remain on the list of third countries from which EU Member States may import animals and animal products. The list of countries and commodities with approved residue monitoring plans is in the Annex to Commission Decision 2011/163/EU.

Implementation of the residue monitoring plan

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive and must, in particular, meet the requirements of Article 4 and specify the particulars laid down in Article 7. Article 4(2)(b) and (c) of Council Directive 96/23/EC lays down the requirements for central competent authorities in co-ordinating the activities of all bodies involved in residues controls. Articles 5 and 12 of Council Directive 96/23/EC deal with aspects pertaining to the implementation of the residue monitoring plan. Sampling requirements are specified in Annex IV to Council Directive 96/23/EC and Commission Decision 97/747/EC and Commission Decision 98/179/EC lays down the rules for official sampling under the residue monitoring plan. EU methods of sampling for the official control of a wide range of residues in products of animal origin are laid down in several pieces of EU legislation: Commission Directive 2002/63/EC (pesticides); Commission Regulation (EU) No 252/2012 (dioxins, dioxin-like PCBs and non-dioxin-like PCBs); Commission Regulation (EC) No 333/2007 (certain chemical elements);

Commission Regulation (EC) No 401/2006 (mycotoxins).

Other residues monitoring programmes

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

Follow-up of non-compliant results

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

Laboratories

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive. Article 15 of Council Directive 96/23/EC requires that official samples are examined in approved laboratories. Requirements for accreditation of laboratories are laid down in Point 1.2. of the Annex to Commission Decision 98/179/EC. The rules for analytical methods to be used in the testing of official samples taken pursuant to Article 15(1) of Council Directive 96/23/EC are laid down in Commission Decision 2002/657/EC – in particular Articles 3, 4, 5 and 6 which cover *inter alia*, validation requirements and quality control. More specific requirements for analytical methods for certain substances are laid down in the annexes to Commission Regulation (EU) No 252/2012 (dioxins, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs), Commission Regulation (EC) No 333/2007 (chemical elements in foodstuffs) and Commission Regulation (EC) No 401/2006 (mycotoxins).

Veterinary medicinal products and medicated feedingstuffs:

Authorisation, distribution and use

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

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

According to Article 11(2) of Council Directive 96/22/EC, Member States may not import live animals or animal products from third countries which authorise the use of stilbenes or thyrostats in food producing animals. Member States are also prohibited from importing products of animal origin for human consumption if the animals from which such products have been derived have

been treated at any time with either thyrostatic substances, stilbenes, stilbene derivatives, their salts and esters, oestradiol 17β and its ester-like derivatives, and beta-agonists if administered for the purposes of growth promotion.

The relevant provisions in EU law governing the marketing authorisation of veterinary medicinal products are laid down in Articles 5-15, 21-30, 58-62 and 83 of Directive 2001/82/EC and for certain products authorised on an EU-wide basis, in Articles 30-40 of Regulation (EC) No 726/2004. Provisions governing the distribution and use of veterinary medicinal products are laid down in Articles 65-71 of Directive 2001/82/EC. Veterinary medicinal products which are authorised for use in food producing animals may only contain pharmacologically active substances which have been assessed in accordance with the provisions of Regulation (EC) No 470/2009 and which are listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010. Article 67(aa) of Directive 2001/82/EC requires that veterinary medicinal products for food producing animals are only dispensed to the public under a veterinary prescription unless exempted under the conditions laid down in Article 2 of Commission Directive 2006/130/EC.

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

Controls on the distribution and use of veterinary medicinal products

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

The relevant provisions in EU law governing competent authorities' obligations to carry out inspections throughout the distribution chain of veterinary medicinal products in order to verify compliance with the provisions of the EU code relating to veterinary medicinal products (Directive 2001/82/EC) are laid down in Articles 65, 66, 68, 69 of that Directive. With regard to ensuring that the production of medicated feedingstuffs is in accordance with Council Directive 90/167/EEC, the rules governing control functions by the competent authorities are laid down in Articles 4, 9 and 13 of said Directive.