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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

THE RUSSIAN FEDERATION

FROM 16 TO 27 JUNE 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 the Russian Federation, carried out from 16 to 27 June 2014, as part of the published programme of FVO audits.

The objective of the audit was to evaluate the performance of competent authorities 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 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 control systems in these areas were also part of the audit. Attention was also paid to examining the implementation of corrective actions promised in response to recommendations made in the report of a previous FVO residues audit to the Russian Federation.

Overall, it is concluded that the current system for the control of residues in food of animal origin and the authorisation, distribution and use of veterinary medicinal products still presents significant shortcomings and in general cannot be considered to offer guarantees of full equivalence to EU rules.

Notwithstanding improvements made in the elaboration of the residue monitoring plan, the fact that the overall layout of the plan remains unchanged, makes it difficult to judge if it is in line with EU requirements. Furthermore, as in 2011, the effectiveness of residue controls continue to be compromised by a number of factors. These include the limited scope of testing compared to the availability and potential use of a range of pharmacologically active substances in food animal production, the pre-announcement of visits to food business operators, the taking of samples from processed products and the lack of application of targeting criteria for sampling. However, there has been an improvement in the general timeliness of the follow-up actions taken, and the development and application of a new information technology tool for this purpose.

In relation to the performance of the residue testing laboratories, progress has been seen with the international accreditation of laboratories (although the number of methods within the scope of accreditation is limited) and method validation. In spite of this it remains the case that there are no methods in place for certain substance groups and non-validated analytical methods are still being used. Allied with the fact that quality controls on method performance are not routinely implemented in some laboratories, these issues collectively undermine the effectiveness of residue controls in the Russian Federation.

Concerning veterinary medicinal products, progress has been made in gradually aligning residue limits with EU ones although the approach taken to the licensing of veterinary medicinal products continues to differ with that in the EU, with no link being made between the revised limits and corresponding product/formulation-specific drug withdrawal periods. Improvements have also been seen in the implementation of controls on the distribution and use of veterinary medicinal products, although the influx and free distribution on the market of certain veterinary medicinal products registered in other Customs Union countries increases the probability of the occurrence of residues of substances which are not authorised in the EU.

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

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Abbreviations and definitions used in this report

Abbreviation	Explanation
AAS	Atomic Absorption Spectroscopy
AOZ and AMOZ, AHD and SEM	Marker residues of the nitrofuran drugs furazolidone, furaltadone, nitrofurantoin and nitrofurazone respectively
ARRIAH	Federal Governmental Veterinary Institute "Federal Centre for Animal Health"
CCα / Ccβ	Decision Limit / Detection Capability
CSMVL	Central Scientific and Methodical Veterinary Laboratory, Moscow
DAkkS	*Deutsche Akkreditierrungstelle*
DDT	Dichlorodiphenyltrichloroethane
EEC CU	Eurasian Economic Commission of the Customs Union of Russia, Belarus and Kazakhstan
ELISA	Enzyme-linked immuno-sorbent assay
EU	European Union
FVO	Food and Veterinary Office
GOST	State Standard of the Russian Federation
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC:
HCH	Hexachlorocyclohexane
HPLC –DAD	High Performance Liquid Chromatography with Diode Array Detector
HPLC-MS/MS	High Performance Liquid Chromatography-(Tandem) Mass Spectrometry
ISO	International Organisation for Standardisation
ML	Maximum Level
MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
NCSFAP	National Centre for Safety of Fishery and Aquaculture Products, Moscow
NSAIDs	Non-Steroidal Anti-Inflammatory Drugs
RASFF	Rapid Alert System for Food and Feed
RMP	Residue Monitoring Plan
Rosselkhoznadzor	Federal Service for Veterinary and Phytosanitary Surveillance
SIRANO	Computerized information system similar to the RASFF system
SOP	Standard Operating Procedure
VGNKI	All Russian State Centre for Quality and Standardisation of Veterinary Drugs and Feeds, Moscow

1 Introduction

The audit took place in the Russian Federation from 16 to 27 June 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 16 June 2014 with the central competent authority, the Federal Service for Veterinary and Phytosanitary Surveillance (*Rosselkhoznadzor*) responsible for (a) the monitoring of residues and contaminants in live animals and animal products and for controls on veterinary medicinal products, feed additives (coccidiostats) and (b) the authorisation of veterinary medicinal products. At this meeting, the objectives of, and itinerary for, the audit were confirmed and the control systems were described by the authorities. Representatives from the central competent authority 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.

Attention was also paid to examining the implementation of corrective actions promised in response to recommendations made in the report of a previous FVO residues audit carried out in the Russian Federation (DG(SANCO)/8905/2011) in September 2011.

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		No	Comments
Competent authorities	Central	2	Opening and closing meetings with *Rosselkhoznadzor*
	Regional	2	Meetings at the *Rosselkhoznadzor* territorial administration in Krasnodar and Briansk
Laboratories		5	All Russian State Centre for Quality and Standardisation of Veterinary Drugs and Feeds (VGNKI), National Centre for Safety of Fishery and Aquaculture Products (NCSFAP), Reference Centre in Krasnoyarsk and inter-regional (*interoblast*) laboratories in Krasnodar and Briansk
Farms		3	Aquaculture, dairy and poultry farms
Establishments		2	One slaughterhouse for cattle and pigs, one honey packing centre
Other sites		3	One feed mill producing medicated feed, two veterinary pharmacies

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 the Russian Federation's Residue Monitoring Plan (RMP) is approved in accordance with Directive 96/23/EC for bovine, ovine/caprine, swine, poultry, milk, eggs, farmed game (reindeer from Murmansk and Yamalo-Nenets regions only) and honey.

Both the 2013 and 2014 RMP and 2012, 2013 results covered all the above commodities as well as equine, aquaculture, rabbits and wild game. In 2013 the competent authority requested the Commission to extend the approval to aquaculture, rabbits and wild game.

Both during the opening and the closing meeting the competent authority confirmed its interest that the Russian Federation be listed in the next amendment of Decision 2011/163/EU for all commodities covered by the RMP.

4.2 Summary of previous FVO audit reports

Official controls on residues and contaminants and the use of veterinary medicinal products were audited by the FVO in 2009 (DG (SANCO)/2009-8279 MR Final) and 2011 (DG (SANCO)/2011-8905 MR Final). The reports of both audits, henceforth referred to as the 2009 and 2011 FVO audits, respectively, have been published on the website of the Directorate–General for Health and Consumers here: http://ec.europa.eu/food/fvo/ir_search_en.cfm.

The most recent report pointed out that shortcomings in the design and implementation of the RMP identified during the 2009 FVO audit had not been rectified and delays allied with the pre-announcement of control visits hampered the effectiveness of follow-up actions. The absence of internationally recognised accreditation of laboratories and continued use of unvalidated methods combined with a lack of quality controls in place undermined the reliability of the RMP results.

The report concluded that the system in place for the control of residues in the Russian Federation was not considered to offer guarantees equivalent to those foreseen by EU legislation and the competent authorities were requested to rectify the deficiencies identified.

4.3 Rapid Alert System for Food and Feed (RASFF) notification

Since the 2011 FVO audit to date there have been no RASFF notifications for residues of veterinary medicinal products in food products of animal origin imported from the Russian Federation.

4.4 Production and Trade Information

At the time of the audit the Russian Federation exported to the EU dairy products, finished meat products and pig meat, fat and casings, farmed game from approved regions, honey and wild-caught fishery products. Also certain products of animal origin were exported for technical use only.

National production figures, as provided with the response to the Pre-Audit Questionnaire, were as follows: cattle: 4,556,300 animals, pigs: 13,060,140 animals, sheep: 7,641,300 animals, poultry: 2,644,092.45 tonnes, milk: 12,033,470.3 tonnes, eggs: 850,000,000, honey 96,541.53 tonnes, fish: 897,591.6 tonnes, other aquaculture products: 29,831.7 tonnes, rabbits: 22,365.9 tonnes of meat.

EU-approved establishments comprised: five meat product processing plants (all in Kaliningrad region), one slaughterhouse for farmed game, 15 raw milk and dairy products processing plants, two casing processing plants, 414 fish processing plants and vessels. In addition, for animal by-products not intended for human consumption there were two slaughterhouses, two dairy plants, 14 processing plants and 41 other facilities approved. Details can be found here http://ec.europa.eu/food/food/biosafety/establishments/third_country/index_en.htm

5 Findings And Conclusions

5.1 Residue monitoring

5.1.1 Competent authorities involved

The description of the central competent authorities involved in the planning and implementation of the RMP has been provided in the report of the 2009 FVO audit. At the time of the audit *Rosselkhoznadzor* had 59 territorial offices, three research institutes, 12 laboratory reference centres and 21 veterinary laboratories.

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

1. The legal basis for the RMP plan remains as described in the 2011 FVO audit report. It is supported by Decree No 717 of 14 July 2012 of the Government of the Russian Federation.
2. According to the *Rosselkhoznadzor* the RMP is based on national production and fulfils the requirements of Directive 96/23/EC. However, sampling continues not to cover live animals as required by Article 15 and Annex IV to Directive 96/23/EC but frequently covers processed products (see findings 17, 51).
3. The planning process was modified in 2012 through the *Rosselkhoznadzor* Letter No FS-EN-2/1226 of 1 February 2012. Since that date the regional *Rosselkhoznadzor* offices have to collect and transfer to regional laboratories (before first December of the current year) the

information concerning domestic production volumes and the number of establishments (farms, slaughterhouses, feed mills etc), number of animals in holdings per species, the number of imported animals and products of animal origin from Customs Union members (Belarus, Kazakhstan) and from third countries.

4. Based on this information each regional laboratory is obliged to calculate within 15 working days the minimum number of samples and tests to be performed for its region taking into account the requirement that any single sample should not be tested for more than five "safety indicators" (residues of veterinary medicines, chemical elements with nutritional value, radionuclides etc.). Such plans indicating the substance group/matrix combinations, for which there is a capacity in the region to perform analysis, are sent to the relevant *Rosselkhoznadzor* office(s) served by the regional laboratory in question.

5. The regional *Rosselkhoznadzor* offices in co-operation with the veterinary services of the Russian Federation Regions allocate samples/tests to establishments operating on the territory under their responsibility taking into account, inter alia, monitoring results from the previous three years (non-compliant), veterinary medicine producers, information on veterinary medicines used for animal treatment in the region (pharmacies and veterinary practices). Draft regional RMPs accompanied by a preliminary assessment of the financial support required are sent to central *Rosselkhoznadzor* for approval.

6. All of the regional plans are verified, collated and amended in the central *Rosselkhoznadzor* office taking into account the funds available from the federal budget of the Russian Federation. At the beginning of the year the number of laboratory tests and their distribution between laboratories is approved by the *Rosselkhoznadzor* order. The plan is subsequently revised each quarter to include suspect and follow-up samples (if any) with account being taken of the remaining financial resources.

7. Those tests which cannot be performed in the *interoblast* laboratories are assigned to the All Russian State Centre for Quality and Standardisation of Veterinary Drugs and Feeds (VGNKI), Central Scientific and Methodical Veterinary Laboratory, Moscow (CSVML) and National Centre for Safety of Fishery and Aquaculture Products (NSCFAP) laboratories. Each of these laboratories elaborates its own sampling plans which are subsequently distributed to the territorial *Rosselkhoznadzor* offices for sampling.

8. Although the audit team saw in the regions visited that separate plans are operated for domestic, Customs Union and imported production, the 2014 RMP as presented to the Commission services covers combined sampling of imported, Customs Union and domestic production (though the 2013 results are presented separately for domestic, Customs Union and imported products).

9. Although the layout of the 2014 RMP has been modified compared to previous RMPs, the changes do not address all of the recommendations on this aspect made in both the 2009 and 2011 FVO reports. The 2014 RMP still specifies the number of tests (not the number of samples), and includes testing for microbiological parameters, radionuclides, chemical elements with nutritional value, nitrates, nitrites and unpatented drugs. Consequently it makes it impossible to verify if the number of samples meet the criteria laid down in Directive 96/23/EC.

10. Production figures for the preceding year, although provided in the response to the Pre-Audit Questionnaire, are not included in the 2014 RMP. This makes impossible the assessment of whether sampling levels are in line with requirements laid down in Article 5(c) and Annex IV of Directive 96/23/EC as well as in Article 1 and Annex to Decision 97/747/EC.

11. In the RMP provided to the Commission services the scope of testing for wild game is combined with that for farmed game and animal species are not indicated.

12. As observed in the 2009 and 2011 FVO audit reports, the scope of testing is not representative of the range of veterinary medicinal products available on the market. Examples are as follows:

- olaquindox is on the list of medicines imported from Belarus (for pigs) but is not tested for in pigs;
- several registered medicines for use in aquaculture production including the anthelmintics niclosamide and levamisole, and the antibiotics ciprofloxacin and flumequin are not included in the plan for this commodity. In the aquaculture farm visited some of these were in use.
- a number of veterinary medicines registered to treat honey bees containing, inter alia, clotrimazole, rifampicin, nystatin, fumagillin, fluvalinate, amitraz are not tested for in honey;
- trimethoprim, tilmicosin and avermectin are among veterinary medicinal products authorised for use in rabbits but not tested for.

13. In the 2014 RMP all tests are planned to be carried out in biomaterials which comprise: kidneys, spleen, liver, urine, faeces, and eyeball. The matrices are not separately indicated in the plan. The audit team found that in practice, the majority of tests is carried out in muscle tissue which is not always the most appropriate matrix for testing (see also finding 24).

14. The lists of residues tested under different substance groups are not always indicated in the plan. For example "according to registration (free choice)" is written in case of anthelmintics (B2a) in rabbits, wild game and in case of coccidiostats (B2b) sedatives (B2d) and Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) (B2e) in bovine, ovine/caprine, swine and equine. Such practice does not allow the reader to see the actual scope of testing for those substance groups.

15. In the RMP provided to the Commission services, the testing for coccidiostats (B2b), sedatives (B2d) and NSAIDs (B2e) in bovine, ovine/caprine and swine is combined in substance group B2f (other pharmacologically active substances) and similarly, testing for coccidiostats (B2b) and NSAIDs (B2e) in poultry and rabbits. All such testing is assigned to the VGNKI laboratory. In addition the VGNKI laboratory is the only one listed in the plan for testing anthelmintics (B2a) in swine, poultry, rabbits, and for coccidiostats (B2b) in eggs. However, in the plan implementation table checked by the audit team, some other laboratories (e.g. the one visited in Krasnoyarsk) are also involved in those analyses and the VGNKI is solely responsible for testing coccidiostats in feed and NSAIDs in all matrices.

16. Similar to the situation described in the 2011 FVO report, none of the laboratories visited had methods in place for all of the substance groups/matrix combinations for which they were listed in the 2013 and 2014 RMP as presented to the Commission services. In particular, there were no methods for testing thyrostats (A2), sedatives (B2d) and in NSCFAP for anthelmintics (B2a). Methods for testing NSAIDSs are available only in VGNKI and ARRIAH and for dyes (B3e), confirmatory methods are available only in VGNKI, NCSFAP and CSMVL (see findings 27, 71, 79). Therefore there is a discrepancy between the RMP presented to the Commission services and its factual implementation.

17. The plan allows taking samples from processed products. Although Maximum Levels (MLs) for residues in such products are frequently defined in the Russian Federation legislation, the traceability to the farm of origin is of concern (see findings 2, 51).

Conclusions on planning of residue monitoring

18. The planning process has been successfully changed to adapt to the analytical capacity of laboratories but the layout of the plan has not been significantly changed despite recommendations made in the 2009 and 2011 FVO audit reports. Discrepancies have been noted between the version presented to Commission Services and the one distributed for implementation. The plan continues not to take into account the availability of veterinary medicinal products on the market and their possible use in different production sectors.

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

19. The legal basis for the implementation of the RMP remains as described in the 2011 FVO audit report. Furthermore, in the course of addressing the 2011 FVO audit recommendations the following normative instructions have been issued by the *Rosselkhoznadzor* in 2012: No FS-EN-2/1226; No FS-EN-2/11508 and No FS-HB-2/3953.

20. The 2013 RMP and the 2014 RMP had been made available to regions/laboratories on 18 January 2013 and on 31 December 2013, respectively.

21. Samplers participate in obligatory training on sampling rules and techniques which are provided by specialised centres and the CSMVL.

22. Sampling continues to be carried out according to national standards which are not focussed on residues controls. In the case of meat, standards designed to take samples for organoleptic assessment of freshness of meat (e.g. State Standard of the Russian Federation (GOST) No 7269-79) or for commercial purposes are the most frequently used. According to those standards incremental samples should be taken from different carcases in the lot and combine to form a sample representing a batch or consignment. Therefore traceability to a farm level could not be ensured. For example, at the slaughterhouse visited it was not possible to reconcile samples taken with relevant carcases. These practices could hamper the effectiveness of follow-up actions (see finding 51).

23. Despite the efforts made by the competent authorities involved, the Federal Law No 294-FZ of 26 December 2008 was not amended and sampling continues to be pre-announced as described in the 2011 FVO audit report. Therefore the requirements of not giving prior notice as specified in Article 12 of Directive 96/23/EC and to maintain the element of surprise in case of sampling laid down in Article 15 and Annex III to Directive 96/23/EC and in Article 1 and Annex to Decision 98/179/EC are not satisfied.

24. Samplers are now obliged to identify the analyte (group) for which samples are to be tested for. However, several examples were seen in different regions of the same sample required to be tested for multiple analytes belonging to different substance groups (e.g. pig meat

samples taken at the slaughterhouse visited for testing of residues belonging to substance group A1, A3, A4, A5, A6, B1, B2c, B3c and B3d, a sample of frozen beef requested to be analysed for doramectin, salinomycin, tetracycline, chloramphenicol, diethylstilbestrol and ractopamine) which demonstrates that the principles of targeting as required by Article 15 and Annex III to Directive 96/23/EC are neglected. In addition, the matrix is not the most appropriate for the growth promoters.

25. Samples are promptly delivered to laboratories and although turnaround times are not monitored, it was seen that there were no major delays in sample analysis.

26. In laboratories, the scope of testing within the substance group is frequently limited to a single substance within the group/matrix combination. For example, diethylstilbestrol for group A1, clenbuterol for A5, sulphamethazine for sulphonamides (B1) and, ivermectin for B2a. The scope of testing in regional laboratories varies between regions, and, as was the case in 2011, remains narrow (compare findings 71, 79). This is only to certain extent compensated by testing carried out in central laboratories.

27. There are no validated methods for testing thyrostats (A2) and sedatives (B2d) under the RMP. For thyrostats, method development had been initiated in the VGNKI and for sedatives it is included in the VGNKI 6-year development plan (see finding 60). Testing for A2 is neither carried out nor outsourced. For sedatives, a non-validated method was available only in Federal Governmental Veterinary Institute "Federal Centre for Animal Health" (ARRIAH) with 58 samples tested under the 2013 RMP.

28. Although it is stated in the instructions that positively screened samples should be sent for confirmation to the VGNKI, the audit team noted that whilst in 2013 there were 190 non-compliant results reported for group A6 substances, the VGNKI received for confirmation only 31 samples for all substance groups while 13 samples of milk and 47 samples of eggs were found non-compliant for chloramphenicol based on screening tests. This is not in line with Article 6(1) of Decision 2002/657/EC which states that the result of analysis shall be considered non-compliant if the decision limit of the confirmatory method for the analyte is exceeded.

29. Relative to the 2011 FVO audit, an improvement was noted with regard to the number of tests performed in central laboratories (VGNKI and NCSFAP) which receive samples from the whole territory of the Russian Federation and in particular, with the carrying out of testing of dyes in aquaculture products.

30. All records were well maintained and traceable. This observation refers also to laboratories visited.

31. Laboratories are obliged to send monthly reports on the progress of the plan implementation. Non-compliant results are notified to CSMVL within 24 hours.

32. The RMP implementation is centrally supervised (with the exception of follow-up, see finding 41) and some evidence to confirm this was seen. For example, a letter was dispatched to regional *Rosselkhoznadzor* offices requesting, inter alia, to provide amended plans including sampling in small and middle size milk farms as well as milk collection centres and avoid sample clustering by not taking samples from the same enterprises.

Conclusions on implementation of residue monitoring

33. Some positive improvements have been introduced like central supervision of the plan and increased involvement of central laboratories. Nevertheless, the effective implementation of the RMP is still compromised by pre-announcement of sampling visits, taking samples

of processed products, the lack of certain validated methods and the lack of application of targeting criteria for sampling.

5.1.4 Other residues monitoring programmes

Legal Requirements

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

Findings and observations

34. As was described in the 2011 FVO audit report, the administrative regions of the Russian Federation operate separate residue monitoring programmes of various scope.

35. Establishments visited carried out own-check programmes. For example, the slaughterhouse visited had a plan under its Hazard Analysis and Critical Control Points based system to test the production in its own laboratory for chloramphenicol, tetracyclines and certain pesticides once every 15 days and quarterly for heavy metals. The honey collection centre visited had a policy to test every delivered batch for heavy metals and pesticides in an accredited laboratory.

36. Whilst *Rosselkhoznadzor* can have access to the testing results, so far such results have not been used for the planning of the RMP.

Conclusions on other residue monitoring programmes

37. The other residues testing programmes and own-checks, although the results of which are not used for planning of the RMP, nevertheless contribute to ensuring food safety and cumulatively underpin the chemical safety of tested products.

5.1.5 Follow-up of non-compliant results

Legal Requirements

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

Findings and observations

38. The system for the follow-up of non-compliant results has already been described in the 2009 and 2011 FVO reports. Since the last audit in 2011, a new regulation has entered into force which has an impact on follow-up, approved by a Decision of the Customs Union Commission No 834 of 18 October 2011.

39. An order of the Ministry of Agriculture of Russia No 189 of 02 April 2008, requires that non-compliant laboratory results are communicated within 12 hours to CSMVL. CSMVL then summarises the results obtained and transmits the information to *Rosselkhoznadzor*.

40. Since 1 January 2013 a new computerised system, SIRANO (similar to the RASFF system in the EU), has been introduced to allow for the rapid receipt and transmission of information concerning non-compliant results, and the storage of documentation concerning follow-up actions taken.

41. In December 2012 staff at the *Rosselkhoznadzor* territorial administration offices received an official circular from the central level concerning the use of SIRANO and its role in

recording information concerning the follow-up of non-compliant results. Although the audit team was informed that there is no supervision at central level on the timeliness or effectiveness of follow-up actions taken at territorial level (see finding 32), SIRANO provides a useful tool to potentially monitor and verify the follow-up actions taken for any non-compliant case.

42. As was the case in 2009 and 2011, the responsibility for taking follow-up actions for non-compliant results lies with the *Rosselkhoznadzor* territorial administration offices. Federal Law No 294-FZ of 26 December 2008 sets out the frequency of one control visit per three years for the same owner, and specifies that follow-up visits require the prior agreement of the prosecutor's office. Sanctions or penalties may be imposed in line with the code of administrative offences of the Russian Federation.

43. Under the 2013 RMP there were in total 5668 non-compliant results out of which 4356 were for domestic production and 126 for Customs Union production (the other 1186 non-compliant results concerned imports).

44. The audit team examined the follow-up of non-compliant results in two of the regions visited. Documentary and computerised records were available for review.

45. Checked cases included the detection of tetracyclines in cheese, pig meat and beef, as well as nitrofurans in sausages. Relative to the 2011 FVO audit, an improvement was seen in the timeliness of the follow-up actions taken. Non-compliant results were reported and communicated very promptly, and relevant follow-up actions were also instituted promptly.

46. Following the detection of non-compliant results, relevant veterinary authorities and establishments where sampling took place are promptly informed, and are asked to perform relevant follow-up actions and investigations. These follow-up actions can involve sampling of associated production batches over the following three months. Therefore, if there were no cattle from the farm slaughtered during the next three months, no additional follow-up sampling could take place.

47. Where animals originate from one region, but are slaughtered and sampled in another, there is effective communication between the authorities to ensure that relevant follow-up actions, including follow-up sampling, are implemented in the event of a non-compliant result.

48. In the cases seen by the audit team, the follow-up actions taken were, however, generally not effective in identifying the source of the contamination or use of medicine leading to the non-compliant result. Establishments are also informed of the non-compliant result before any follow-up inspections are performed, which means that such inspections are again not unannounced, which is not in line with Article 12 of Directive 96/23/EC.

49. Under Federal Law No 294-FZ, inspectors are limited in their ability to receive permission from prosecutors to visit farms implicated in non-compliant results. For example, in one case concerning the detection of tetracyclines in cheese, the inspectors could visit the dairy plant where the sample was taken but did not have permission to visit the two farms stated as having delivered the milk used to produce the cheese. These farmers simply submitted letters stating that they had not used tetracyclines during the relevant period. Such limited follow-up actions are not in line with Articles 16-18 and 22-27 of Directive 96/23/EC which require that, inter alia, investigations be carried out on the farm of origin or departure, as appropriate, to determine the reasons for the presence of residues.

50. Although inspectors have the right to perform follow-up inspections at processing establishments and farms where the non-compliant sample was taken, under Federal Law No 294-FZ prosecutors may refuse permission to inspect establishments further back in the

production or supply chain, even if *Rosselkhoznadzor* considers that such inspections are justified.

51. The audit team saw several cases of non-compliant results where processed products rather than raw materials had been sampled under the RMP. In a number of these cases, it was not possible to identify the origin of the raw material, and so, in these cases no more detailed follow-up investigations could be or were performed. Sampling of processed food products is not foreseen by Directive 96/23/EC.

Conclusions on follow-up of non-compliant results

52. The follow-up of non-compliant results is generally well-documented and timely, with the SIRANO computerised system helping to transmit and record relevant information concerning non-compliant results and their follow-up. However, pre-announcing the subsequent follow-up inspections, legal restrictions on the right to enter farms or supplying establishments implicated in non-compliant results, and sampling processed food products rather than animals and primary products of animal origin, all hinder the effectiveness of follow-up actions.

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

53. There are 31 federal governmental laboratories involved in the 2014 RMP comprising the VGNKI, the CSMVL, the ARRIAH, the NCSFAP, the Central Industrial Research Veterinary Laboratory in Barnaul, eight reference centres (in Chita, Krasnoyarsk, Nizny Novogorod, Omsk, Orel, Orenburg, Rostow and Samara) and 18 *interoblast (*inter-regional) veterinary laboratories.

54. Significant progress has been made with regard to international accreditation according to the International Organisation for Standardisation (ISO) standard 17025. At the time of the audit 17 laboratories involved in the RMP operated quality management systems accredited to ISO 17025 either by the Moscow based Association of Analytical Centres *Analitica* or other European accreditation bodies.

55. As indicated in the 2011 FVO audit report, both the VGNKI and CSMVL perform some of the duties of National Reference Laboratories as listed in Article 14 of Directive 96/23/EC. In 2012-2013 the CSMVL organised inter-laboratory comparisons for chemical elements in water solutions, mercury in milk powder and for different mycotoxins in feed. The VGNKI regularly organises proficiency tests for tetracyclines in milk and in 2013 for nitrofurans in poultry meat in which 28 laboratories participated. In December 2013 the VGNKI was granted the status of proficiency test provider by the Federal Agency for Technical Regulation and Metrology.

56. The audit team visited five laboratories: the VGNKI, the laboratory of NSCFAP, both in Moscow, the reference centre Krasnoyarsk and two *interoblast* laboratories in Krasnodar and in Bryansk.

57. Samples were anonymous to the laboratory personnel and were handled largely in line with the requirements.

58. With the exception of VGNKI the scope of testing for antibacterial substances (B1) is limited to the tetracycline group and some microbiological growth inhibition tests. For screening of tetracyclines, a number of laboratories use a commercially available Enzyme-Linked Immuno-Sorbent Assay (ELISA) testing kit which is not sensitive for several other tetracyclines (some of which are available on the Russian market for use in food producing animals) including rolitetracycline, demeklocycline, oxytetracycline, minocycline and doxycycline. The consequence is that, for example, with respect to oxytetracycline, the screening test would not detect residues at the Russian 'Maximum Residue Limit' (MRL) of 10 µg/kg.

5.2.2 All Russian State Centre for Quality and Standardisation of Veterinary Drugs and Feed (VGNKI)

59. In addition to organising proficiency tests, VGNKI has responsibility for developing and validating screening and confirmatory methods for the control of veterinary medicines residues and contaminants in food of animal origin, for carrying out routine testing and performing confirmatory analyses. The laboratory has developed confirmatory methods for β-agonists (including ractopamine and zilpaterol), stilbene derivatives, steroids, resorcylic acid lactones, aminoglycosides, quinoxaline metabolites, avermectins, NSAIDs and dyes.

60. For thyrostats, the laboratory has optimised technical parameters for chromatographic analysis and prepared a draft method description. There is a plan to carry out metrological attestation of method for testing thyrostats in feed, animal body fluids, organs and tissues by High Performance Liquid Chromatography-(Tandem) Mass Spectrometry (HPLC-MS/MS).

61. Method validation follows a dedicated Standard Operating Procedure (SOP) and dedicated software is used for calculation method performance parameters which includes, inter alia, recovery, uncertainty and decision limit (CCα) and detection capability (CCβ) which has been demonstrated for fluroquinolones in poultry meat.

62. The laboratory regularly participates in international proficiency tests both by commercial providers (12 rounds in 2014 for residues of veterinary medicines and contaminants) and by EU reference laboratories for chlortetracycline, monensin, flumequine and heavy metals, with satisfactory results. Reports for anthelmintics and coccidiostats are under preparation.

5.2.3 Laboratory of the National Centre for Safety of Fishery and Aquaculture Products (NCSFAS)

63. The laboratory has in place ELISA screening methods for testing chloramphenicol, nitrofuran metabolites (A6), tetracyclines, sulphamethazine (B1), malachite green (B3e) and confirmatory methods for chloramphenicol, tetracyclines, organochlorines (B3a), organophosphorus compounds (B3b), heavy metals (B3c) and malachite green. In addition to fish and aquaculture samples the laboratory carries out testing of meat and milk samples.

64. Since 2013 the laboratory has been accredited to ISO 17025 by *Analitica.* ELISA methods for chloramphenicol, tetracyclines, nitrofuran metabolites and malachite green as well as confirmatory methods for chloramphenicol, tetracyclines, hexachlorocyclohexane (HCH)

and dichlorodiphenyltrichloroethane (DDT) and Atomic Absorption Spectroscopy (AAS) methods for heavy metals are within the scope of accreditation.

65. During the last two years the staff have received training in various EU laboratories and relative to 2011 FVO audit report progress was noted with regard to method validation and quality control.

66. A commercially available ELISA method for malachite green was validated in line with the Community Reference Laboratories Residues Guidelines of 2010. Calibrations are carried out with every assay series and control samples spiked at Minimum Required Performance Limit (MRPL) are included at the beginning of each analytical run.

67. The HPLC-MS method for malachite green and leucomalachite green was validated just before the time of the audit at three concentration levels and to the standard equivalent to the requirements of Decision 2002/657/EC.

68. A standard, six-point calibration curve covering a concentration range of 0.2 – 4.0 µg/kg and control samples spiked at the MRPL level are run for every assay series. Control charts have been initiated.

69. The confirmatory method for chloramphenicol was validated at 0.3, 0.45 and 0.6 µg/kg. Although the accredited concentration range of 0.01-10.0 mg/kg is much above the MRPL, control samples at the MRPL level are included in each analytical run and there are control charts maintained.

70. Since 2012 the laboratory has participated in proficiency tests for chloramphenicol, malachite green, heavy metals, DDT, HCH by commercial providers and in interlaboratory comparisons organised by VGNKI and CSMVL. All results were satisfactory.

5.2.4 Krasnoyarsk Reference Centre

71. The laboratory has in place ELISA screening methods for diethylstilbestrol (A1), 17β estradiol, 19-nortestosterone, testosterone (A3), zeranol (A4), ractopamine (A5), chloramphenicol, marker residues of furazolidone (AOZ) and furalatadone, (AMOZ) (A6), tetracyclines, penicillin G (B1), salinomycin, monensin, maduramycin (B2b) and mycotoxins (B3d). Instrumental methods are available for ivermenctin (B2a), pesticides and contaminants. Only the methods for mycotoxins and heavy metals are validated but all of the other unvalidated methods are being used for the RMP (see finding 16).

72. Three weeks before the FVO audit the laboratory had received an accreditation audit of The Danish Safety Technology Authority (DANAK) for contaminants in feed which identified, inter alia, five nonconformities relevant for the scope of the FVO audit. The corrective action plan was available.

73. A High Performance Liquid Chromatography with Diode Array Detection (HPLC-DAD) method for ivermectin, an ELISA method for tetracyclines and an AAS method for cadmium were checked by the audit team.

74. For ivermectin a method SOP was in place. No quality control samples were included in analytical runs to verify the quality of results. The audit team noted a significant difference between the retention time value certified for the ivermectin standard and that obtained by the laboratory. The certificate for the ivermectin standard did not include a chromatogram which would allow the purity and retention time of the certified substance to be assessed. The laboratory staff were not aware of the importance of retention time for substance identification.

75. For tetracyclines screening by ELISA a method SOP was available and calibration was run with every assay series but no positive controls were included. The laboratory staff stated that there were no non-compliant results so far. Results for tetracyclines are reported as below the quantification levels indicated in the leaflet of the kit producer.

76. For testing antimicrobials in milk a screening test in line with Methodical Instructions is in use. However, its performance was verified in house only for penicillin G and the verification was limited to parallel testing of negative and positive samples by two operators.

77. For cadmium the method was validated for milk powder, meat and cereal samples at three concentration levels and was found to be comprehensive.

78. The laboratory had successfully participated in inter-laboratory comparisons for mycotoxins and heavy metals organised by the CSMVL and for mycotoxins in feed by a commercial provider. There was no participation in proficiency tests for residues of veterinary medicines.

5.2.5 Krasnodar Interoblast Veterinary Laboratory

79. For the RMP the laboratory uses commercially available ELISA screening methods to test for diethylstilbestrol (A1), trenbolone, nortestosterone (A3), zeranol (A4) clenbuterol (A5) chloramphenicol, AOZ, AMOZ (A6), tetracycline, sulphamethazine (B1), mycotoxins (B3d) and instrumental methods for pyrethroids and carbamates (B2c), pesticides (B3a, B3b) and heavy metals (B3c). Only the methods for chloramphenicol, cadmium and mercury were validated.

80. In addition, a commercially available microbial growth inhibition test is in use for screening antibacterial substances in milk and there are other microbiological screening methods for penicillin G in meat (sensitivity 0.5 units/g/ml) and tetracycline in eggs (sensitivity 0.01 units/ml).

81. There were no confirmatory methods in place to test for residues of veterinary medicinal products. The audit team was informed that a Liquid Chromatography-(Tandem) Mass Spectrometry instrument had been purchased recently and should become operational in the last quarter of 2014.

82. The laboratory has been accredited to ISO 17025 by *Deutsche Akkreditierrungstelle* (DAkkS) since 2012 with methods for mercury in food products and lead and cadmium in feed included in the accreditation scope.

83. The laboratory receives samples from Krasnodarski Kray and several other regions. There was a sample reception instruction in place and this was adhered to.

84. The ELISA method for chloramphenicol and an Inductively Coupled Plasma-Atomic Emission Spectroscopy (ICP-OES) method for cadmium were checked by the audit team.

85. For the chloramphenicol method, a validation experiment (2012) comprised five samples of the following matrices: muscle, milk and honey spiked at three concentration levels comprising the MRPL, and measured during four consecutive days. Precision and repeatability indicators had been assessed but not recovery although data were available. Detection and quantification limits had not been calculated nor had the cut-off level. Nor were positive and negative control samples run in every assay series (see finding 88). Screening negative results are reported as below the detection limit indicated by the kit provider.

86. The validation of the cadmium method was successfully performed by spiking six samples (no blanks measured) of different matrices (milk, cheese, fish, meat, feed) at their respective MLs. Method performance parameters including recovery, precision, repeatability and uncertainty had been assessed for each matrix. The Limit of Quantification was not calculated, as required in Regulation (EC) No 333/2007, but the lowest calibration concentration of 0.01 mg/kg (used to present negative test results) proves that the method meets the sensitivity requirements of the same Regulation. As quality control samples are not included in analytical runs, the quality of the results cannot be ensured.

87. There was only one Certified Reference Material (CRM) available, for cadmium in feed.

88. An SOP for quality control was approved in May 2014. However, it was implemented only for mercury in feed. Quality control samples are also included in analyses carried out by microbiological methods.

89. The laboratory participated in a proficiency test for heavy metals in liver from a commercial provider and in inter-laboratory comparisons organised by CSMVL and VGNKI with satisfactory results.

5.2.6 Briansk Interoblast Veterinary Laboratory

90. The laboratory has in place ELISA screening methods for compounds in groups A1, A3, A4, A5, A6 (only chloramphenicol), B3d, thin layer chromatography screening methods for B2a (ivermectin), B2c, B3a, B3b and confirmatory methods for clenbuterol and ractopamine (A5), nitrofuran metabolites (A6), tetracyclines (B1), ivermectin (B2a), B2b, B2c, B3a, B3b, and B3c. A commercially available microbial growth inhibition test is in use for screening antibacterial substances in milk and there is a microbiological method for penicillin G in milk (sensitivity 0.01 units/g).

91. Since June 2013 the laboratory has been accredited to ISO 17025 by DAkkS. The method for tetracyclines by HPLC-MS/MS and for heavy metals by AAS are within the scope of accreditation.

92. The confirmatory methods for tetracyclines, nitrofuran metabolites, clenbuterol, ractopamine and heavy metals as well as the screening methods for diethylstilbestrol, trenbolone, chloramphenicol, zeranol, and mycotoxins (B1, M1) are validated to the standard equivalent to the requirements of Decision 2002/657/EC.

93. The methods for nitrofuran metabolites and for clenbuterol and ractopamine by HPLC-MS/MS and the screening method for diethylstilbestrol in muscle were checked by the audit team.

94. Internal deuterated standards are in use and six-point matrix-matched calibration curves for nitrofuran metabolites, clenbuterol and ractopamine are run in every assay series.

95. Validation reports for these methods were available (both from 2014), and were found to be comprehensive and equivalent to requirements laid down in Decision 2002/657/EC. However, the formulae used for CCα and CCβ calculations were not in line with the requirements laid down in Decision 2002/657/EC resulting in the under-estimation of the CC values.

96. A screening ELISA method for diethylstilbestrol in muscle was very recently validated for concentration 0.1 µg/kg and detection capability (CCβ) was calculated and implemented. In June 2014, the laboratory started to include in analytical runs control samples spiked at 0.2 µg/kg.

97. An SOP for quality control of the tetracyclines and nitrofuran metabolites by HPLC-MS/MS methods was in place. It requires the internal standard(s) recovery to be checked for every assay series. If the recovery is out of the range 40-130%, the analysis needs to be repeated.

98. Control charts are maintained for assessment of accuracy and recovery stability at 0.2 µg/kg. However, since the upper and lower limits are recalculated after each run, the chart is not suitable for demonstrating the method performance over time.

99. The laboratory has participated in a number of proficiency tests and interlaboratory comparisons for residues of veterinary medicinal products (chloramphenicol, nitrofurans, tetracyclines, coccidiostats, mycotoxins) and heavy metals by commercial providers, VGNKI, CSMVL and European Union Reference Laboratory with largely satisfactory results.

Conclusions on laboratories

100. Important progress have been observed, compared to the 2011 FVO audit report, with regard to the accreditation of laboratories to ISO 17025 and method validation. However, the scope of testing in individual laboratories continues to be limited with regard to substance groups covered and is frequently limited to one substance per group. Notwithstanding the largely satisfactory participation of laboratories in proficiency tests, the continued use of unvalidated or inadequately validated analytical methods and the lack of quality controls in some laboratories undermine confidence in the quality of analytical results.

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

101. The system for the authorisation, distribution and use of veterinary medicines has already been described in the 2009 and 2011 reports. *Rosselkhoznadzor* is responsible for the registration and circulation of veterinary medicinal products and maintenance of the State register of medicines. The legal basis for these responsibilities is the Federal Law 61-FZ of 12 April 2010.

102. The *Rosselkhoznadzor* website lists, in a publicly accessible database, details of all veterinary medicines registered in the Russian Federation. Veterinary medicines registered in other Customs Union countries (Belarus and Kazakhstan) can circulate freely in the Russian Federation. Lists of these veterinary medicines are also published on the internet.

103. Veterinary medicines which are not authorised in the Russian Federation, but which are authorised in other Customs Union countries, may enter from those countries and could potentially be used in animals or products in the Russian Federation which are eligible for export to the EU. The audit team was informed by *Rosselkhoznadzor* that some feed additives containing antibiotics from those Customs Union countries, which are not

authorised in the Russian Federation, have recently been detected on the Russian market and impounded.

104. Federal Act No 88-FZ of 12 June 2008 lays down MRLs for chloramphenicol, tetracyclines, streptomycin and penicillin in milk and are mostly expressed in units/g which are not easily comparable with MRLs in EU legislation.

105. The MRLs for antibiotics, coccidiostats and antiprotozoal agents which are laid down in Customs Union Decision No 299 of 28 May 2010 are broadly in line with the MRLs and MRPLs applicable in the EU. Updated requirements for nitrofurans, nitroimidazoles (not allowed above the limit of quantification of analytical methods), and MRLs for rifampicin, rifamixin and flavomycin had entered into force on 1 January 2012. The audit team was not informed of any case where the withdrawal period of an already registered veterinary medicine had been amended to take account of a subsequent change in the MRL.

106. Since the last audit, a new concept of establishing Customs Union technical regulations (TR) for different sectors of food production and processing was initiated by Customs Union framework decision No 880 of 09 December 2011 (TP TC 021/2011) on the safety of food production where in Annex 3, MLs for contaminants and certain pesticides are listed.

107. In October 2013 two TRs - No 67 (TS 033/2013, milk and dairy products) and No 68 (TS 034/2013 covering meat and meat products except poultry meat) were approved by the Customs Union Commission. Annex 5 to TR No 68 lists MRLs for a range of antibiotics (except tetracyclines and bacitracin), antiprotozoal agents and amitraz. The requirements laid down in Annex 4 to TR No 67 are limited to chloramphenicol (not allowed above 0.3 µg/kg, entering into force on 01.07.2015), tetracyclines, streptomycin and penicillin. For farmed fish a specific Customs Union TR has not yet been issued, and so the Decision of the Commission of the Customs Union No 299 of 28 May 2010 continues to apply.

108. A recommendation of the Chief Veterinary Inspector of the Russian Federation No 13-7-I/900 of 4 October 1999 prohibits the use of stilbenes, thyrostats and steroids (but not beta-agonists) for growth promotion purposes. Beta-agonists are not registered in the Russian Federation as feed additives or veterinary medicines.

109. In contrast to the situation in the EU, chloramphenicol, nitroimidazoles and nitrofurans which are prohibited for use in food producing animals as laid down in Table 2 of the Annex to Regulation (EU) No 37/2010, can be used in the Russian Federation. Examples of such use were seen in the honey procesing plant, the feed mill visited (see findings 110, 112) and on the dairy farm visited where the list of medicinal products being used included medicines containing levomycetin (chloramphenicol) and furazolidone. Also a list of currently authorised veterinary medicines for rabbits (including farmed rabbits for food production) provided to the audit team, included a product containing levomycetin and furacilin (nitrofurazone) which was stated as having an indefinite registration in the Russian Federation.

110. The honey processing plant visited by the audit team held copies of detailed treatment records from farmers supplying honey to the plant. These showed that various medicines containing metronidazole and oxytetracycline were used to treat the bees, while the *Rosselkhoznadzor* website also showed that products containing rifampicin are also registered to be used in bees. Such antibiotics are not authorised to be used in honey bees in the EU.

111. The audit team was informed that in October 2013, an expert group of the Eurasian Economic Commission of the Customs Union of Russia, Belarus and Kazakhstan (EEC CU) met and issued an opinion that the use of various substances should be directly prohibited in

food-producing animals, namely chloramphenicol, nitrofurans, nitroimidazoles, malachite green, crystal violet, carbadox, olaquindox, stilbenes, thyrostats, steroids, beta-agonists and resorcylic acid lactones. The audit team was informed that in March 2014 the Consultative Committee of the EEC CU accepted the expert group's recommendation and that the prohibition of these substances should enter into force following a formal procedure.

112. In the feed mill visited, producing feed for pigs and poultry, the audit team saw that veterinary medicines containing dimetridazole, metronidazole, furazolidone, oxytetracycline and flavomycin were incorporated in feed based on a prescription from the farmer's veterinarian for the purposes of prophylaxis/therapy.

113. The feed mill visited had its own procedures in place to ensure the homogeneity of feed produced, and to avoid cross-contamination between feed containing medicines and feed without. The audit team was informed that, similar to 2011, there are still no national rules in place to minimise cross-contamination in the production and distribution of medicated feedingstuffs, but that the preparation of such rules is under consideration.

114. A number of products containing dyes (malachite green and methylene blue) are registered as veterinary medicines in the Russian Federation, but the accompanying instructions state that they should not be used in fish used for food production. The fish farm visited routinely used dyes such as crystal violet for prophylactic purposes, based in part on a recommended list of veterinary medicines and dyes to be used on fish farms for the treatment or prevention of various diseases received from a dedicated and specialised advisory centre.

115. In recent years VGNKI has detected numerous non-compliant results for dyes (including brilliant green and crystal violet) in domestic aquaculture production. In 2014 to date, 14 of 75 samples were non-compliant (18.6 %); in 2013, 3 of 21 samples (23.1 %); and in 2012, 2 of 18 samples (11.1 %).

116. At the aquaculture farm visited, the veterinarian in charge used a reference set of instructions on treating fish diseases issued in 1998 in which medicines containing, inter alia, furazolidone, chloramphenicol, tetracycline and bacitracin were recommended for treating fish diseases. In addition, the farm's annual plan for veterinary-sanitary and prophylaxis/treatments includes, inter alia, the prophylactic application of dyes and disinfection with 2-3% formaldehyde. The farm had used levomycetin (chloramphenicol) in 2013.

117. Detailed records of treatments with veterinary medicines were present on the fish, poultry and dairy farms visited. Copies of treatment records were also available in the honey processing plant for supplying farmers.

Conclusions on authorisation, distribution and use of veterinary medicinal products

118. Since the last FVO audit, the Russian Federation has made further progress in introducing and progressively aligning residue limits with those applicable in the EU. However, there is no evidence that withdrawal periods of authorised veterinary medicinal products have been amended to ensure that any revised MRLs can be complied with. Various veterinary medicines and dyes which are not permitted or authorised to be used in the EU are used in the Russian Federation in animals or products which could be potentially exported to the EU, thus presenting the risk of residues of such substances being present in food of animal origin exported to the EU.

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

119. The system for official controls on the distribution and use of veterinary medicinal products has already been described in the 2011 report. Some additional orders have been introduced since the last audit in 2011, including the order of the Ministry of Agriculture of Russia No 149 of 26 March 2013 and the order of the Ministry of Agriculture of Russia No 357 of 10 October 2011.

120. Federal Law No 294-FZ of 26 December 2008 remains in force and dictates that premises such as veterinary medicinal product wholesalers and retailers, feed mills and farms can be subject to a scheduled inspection no more frequently than once every three years. Unplanned inspections can be performed if a specific complaint is received, or in case of emergency, or if a governmental instruction is received from *Rosselkhoznadzor*.

121. Each year a list of enterprises planned to be inspected is submitted by the territorial *Rosselkhoznadzor* offices to the prosecutor's office. Once approved, the list of enterprises to be inspected is published, and enterprises also receive at least three days' advance notice of planned inspections.

122. The audit team was informed that the Federation Council of the Federal Assembly of the Russian Federation, at its meeting of 24 June 2013, made a recommendation to improve the system of food safety controls by changing Federal Law No 294-FZ to introduce an element of surprise and unannounced visits during state control inspections.

123. Controls on the distribution of veterinary medicinal products are performed by *Rosselkhoznadzor* territorial administrations and inter-district offices, under the provisions of Federal Law No 61-FZ of 12 April 2010.

124. The audit team saw that controls on the distribution and use of veterinary medicines are carried out regularly, usually at a frequency of not more than once every three years. In the cases seen by the audit team, any non-compliances detected, for example on farms or in veterinary medicine retailers (e.g. concerning storage or labelling of products), were followed up in a timely and effective manner, and, in some cases, financial penalties were applied.

125. The feed mill visited by the audit team had been in operation for approximately one year, and so had not yet been inspected. It was confirmed that if the company changed its name or legal status within this initial three year period of operations, inspectors could have to wait for a further three years before they could perform an inspection. The feed mill had received a certificate of conformity from the Federal Agency on Technical Regulating and Metrology to produce certain specific feeds, according to the relevant GOST standard, and did not need any additional official registration to enable it to add medicines to such feed.

126. Since December 2011, such licences are now valid for an indefinite period rather than for five years. Under Federal Law No 99 of 4 May 2011, once licensed, retailers of veterinary medicines may be inspected within one or one and a half years, and then every three years from when the first inspection took place. Such inspection requests also need to be approved by the prosecutor's office. In one of the regions visited, the audit team was informed that the prosecutor approves approximately 40% of such requests for inspections, and, in the case of

those not approved, another application to the prosecutor is submitted the following year to inspect the premises.

127. Detailed records were available in the veterinary medicinal product wholesaler and retailer visited. A small number of products (both of Russian Federation and Customs Union origin) were identified (containing metronidazole, furazolidone and oxytetracycline) which had no authorisation numbers indicated on the product label or leaflet, although this is a requirement of the Russian Federation. A number of products originating from other Customs Union countries (Belarus and Kazakhstan) were on display at the retailer and in the wholesaler visited.

128. Products were also identified in the retailer and feed mill which were not included in the *Rosselkhoznadzor* database of authorised veterinary medicines. It was explained that this was because the marketing authorisations were currently being renewed and the medicines could still be sold and used while these renewal processes were underway.

129. Certificates accompanying animals to slaughter detail any recent vaccinations and anti-parasite treatments. In comparison to food chain information requirements in the EU, a specific statement as to whether any other veterinary medicines have been recently used, or whether all relevant withdrawal periods have been observed, is not required as under the Veterinary Rules of 27 December 1983, animals under the withdrawal time cannot be sent for slaughter.

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

130. The system in place for official controls on the distribution and use of veterinary medicinal products is weakened by the need to pre-announce inspections and the fact that inspections cannot take place without the specific permission of prosecutors.

5.4 Follow-up of relevant recommendations made in previous FVO report on residues (DG (SANCO) 2011-8905 MR Final)

N	Recommendation	Findings
1	In accordance with the provisions of Article 29 of Directive 96/23/EC, ensure that the national residue monitoring plan presented to the Commission services is laid out in such a way that it includes only monitoring for residues and contaminants, is based solely on domestic production, clearly specifying the matrices tested for each species, the particular analytes tested for, their analytical limits of detection and the laboratories to be used (which should have suitable analytical methods in place).	Although the layout of the RMP has been modified, the changes do not address all of the requirements listed in the recommendation. See findings 8, 9, 11, 13, 14, 15, 16. See recommendation 1 of the current audit report.

2	Ensure that the scope of testing in the residue monitoring plan takes into account risk factors including laboratory analytical capacity and capability and the likely use of veterinary medicinal products in the various animal production sectors, in order to increase the overall effectiveness of the plan and provide guarantees with an effect equivalent to those described in Article 7 of Directive 96/23/EC.	Laboratory analytical capacity and capability is partially taken into account. However, the scope of testing continues to be not representative of the availability of veterinary medicinal products on the market. See finding 12 See recommendation 2 of the current audit report.
3	In accordance with Council Directive 96/23/EC (upon which the national residue monitoring plan is based), ensure that the substance groups, tested compounds and numbers of samples are specified in the regional plans and that samplers are aware of the identity of the analyte (group) for which samples are to be tested in order to fulfil the targeting criteria laid down in Annex III to Directive 96/23/EC and in Commission Decision 98/179/EC.	Addressed
4	Ensure that samples for the national residue monitoring plan are (a) taken without prior notification and (b) that sampling is spread over the whole calendar year in order to provide guarantees with an effect equivalent to that described in Article 12 of Directive 96/23/EC and in the Annex to Commission Decision 98/179/EC.	Although the sampling is now spread over the whole calendar year, the recommendation was not addressed as all RMP sampling is pre-announced. See finding 23. See recommendation 3 of the current audit report.
5	Ensure that testing of all substance groups is carried out on samples drawn from throughout the national territory in order to provide guarantees with an effect equivalent to those detailed in Annex IV to Directive 96/23/EC.	Addressed
6	Take measures which will ensure effective central co-ordination of implementation of the residue monitoring plan in order to have an effect equivalent to that foreseen by Article 4 (b) and (c) of Directive 96/23/EC.	Addressed
7	Ensure that all screening positive results are subject to chemical confirmation to unambiguously identify and quantify the residue in question in order to have an effect equivalent to that required by Article 6 of Commission Decision 2002/657/EC.	As instructions to send all positively screened samples to the VGNKI were not followed, the recommendation was only partially addressed. See finding 28. See recommendation 4 of the current audit report.

8	Ensure that when non-compliant results are obtained, timely, unannounced and effective follow-up investigations are performed which have an effect at least equivalent to that described in Articles 16-18 and 22-27 of Directive 96/23/EC.	The follow-up of non-complaint results is timely but not unannounced or generally effective. See findings 48, 49, 50. See recommendation 5 of the current audit report.
9	Ensure that all of the analytical methods used for the residue monitoring plan are validated to a standard equivalent to that required by Article 3 of Commission Decision 2002/657/EC (residues of veterinary medicines), Commission Regulation (EC) No 333/2007 (chemical elements) and Commission Regulation (EC) No 401/2006 (mycotoxins).	The vast majority of methods are in place. However, some methods used for testing residues of veterinary medicinal products are not validated. Thus the recommendation has only been partly addressed. See findings 16, 27, 71, 79 and 85. See recommendation 6 of the current audit report.
10	Ensure that residue testing laboratories put in place quality control procedures for monitoring the reliable performance of all residue testing in order to provide guarantees with an effect equivalent to that foreseen by Articles 3(c) and 5 of Commission Decision 2002/657/EC.	Although significant progress has been achieved with the majority of laboratories having international accreditation, there were methods examined by the audit team where there was no evidence of quality control procedures being introduced. See findings 74, 75, 85, 86, 98. See recommendation 7 of the current audit report.
11	Ensure that recommended withdrawal periods for veterinary medicinal products authorised to be used in the Russian Federation are, in respect of those products of animal origin eligible to be exported to the EU, sufficiently long to ensure that maximum residue limits listed in Regulation (EU) No 37/2010, or, where applicable, EU minimum required performance limits established pursuant to Commission Decision 2002/657/EC, are not exceeded. For those pharmacologically active substances for which EU limits have not been established, withdrawal periods should be sufficiently long to ensure that that no detectable levels of residues are present in food of animal origin exported to the EU.	Since the last FVO audit, the Russian Federation has made further progress in introducing and progressively aligning residue limits with those applicable in the EU. However, there is no evidence that withdrawal periods of authorised veterinary medicinal products have yet been amended to ensure that any revised MRLs can be complied with. See finding 105. See recommendation 8 of the current audit report.

6 Overall Conclusions

The current system for the control of residues in food of animal origin and the authorisation, distribution and use of veterinary medicinal products still presents significant shortcomings and in general cannot be considered to offer guarantees of full equivalence to EU rules.

Notwithstanding improvements made in the elaboration of the residue monitoring plan, the fact that the overall layout of the plan remains unchanged, makes it difficult to judge if it is in line with EU requirements. Furthermore, as in 2011, the effectiveness of residue controls continue to be compromised by a number of factors. These include the limited scope of testing compared to the availability and potential use of a range of pharmacologically active substances in food animal production, the pre-announcement of visits to food business operators, the taking of samples from processed products and the lack of application of targeting criteria for sampling. However, there has been an improvement in the general timeliness of the follow-up actions taken, and the development and application of a new information technology tool for this purpose.

In relation to the performance of the residue testing laboratories, progress has been seen with the international accreditation of laboratories (although the number of methods within the scope of accreditation is limited) and method validation. In spite of this it remains the case that there are no methods in place for certain substance groups and non-validated analytical methods are still being used. Allied with the fact that quality controls on method performance are not routinely implemented in some laboratories, these issues collectively undermine the effectiveness of residue controls in the Russian Federation.

Concerning veterinary medicinal products, progress has been made in gradually aligning residue limits with EU ones although the approach taken to the licensing of veterinary medicinal products continues to differ with that in the EU, with no link being made between the revised limits and corresponding product/formulation-specific drug withdrawal periods. Improvements have also been seen in the implementation of controls on the distribution and use of veterinary medicinal products, although the influx and free distribution on the market of certain veterinary medicinal products registered in other Customs Union countries increases the probability of the occurrence of residues of substances which are not authorised in the EU.

7 Closing Meeting

A closing meeting was held on 27 June 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 with the main findings and preliminary conclusions and stated that they would take further actions necessary to improve the current system. In particular, the audit team was informed that a draft "Action Plan aimed at ensuring the effective functioning of the agricultural sector in the World Trade Organisation" of the Ministry of Agriculture of the Russian Federation of 26 June 2014, for approval by the Deputy Prime Minister of the Russian Federation, includes the preparation of proposals for changes to Federal Law No 294-FZ, to allow for a more effective federal program of monitoring food safety and conducting official veterinary controls. This proposal has a target deadline of March 2015 for completion.

The authorities provided also some additional documents requested during the course of the audit. EU requirements with regard to a split system for residues control in those species for which the Russian Federation is not currently listed for were discussed.

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.	In accordance with the provisions of Article 29 of Directive 96/23/EC, to ensure that the national residue monitoring plan presented to the Commission services includes only monitoring for residues and contaminants in unprocessed products, is based solely on domestic production, clearly specifying the matrices tested for each species, analytical limits of detection and the laboratories to be used (which should have suitable analytical methods in place). Conclusions upon which this recommendation is made: 18, 33. Associated findings and observations: 8, 9, 10, 11, 13, 14, 15, 16, 17, 51.
2.	To ensure that the scope of testing carried out under the residue monitoring plan includes all relevant substances in line with the range of veterinary medicinal products on the market, as laid down in Article 7 of Directive 96/23/EC. Conclusions upon which this recommendation is made: 18. Associated findings and observations: 12.
3.	To ensure that sampling is carried out without prior notice in order to provide guarantees with an effect equivalent to that required by Article 12 of Directive 96/23/EC. Conclusions upon which this recommendation is made: 33. Associated findings and observations: 23.
4.	To ensure that the screening of positive results is subject to chemical confirmation to unambiguously identify and quantify the residue in question in order to have an effect equivalent to that required by Article 15.2 of Directive 96/23/EC. Conclusions upon which this recommendation is made: 33.Associated findings and observations: 28.
5.	To ensure that when non-compliant results are obtained, unannounced and effective follow-up investigations are performed which have an effect at least equivalent to that provided for by Articles 16-18 and 22-27 of Directive 96/23/EC. Conclusions upon which this recommendation is made: 52.Associated findings and observations: 48, 49, 50.
6.	To ensure that all analytical methods used for the residue monitoring plan are validated to a standard equivalent to Article 3 of Decision 2002/657/EC and are demonstrably fit for purpose, as laid down in part 2 of Annex I to and Article 4 of this Decision. Conclusions upon which this recommendation is made: 33, 100. Associated findings and observations: 16, 27, 71, 79, 85.
7.	To ensure that appropriate quality control procedures are carried out in the laboratory network in line with Article 5 of Decision 2002/657/EC. Conclusions upon which this

N°.	Recommendation
	recommendation is made: 100.Associated findings and observations: 74, 75, 85, 86, 98.
8.	To ensure measures to guarantee that animals and products derived thereof, eligible for export to the EU, contain no detectable residues of substances which are either prohibited in the EU or for which no EU MRL exists, as set out in Tables 2 and 1, respectively, of the Annex to Regulation (EU) No 37/2010.Conclusions upon which this recommendation is made: 118. Associated findings and observations: 103, 105, 109, 114.

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=2014-7031

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
Horse identification (passport)		
Reg. 504/2008	OJ L 149, 7.6.2008, p. 3-32	Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae
Medicines essential for the treatment of equidae		
Reg. 1950/2006	OJ L 367, 22.12.2006, p. 33-45	Commission Regulation (EC) No 1950/2006 of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae

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.