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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

SPAIN

FROM 22 TO 31 JANUARY 2013

IN ORDER TO EVALUATE THE CONTROL OF RESIDUES AND CONTAMINANTS IN LIVE
ANIMALS AND ANIMAL PRODUCTS

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in Spain, carried out from 22 to 31 January 2013, as part of the published programme of FVO audits on the monitoring of residues in live animals and animal products in European Union (EU) Member States and in third countries.

The objective of the audit was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products. The evaluation was based on the standards set out in Council Directive 96/23/EC, and other relevant EU legislation in this field. The audit assessed the performance of the competent authorities and other officially authorised entities involved in residues controls and the legal and administrative measures put in place to give effect to the relevant EU requirements. Attention was also paid to examining the implementation of corrective actions promised in response to relevant recommendations made in the report of a previous FVO residues audit to Spain (DG (SANCO)7781/2008) in March 2008.

It is concluded that comprehensive instructions are in place for planning of the national residue monitoring plan (RMP) and the elaboration of individual Autonomous Community plans are carried out in a timely manner, involving all relevant parties and taking into account relevant data. Nationally, the plan covers all required species and substance group/matrix combinations. With regard to implementation, at national level, the negligible shortfall in samples taken vs planned indicates that supervision of implementation has been effective. However, this masks differences in the performance of individual Autonomous Communities with regards to the Autonomous Community residue monitoring plan (AC-RMP) implementation like the clustering of sampling and sampling not being spread evenly through the year, which undermines the effectiveness of residues controls. With regard to food chain information, it is recognised that improvements have been made relative to the 2008 FVO audit. Nevertheless, its current format could give a false impression of the residues status of slaughtered animals. Furthermore, shortcomings in identification of incomplete/incorrect food chain information undermine confidence in the implementation of controls and, the absence of audits to verify the effectiveness of the implementation of residue controls by the Department of Health in the Autonomous communities visited, may have contributed to the fact that these shortcomings had not been detected. Also no audits to verify the effectiveness of the residue controls tasks carried out by the central competent authority had taken place.

With regard to the identification of equidae, again, improvements have been made relative to the previous FVO residues audit in 2008. Notwithstanding the relatively small number of samples taken nationally, particularly in light of the substantial increase in the number of horses being slaughtered, the regular checks on the use of veterinary medicinal products carried out on horse farms and actions taken where non-compliances were detected, gives some confidence in the residues status of horse meat.

The system in place for the follow-up of non-compliant results is comprehensive and, in general, well co-ordinated and executed. However, in some cases its effectiveness has been undermined by delays in initiating actions, and by actions which have been insufficient to protect consumers from exposure to potentially contaminated product.

The fact that laboratories are now all accredited to ISO 17025 and that methods used for the RMP are to a very large extent validated in accordance with EU rules gives the competent authorities confidence in the reliability of laboratory performance and underpins guarantees on the residues status of food of animal origin. This is also supported by the good progress made regarding the inclusion of methods in the laboratories respective scopes of accreditation and the undertakings to progressively include all methods in the laboratories' scopes of accreditation.

The performance of the NRL is to a large extent in line with the requirements of Article 14 of Council Directive 96/23/EC. However, the overall effectiveness of the laboratory network is weakened by the fact that a few decision limits are substantially greater than the EURL recommended values, an issue which has not been addressed by the NRL as part of its task to co-ordinate the standards and methods of analyses used. Thus the capability to detect the potential abuse of the substances in question is compromised.

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

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

AC-RMP	Autonomous Community-Residue Monitoring Plan
CC α / CC β	Decision Limit / Detection Capability
DG(SANCO)	Health and Consumers Directorate-General
EC	European Community
EU	European Union
EU RL	European Union Reference Laboratory
FVO	Food and Veterinary Office
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC:
ISO	International Organisation for Standardisation
LC-MS/MS	Liquid Chromatography-(Tandem) Mass Spectrometry
ML	Maximum Level
MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
NRL	National Reference Laboratory
RASFF	Rapid Alert System for Food and Feed
RMP	Residue Monitoring Plan
SOP	Standard Operating Procedure

1 INTRODUCTION

The audit took place in Spain from 22 to 31 January 2013. The audit team comprised two auditors from the Food and Veterinary Office (FVO) and one expert from a European Union (EU) country. The audit was undertaken as part of the FVO's planned audit programme, evaluating control systems and operational standards in the residues sector.

Representatives from the central competent authority accompanied the audit team during the whole audit. An opening meeting was held on 22 January 2013 with the central competent authority and other Autonomous Communities responsible for implementing residue monitoring in live animals and animal products. At this meeting, the objectives of, and itinerary for, the audit were confirmed and the control systems were described by the authorities.

2 OBJECTIVES

The objective of the audit was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products. The audit was based on Council Directive 96/23/EC and other relevant EU legislation in this field. The audit focused on the roles of the competent authorities at central and regional levels, the legal and administrative measures in place to give effect to the relevant EU requirements, residue controls and the performance of residue laboratories. Attention was paid to examining the implementation of corrective actions promised in response to relevant recommendations made in the report of a previous FVO residues audit to Spain (DG (SANCO)/7781/2008) in March 2008 which has been published under the cover of a general audit report (DG (SANCO)/8347/2008) on the website of the Directorate-General for Health and Consumers. The table below lists sites visited and meetings held in order to achieve that objective.

MEETINGS/VISITS		n	COMMENTS
COMPETENT AUTHORITIES	Central	2	Opening and closing meeting with the representatives of the Spanish Food Safety and Nutrition agency and the Ministry of Agriculture, Food and Environment as well as the Autonomous Communities Andalucía and Castilla-La Mancha and other Autonomous Communities.
	Regional	2	Meetings with Autonomous Community authorities of Andalucía and Castilla-La Mancha.
	Local	2	Meetings with the municipal competent authority of Seville in Andalucía and the provincial competent authority of Toledo in Castilla-La Mancha.
LABORATORIES		3	National Reference Laboratory for Contaminants and Residues (NRL) in Majadahonda; Animal Production and Health Laboratory in Cordoba in Andalucía; Public health Laboratory in Toledo in Castilla-La Mancha.
FARMS		3	One dairy farm, one pig farm, one horse collection centre.
ESTABLISHMENTS		3	Three slaughterhouses for bovines, equines, ovines and porcines.

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3 LEGAL BASIS

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

- Article 21 of Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products, and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC.
- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

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

4 BACKGROUND

4.1 SUMMARY OF PREVIOUS FVO AUDIT RESULTS

The residues sector was audited by the FVO in 2008 (DG (SANCO)/7781/2008). The report of the audit (henceforth referred to as the 2008 FVO audit) has been published under the cover of a general audit report ([DG \(SANCO\)/8347/2008](#)) on the website of the Directorate-General for Health and Consumers (DG SANCO) here: http://ec.europa.eu/food/fvo/ir_search_en.cfm. The report concluded that there was a robust system of residues controls in place, which was largely in line with EU requirements. However the effectiveness of this system was undermined by significant shortcomings in the laboratory network with regards to limited laboratory accreditation and validation of methods. The system of horse identification and horse passports was audited as part of an audit by the FVO in 2011 ([DG \(SANCO\) 2011/6021](#)). The report found that identification requirements of Regulation (EC) No 504/2008 were mainly fulfilled.

5 FINDINGS AND CONCLUSIONS

5.1 RESIDUE MONITORING

5.1.1 Competent authorities involved

A description of the structure of the competent authorities involved in carrying out controls on residues in live animals and animal products can be found in the Country Profile for Spain which has been published on the website of DG SANCO here: http://ec.europa.eu/food/fvo/country_profiles/CP_spain.pdf

5.1.2 Planning of the residue monitoring plan

Legal Requirements

Article 5 of Council Directive 96/23/EC provides that EU Member States shall submit to the Commission a plan setting out the national measures to be implemented for the detection of residues or substances listed in Annex I to the Directive, and subsequently, Member States shall submit any update of residue monitoring plans previously approved on the basis of the experience of the preceding year or years, by 31 March at the latest of the year of the update.

The following EU legislation has a direct bearing on the elaboration/updating of the residue monitoring plan.

Article 3 of Regulation (EC) No 882/2004 deals with the general obligations with regard to the organisation of official controls. Articles 3 to 7 of Council Directive 96/23/EC deal with the requirements for residue monitoring plans. Commission Decision 97/747/EC lays down levels and frequencies of sampling for residues. Table 1 of the Annex to Commission Regulation (EU) No 37/2010 lays down Maximum Residue Limits (MRLs) for residues of pharmacologically active substances in food. 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 certain contaminants in food. Minimum Required Performance Limits (MRPLs) are defined in Article 4 of Commission Decision 2002/657/EC.

Findings

The audit team visited in addition to central competent authorities, several authorities, laboratories, and establishments in two Autonomous Communities, Castilla-La Mancha and Andalucía.

Royal Decree 1749/1998 amended by Royal Decree 1080/2012, lays down measures to monitor certain substances and residues thereof in live animals and in animal products, transposing the requirements laid down in Council Directive 96/23/EC and in Commission Decision 97/747/EC.

Article 4 of the Royal Decree 1749/1998 establishes a co-ordinating body for the national Residue Monitoring Plan (RMP) - the National Commission for co-ordination of the investigation and control of residues or substances in live animals and their products.

The National Commission is comprised of, amongst others, representatives from the relevant competent authorities from the Autonomous Communities and the central level. It is assisted in its work by the National Reference Laboratories (NRLs).

The National Commission draws up the RMP, which describes who is responsible for planning and implementation, what measures to take in case of non-compliant results and which laboratories are involved in RMP sample analysis. The detailed planning is the full responsibility of the 17 Autonomous Communities. Sample numbers are based on the individual Autonomous Communities' production data. The selection of substances to be tested within each substance group is not decided centrally but by each Autonomous Community as per national rules (Royal Decree 1749/1998), also in light of the information provided at the meetings of the National Commission.

In each Autonomous Community two departments - Public Health and Agriculture - are involved in the planning of the Autonomous Community-RMP (AC-RMP). In some Autonomous Communities, these two departments have designated one joint co-ordinating official who has a seat on the National Commission and is responsible for communication with the central competent authority. In other Autonomous Communities a person comes from each department.

The National Commission aggregates all of the individual AC-RMPs and the test results of the previous years from the 17 Autonomous Communities to get to the national RMP. It further evaluates the sampling figures and the methods used in each Autonomous Community to see if the resulting national RMP is compliant with EU requirements. To co-ordinate this, a report, recommending required changes, is sent to all Autonomous Communities. The National

Commission sends the collated national RMP to the Commission services.

At national level instructions have been created with regard to the responsibilities for planning of the RMP and the basic risk criteria to take into account when planning sampling e.g. at slaughterhouse or on-farm level.

The audit team noted that:

- The planning and co-ordination of the AC-RMPs and at central and National Commission level is carried out in a timely fashion, involving all relevant bodies.
- Neither the National Commission nor the central competent authority has the authority to insist on Autonomous Communities amending their respective AC-RMPs if these are found not to comply with Community requirements. However, the National Commission and the NRLs can and do make suggestions on how the AC-RMPs could be improved. Insofar as they can, the Autonomous Communities do pay attention to the findings of the national Commission and the NRLs in certain cases.
- The national RMP fulfils the requirements of Council Directive 96/23/EC with regard to the number of samples to be taken per commodity/species/matrix, the number of samples taken at slaughterhouses or on farm and the substances to analyse for, even though in the two Autonomous Communities visited not every commodity/species/matrix combination was covered. Thus **recommendation Nos. 1 and 2** of the 2008 FVO audit report have been addressed.
- The AC-RMPs are based on relevant data like slaughter production data and other important data, which allow a risk-based approach for sampling (e.g. non-compliances from previous years, results of other official control programmes, etc.) at Autonomous Community and regional level visited. The audit team saw in Andalucía that in spite of the substantial increase in horse slaughter in 2012 the number of RMP samples did not increase. However, the competent authority of Andalucía informed the audit team that an increase is planned for 2013 (See 5.1.3).

Conclusions on planning of the residue monitoring plan

Comprehensive instructions are in place for planning of the RMP and the elaboration of individual AC-RMPs are carried out by each Autonomous Community in a timely manner, involving all relevant parties and taking into account relevant data. It further covers all required species and substance group/matrix combinations, thus at the national level the RMP fulfils EU requirements.

5.1.3 Implementation of the residue monitoring plan

Legal Requirements

Articles 3, 4 and 12 of Council Directive 96/23/EC deal with aspects pertaining to the implementation of the residue monitoring plan. 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.

General principles governing the co-ordination of activities and ensuring the co-operation between the various competent authorities are laid down in Articles 4(3), 4(4) and 4(5) of Regulation (EC) No 882/2004. Article 3 of this Regulation deals with the general obligations with regard to the organisation of official controls; Article 4(6) requires competent authorities to audit control

activities, ensuring that such audits are carried out in a transparent manner, are subject to independent scrutiny and that appropriate measures are taken in light of their results. Article 8(3) places the obligation on competent authorities to, inter alia, ensure that corrective action is taken when needed.

Commission Decision 97/747/EC lays down levels and frequencies of sampling for residues 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).

The veterinary medicines record-keeping requirements of stock owners are laid down in Article 69 of Directive 2001/82/EC, Article 10 of Council Directive 96/23/EC and Annex I, Part A III, point 8(b) to Regulation (EC) No 852/2004.

The requirements for food chain information accompanying animals submitted for slaughter for human consumption are laid down in Annex II, Section III, point 3(c) to Regulation (EC) No 853/2004. In accordance with Articles 4(4), 5 and Annex I, Section I, chapter IIA, point 1 of Regulation (EC) No 854/2004, food chain information must be checked by the official veterinarian in the slaughterhouse and he/she must verify that animals accepted for slaughter by the food business operator have been properly identified in accordance with Annex I, Section II, Chapter III, point 1 to Regulation (EC) No 854/2004. Section IX of the equine passport as established by Commission Regulation (EC) No 504/2008 is considered as part of the food chain information for equine animals as in this section the horse may be permanently or temporarily excluded from the food chain.

Findings

The national legal basis for the implementation of the RMP is the Royal Decree 1749/1998, amended through Royal Decree 1080/2012. In each Autonomous Community on-farm sampling is generally the responsibility of the Department of Agriculture and sampling of animal products in food business operators is the responsibility of the Department of Health.

The system for official sampling and testing in Spain is covered in Article 13 of Royal Decree 1749/1998. Each official sample is divided into three homogeneous specimens, sealed separately under the same seal number. The first and third specimens are held by the competent authority. The second specimen is held, by the food business operator, if he desires. The first specimen is tested as a routine sample. If the result of the (initial) screening test is non-compliant, the same specimen is subjected to a confirmatory test (this is not required when the initial method is the confirmatory method). The food business operator may send the second specimen for a new test in a laboratory of his choice. If there is a discrepancy between both results, then the competent authority sends the third specimen to the NRL for a so-called arbitration test. Thus **recommendation No. 4** of the 2008 FVO audit report has been addressed.

Supervision of implementation of the RMP is the responsibility of the competent authority in each Autonomous Community. The central competent authority in Spain leads and is involved in regular co-ordination activities related to RMP planning and implementation in the Autonomous Communities. This is largely facilitated through its membership activities in the National Commission. The central competent authority is also informed about all non-compliances through a national alert system (*Sistema Coordinado de Intercambio Rápido de Información*) as well as through follow-up reports of non-compliances found at Autonomous Community level (See chapter 5.1.5.). In this way **recommendation No. 5** of the 2008 FVO audit report has been addressed.

Results of each AC-RMP need to be submitted to the central competent authority via a central database at the beginning of the following year in order to allow it to send the aggregated national RMP to the European Commission by 31 March.

According to the central competent authority, the identification of horses, as required by Regulation (EC) No 504/2008 has been completed and, in doing so, **recommendation No. 12** of the 2008 FVO audit report has been addressed.

The audit team noted that:

- The organisation of the programme implementation is the responsibility of each Autonomous Community and comprises both random and targeted sampling. In both Autonomous Communities visited, suspect sampling also took place frequently.
- Planned sample targets for the whole of Spain have been fully met in 2011, apart from just one commodity (aquaculture) to be analysed for one substance group (B3d – Mycotoxins) where two out of ten planned samples were taken. The 2011 sampling targets were fully met in Andalucía. In Castilla-La Mancha no slaughterhouse samples from cattle were analysed for group A1, A3 and A4 substances. The competent authority informed the audit team that in the meantime it had changed the laboratory in charge, to ensure that samples will be analysed for these substances for the 2012 plan.
- Training was organised by each organisation involved in the RMP. RMP-relevant training had been regularly given to the central competent authority staff in charge of RMP development and co-ordination. In Andalucía the Department of Health had a comprehensive training plan including RMP-relevant topics. The Department of Agriculture, however, had no such plan and the last training relevant for RMP implementation was given in 2009. In Castilla-La Mancha RMP-relevant training had been given regularly to staff of the Departments of Health and Agriculture.
- At national level there are no comprehensive instructions regarding sampling, e.g. covering issues such as the need to take samples evenly through the year, avoiding multiple sampling from individual producers and handling samples to ensure analyte stability and integrity in the event of long storage and/or transport times to the laboratory. The central competent authority informed the audit team that instructions laid down in European legislation provide guidance to the Autonomous Communities when planning and conducting sampling activities.
- In Andalucía, sampling instructions existed for both the sampling at slaughterhouse and on-farm level. However, they required that samples for different species/commodities and substance groups had to be taken in most cases once or twice during a year in a short period of one to four weeks due to laboratory constraints. Thus sampling activities are not evenly spread over the year as required by Commission Decision 98/179/EC. There were also no instructions to avoid multiple sampling from individual producers. In contrast, in Castilla-La Mancha comprehensive sampling instructions existed both for sampling at slaughterhouse and on-farm level, which required the even spread of sampling over the year and avoidance of multiple sampling from one producer. Sampling instructions in both Autonomous Communities included guidance that samples should be stored and transported to the laboratory in order to ensure analyte stability and integrity.
- (As expected from the policy outlined in the sampling instructions) in Andalucía the audit team found that sampling was not evenly spread over the whole year for many commodities

and substance groups, but was taken mostly in one or two periods of one to four weeks. For example, samples of bovine muscle for group B1 had to be and were largely taken only during 21 to 25 May, pig-/ sheep-/ caprine muscle for group A6 (chloramphenicol) had to be taken during the first week of May and poultry fat for group B3b Organophosphates had to be taken between 28 May and 15 June. In Castilla-La Mancha it was spread over the whole year.

- In two slaughterhouses of the Autonomous Communities visited, frequent multiple sampling from individual producer(s) took place. This is not in line with requirements of Article 2.1 and 2.3.3.1 of Commission Decision 98/179/EC.
- Officials in charge of RMP sampling at slaughterhouses and farms of the two Autonomous Communities visited, were aware of targeting criteria for sampling, knew how to take a sample and had received RMP relevant training.
- Sampling was carried out in both Autonomous Communities visited without prior warning as outlined in the national RMP and in compliance with Article 12 of Council Directive 96/23/EC and Article 3.2 of Regulation (EC) No 882/2004.
- Food business operators, who wanted to keep the second specimen of a sample themselves, were advised on the official sampling form in both Autonomous Communities visited, to store the specimen in a frozen state.
- With regard to RMP implementation, regular and satisfactory supervision existed in the Autonomous Communities visited.

With regard to **food chain information** and **veterinary medicine treatment records** the audit team noted that:

- The minimum data that food chain information should contain have been laid down nationally. These minimum data are then put in standard templates created by the Autonomous Communities and such templates were used in all establishments visited by the audit team. By requirements laid down in Royal Decree 361/2009, the animals' keeper is required to declare if the animals, identified in the food chain information and in accompanying transport documents, have remained on the holding for at least the last 30 days before slaughter and to provide details of any veterinary medicinal products with a withdrawal period greater than zero days which have been administered to the animals during this period of time. The keeper is required to declare whether any such veterinary medicinal products have been administered during this time but not whether any applicable withdrawal periods have been respected prior to the animals being sent to slaughter. The competent authority acknowledged that there are veterinary medicines on the Spanish market with withdrawal periods longer than 30 days and, as such the information provided concerning the use of veterinary medicinal products during this period does not cover the use of such medicines. The format of the food chain information document therefore does not satisfy the relevant requirements of Annex 2 section III to Regulation (EC) No 853/2004 as the relevant period of 30 days is insufficient and, Article 5 of Regulation (EC) No 854/2004.
- In the slaughterhouses visited, it could be seen that food chain information arrived with the animals but in 5-10% of cases, the sections concerning the minimum time which the animals had remained on the holding prior to going to slaughter and the declarations concerning the

use (or not) of veterinary medicinal products were not completed. In some cases, the food chain information had not been signed by the keeper of the animals. These shortcomings had generally not been noted by either the slaughterhouse operators or the official veterinarians.

- In both Autonomous Communities, shortcomings with regard to, e.g. incorrectly completed or unsigned food chain information, had not been noted by the competent authority in charge of supervision at the three slaughterhouses visited. These last two findings are not in line with Article 4 (2) of Regulation (EC) No 882/2004.

With regards to *equidae* the audit team noted that:

- According to data provided by the competent authorities, in 2011 approximately 450 horses were slaughtered in the two Autonomous Communities visited. In contrast the operators of the three slaughterhouses visited reported that in 2012 a combined total of approximately 20-25,000 animals had been slaughtered by them. According to the competent authority and the operators, the main reason for this considerable increase in animals being slaughtered is due to the economic crisis. Checks of the documentation showed that while food chain information had accompanied all animals to the slaughterhouse, similar deficiencies to those described above were seen in many of the 100 examples checked by the audit team and these deficiencies had not been noted in two of the three slaughterhouses visited.
- In some cases, it was possible to examine the horse passports on-the-spot (as these are normally returned to the registration body directly after slaughter). In all cases section IX of the passport was available. In none of the passports was it recorded that the animals had received essential medicines (listed in Regulation (EC) No 1950/2006). None of the horses had been signed out of the food chain.
- Six passports were randomly selected by the audit team in one slaughterhouse and in one, it was not possible to link the section IX with the rest of the passport as the code numbers differed. Neither the operator nor the official veterinarian responsible for checking this information could explain this discrepancy.
- In one slaughterhouse visited, a documented system had been put in place by the operator and official vets, in which deficiencies in the identification of *equidae* or in the accompanying documents (food chain information, passport and transport document) were recorded. When deficiencies were detected, the carcasses of the animals concerned were detained in the slaughterhouse pending the receipt of missing information. Where this was not provided or the identification of the animal could not be confirmed, the carcasses were sent for destruction as Category 1 animal by-products. Copies of commercial documents used for the transport of these carcasses to destruction sites were available. The records of deficiencies showed that frequent issues had been identified with food chain information and in reading microchips (transponders).
- The use of veterinary medicinal products on farms fattening horses was checked regularly during controls on animal health and welfare. In Andalucía it was possible to verify that check-lists had been completed during such controls which included checks on the storage and documentation recording the use of veterinary medicinal products. In some cases, deficiencies had been identified including the use of anabolic steroids. Documented evidence was available to show that follow-up actions had been implemented and legal proceedings initiated.

- The horses kept at the collection centre visited were all identified in accordance with Regulation (EC) No 504/2008 and passports were available for all horses present at the time of the visit. Similarly, slaughterhouse records showed that, apart from some horses abandoned at the gates, all animals arriving were accompanied by a passport. These findings are in accordance with those described in section 5.2.1.1 of FVO audit report (DG (SANCO) 2011/6021).
- Records for the use of veterinary medicinal products on farms visited generally fulfilled the requirements of Article 10 to Council Directive 96/23/EC. However, one horse collection centre/trader in Castilla-La Mancha had only started in 2012 to keep a register for veterinary medicinal product treatment although animal movement records showed that many horses had passed through the establishment since 2010. It was acknowledged by the owner that veterinary medicinal treatments had been administered to animals prior to 2012 which were not documented in a register for veterinary medicinal product treatments. Treatment registers, prescription records and labelling of veterinary medicines evaluated by the audit team on a dairy farm in Castilla-La Mancha and on a pig farm in Andalucía were adequate.

With regards to **internal and external audits**, the audit team noted that:

- In general, a system of internal and external audits (of official controls) existed at central competent authority and Autonomous Community level. At central competent authority level (Ministry of Public Health and the Ministry of Agriculture Food and Environment) no internal or external audits had been performed to check their own effectiveness of controls and tasks covered by Council Directive 96/23/EC. In both Autonomous Communities visited such internal audits had been carried out in the Department of Agriculture but not in the Department of Health. This is not in line with Article 4.6 of Regulation (EC) No 882/2004. The audit team found that shortcomings detected in the internal audits of the Department of Agriculture (e.g. delay of communication of analysis results, unequal criteria for selecting farms for AC-RMP on-farm sampling, lack of laboratory accreditation for a certain matrix/substance combination etc.) had been fully addressed and were documented in the respective reports.

Conclusions on implementation of the residue monitoring plan

At national level, the negligible shortfall in samples taken vs planned indicates that supervision of implementation has been effective. However, this masks differences in the performance of individual Autonomous Communities with regard to the AC-RMP implementation like the clustering of sampling and not to spread sampling evenly through the year, which undermines the effectiveness of residues controls.

With regard to the implementation of food chain information, it is recognised that improvements have been relative to the 2008 FVO audit. Nevertheless, its current format could give a false impression of the residues status of slaughtered animals. Furthermore, shortcomings in identification of incomplete/incorrect food chain information undermine confidence in the implementation of controls and, the absence of audits to verify the effectiveness of the implementation of residue controls by the Department of Health in the Autonomous Communities visited, may have contributed to the fact that these shortcomings had not been detected. Also no audits to verify the effectiveness of the residue controls tasks carried out by the central competent authority had taken place.

With regard to identification of *equidae*, again, improvements have been made relative to the previous FVO residues audit. Notwithstanding the relatively small number of samples taken

nationally, particularly in light of the substantial increase in the number of horses being slaughtered, the regular checks on the use of veterinary medicinal products carried out on horse farms and actions taken where non-compliances were detected, gives some confidence in the residues status of horse meat.

5.1.4 Other residues monitoring programmes

Legal Requirements

In addition to the residue monitoring plan required by Article 5 of Council Directive 96/23/EC, Article 11 of said Directive gives Member States the option of conducting other residues testing, particularly in relation to detection of illegal treatment of food producing animals. Article 9 of the Directive foresees the application of own-checks by food business operators. Article 8(2) of Regulation (EC) No 882/2004 obliges Member States to have the legal provisions in place to allow competent authorities to have access to such information. Competent authorities are obliged to examine, inter alia, records (of own-checks) as laid down in Article 10(2)(e) and (g) of Regulation (EC) No 882/2004.

Findings

In addition to the RMP, three other official residue monitoring programmes have been implemented in Spain under the National Food Chain Control Plan 2011-2015. In Part B, section II of this plan, raw milk samples are analysed for presence of antibiotic residues and under section III, programme number 5, analysis is done for contaminants in food and under programme 6 pesticides residues in food are analysed.

Food business operators are required to have own-check programmes in place and to notify the competent authority of any non-compliances detected.

The audit team also noted that:

- Results of the above outlined official residue monitoring were available to and consulted by the competent authorities and the National Commission responsible for the planning of the RMP (see 5.1.2).
- Food business operators visited had own-check programmes in place as required, which in one slaughterhouse visited covered, e.g. analysis for residues of prohibited group A substances. The food business operators met confirmed that they had to notify the competent authority of non-compliant results from own-check programmes to avoid placing unsafe food on the market in line with Article 14(1) of Regulation (EC) No 178/2002.

Conclusions on other residue monitoring programmes

Other official residue monitoring programmes are in place, thus providing additional assurances about the residue status of animal products.

5.1.5 Follow-up of non-compliant results

Legal Requirements

The measures to be taken by the 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. In addition, Article 54 of Regulation (EC) No 882/2004 lays down the principles to be followed in the application of national enforcement measures and actions to be taken in cases of

non-compliance.

Findings

The system in place for the follow-up of non-compliances detected in the RMP or through the Rapid Alert System for Food and Feed (RASFF) system is largely as described in the 2008 FVO audit report. All levels of the Ministries of Health and Agriculture and Rural Development have defined responsibilities within their respective scope of activities when a non-compliant sample result is detected. There is a system for the rapid exchange of information (*Sistema Coordinado de Intercambio Rápido de Información*).

As described in the 2008 FVO audit report, the measures to be taken when non-compliant sample results are detected in the RMP are set down in instructions developed by the so-called '*Acuerdos de Santiago*' and, according to the central competent authority, these have been adopted by most Autonomous Communities including the two visited. These are based on the general requirements set down in Articles 15 to 19 and 22 to 25 of Council Directive 96/23/EC. The national instructions specify that movement restrictions should be applied for a period of 12 months when prohibited substances are detected and for six months where MRLs (for authorised substances) are exceeded. In case of prohibited substances these periods of restriction are divided into two equal segments. During the first, animals sent for slaughter must be sampled, carcasses and offal seized and only released for human consumption if the results are compliant. During the second segment, at least one sample must be collected every two months from farms where prohibited substances have been detected. In the case of authorised substances, follow-up checks will be carried out at the slaughterhouse for a period of three months, with a programme of sampling and immobilisation of carcasses and offal, which are released for human consumption if the results are compliant. In case of repeated infringements, the measures will be applied for a period of six months. The farms under suspicion are listed in a database which can be accessed by official veterinarians working in the slaughterhouse and such information is also included in transport documents accompanying animals from these farms to slaughter (see 5.1.3.). The instructions were modified in July 2012, mainly to reduce the time when animals with a short production cycle (like poultry) had to be subject to movement restrictions, on the holdings in which non-compliant results had been found in the samples, in line with the animals' or animal lots life spans. The legal basis for imposing sanctions including financial penalties is as described in the 2008 FVO audit report.

According to data provided by the central competent authority in 2011, a total of 64 non-compliant RMP samples were detected in Spain, with all except two relating to group B substances.

In the period 2010 to 2012 there were no relevant RASFF alerts detected in Spain involving Spanish products of animal origin. The Spanish authorities were informed of one finding of sulphadimethoxine (263.7 µg/kg) in pig carcasses and of one finding of sulphadiazine (154 µg/kg) in sheep meat via RASFF in the same period.

Documentation relating to the actions taken in response to one finding of chloramphenicol in milk and three findings of group B1 substances in pig and sheep tissues was reviewed in the Autonomous Communities visited. Additional files from other Autonomous Communities were also reviewed and included one case relating to the detection of chloramphenicol in milk and three for the detection of B1 substances in animal tissues.

The audit team noted that:

- Officials met who were responsible for follow-up of non-compliant samples were aware of the procedures to be followed. Comprehensive files were available demonstrating the actions taken at each stage of the follow-up process.

- In all cases reviewed by the audit team, the movement restrictions set down in the '*Santiago de Acuerdos*' instructions had been imposed on the animals present on farms which were the subject of non-compliant sample results. It was possible to confirm that official veterinarians had access to the list of suspect farms and that animals sent to slaughter from such farms had been sampled as required. In several cases, related to MRL violations in sheep, more than 350 samples had been taken during the period of suspicion. None of these were non-compliant.
- In the cases examined, the analytical results for non-compliant samples were available within four to six weeks of the sample being taken. In the cases examined in Castilla-La Mancha, the results had been notified promptly to the relevant competent authorities and on-farm investigations had been carried out by the local level of the Department of Agriculture within a week of being notified of the results. The situation differed in Andalucía where delays at various stages in the exchange of information between and within the competent authorities and the time taken by the competent authorities to decide the scope of the follow-up investigations, resulted in a cumulative delay of 20 days before an on-farm investigation was carried out in response to the finding of chloramphenicol in milk delivered to a dairy and a delay of nearly six weeks in following-up on-farm a finding of doxycycline in poultry. These two cases illustrate that in this Autonomous Community efficient and effective co-operation and co-ordination as required by Article 4 (5) of Regulation (EC) No 882/2004 was not evident. Thus **recommendation No. 3** of the 2008 FVO audit report has not been addressed.
- With regards to some banned substances, the time from sample taking to the availability of the sample result had improved vs the situation described in the 2008 FVO audit report, however, still exceeded three months in approximately 7% and 13% of the samples taken in Andalucía and Castilla-La Mancha, respectively in 2011 (2012 data were not yet available). Thus **recommendation No. 3** of the 2008 FVO audit report has not been addressed.
- Regarding the two chloramphenicol cases (in milk), in the first case, a block was placed on the movement of animals and their products pending the (compliant) outcome of additional milk samples taken on the farm in line with the procedures of the '*Santiago de Acuerdos*' instructions. In the second case, only the dairy cows were subject to movement restrictions and the milk continued to be placed on the market without any measures being taken (such as follow-up sampling) to exclude the possibility that it would also contain residues of chloramphenicol. This policy did not respect the requirements of Article 14(6) of Regulation (EC) No 178/2002.
- According to the competent authorities in both Autonomous Communities visited, legal procedures are initiated when a non-compliant sample result is notified which normally results in the imposition of fines. In the cases reviewed by the audit team, these ranged from €1,000 to €5,000.

Conclusions on follow-up investigations/actions

The system in place for the follow-up of non-compliant results is comprehensive and, in general, well co-ordinated and executed. However, in some cases its effectiveness has been undermined by delays in initiating actions, and by actions which have been insufficient to protect consumers from exposure to potentially contaminated products.

5.2 LABORATORIES

Legal Requirements

Requirements for designating laboratories are laid down in Article 12(1) of Regulation (EC) No 882/2004 and Article 14 of Council Directive 96/23/EC. Requirements pertaining to the capacity and capability of laboratories are described in Article 4(2) (c) of Regulation (EC) No 882/2004. Requirements for accreditation of laboratories are laid down in Point 1.2. of the Annex to Commission Decision 98/179/EC and in Article 12(2) and (3) of Regulation (EC) No 882/2004. Requirements for the validation of analytical methods for residues of pharmacologically active substances and certain contaminants are laid down in Articles 3, 4, 5 and 6 of Commission Decision 2002/657/EC. Requirements for analytical methods are also laid down in the annexes to Commission Regulation (EC) No 1883/2006 (dioxins and dioxin-like PCBs in foodstuffs), Commission Regulation (EC) No 333/2007 (chemical elements in foodstuffs) and Commission Regulation (EC) No 401/2006 (mycotoxins).

5.2.1 General description

Findings

Spain has three NRLs two of which are based in Madrid and one in Granada for all commodities and all substance groups listed in Annex I to Council Directive 96/23/EC. The NRLs reside under the Ministry of Agriculture Food and Environment and under the Ministry of Public Health. The NRLs report to their respective Ministries and to the National Commission for the RMP.

There are 53 governmental routine testing laboratories in Spain performing residue analysis under the scope of the RMP. They are, according to the central competent authority, all accredited according to ISO/IEC 17025 by the national accreditation body (*Entidad Nacional de Acreditación*). Laboratories which are not accredited have been taken off the list of laboratories allowed to conduct RMP analysis. In this way **recommendation No. 6** of the 2008 FVO audit report has been fully addressed.

Within each Autonomous Community visited, a number of laboratories are responsible for screening and confirmatory analysis of RMP samples. Each of them analyses RMP samples for a predefined set of compound groups, species and matrix combinations. Andalucía has six laboratories based in Cordoba (two), Almeria, Granada, Huelva and Jaen. Castilla-La Mancha has seven laboratories based in Albacete, Ciudad Real, Cuenca (two), Guadalajara, Talavera de la Reina and Toledo.

The audit team noted that:

- The competent authorities of all Autonomous Communities had, according to the central competent authority, not outsourced any RMP testing to any other than the 53 governmental laboratories. This was confirmed by the competent authorities in the two Autonomous Communities visited.
- Based on information provided by the central competent authority 66% of methods used for RMP analysis (nationally) were within the scopes of accreditation of the national laboratories. The percentage of accredited methods varied between 20 and 80% depending on the substance group, commodity and matrix. The central competent authority informed the audit team that all laboratories intend to have all methods progressively included in their respective scopes of accreditation and stated that all the methods used in the RMP are either accredited or validated.

5.2.2 On the spot visits in the laboratories

The audit team visited three laboratories and noted that:

- The laboratories were very well equipped, e.g. with LC-MS/MS and other instruments which were state-of-the-art and properly maintained.
- They had suitably qualified and well trained staff. Training records were checked and found to be satisfactory.
- Standard operating procedures (SOPs) were available for methods of analysis and for validation of methods according to Commission Decision 2002/657/EC.
- Samples received were properly sealed, identified and stored as required by laboratory instructions.

5.2.2.1 National Reference Laboratory in Majadahonda

Findings

The audit team noted that:

- This NRL is responsible for the following substance groups covered by the RMP: A1, A3, A4, A5, A6, B1, B2f and B3e and has a flexible scope accreditation to cover the range of analyte-matrix combinations that it is responsible for.
- It does not perform routine analysis of samples from the RMP, but only performs third sample specimen analysis in cases of non-compliant results found by a routine laboratory which were not confirmed in the second sample specimen analysis. The result of the third sample specimen analysis legally decides if the sample is compliant or not.
- A file checked by the audit team, related to analysis of a third sample specimen for dihydrostreptomycin in eggs showed that the procedure adopted was satisfactory including the validation of the method.
- Between 2010 and 2012 the NRL participated in a wide spectrum of proficiency tests for various analyte/matrix combinations available worldwide and achieved satisfactory results in all except one. This unsatisfactory result had been rectified by the laboratory.
- The NRL stated that in general, laboratories participating in NRL-organised proficiency tests showed improvement relative to previous tests. The selection of an analyte-matrix combination for the proficiency tests is based on earlier results and difficulties met with certain methods of analysis by the routine laboratories.
- This NRL also evaluates the laboratory part of the national RMP as far as it is in charge of the respective matrix-analyte combinations. It sends its report to the National Commission for the RMP. In the report for 2012 ten major non-conformities were listed, including, the validation status of methods. However, the report neither indicated which (Autonomous Community) laboratories were implicated nor were the deficiencies described detailed enough to allow the National Commission to make specific recommendations (to the Autonomous Communities in question) to rectify those shortcomings.
- The NRL visited executes its tasks to a large extent in accordance with Article 14 of Council Directive 96/23/EC. Thus **recommendation No. 7** of the 2008 FVO audit report has been

addressed to a large extent. However, some routine testing laboratories in Spain have 2012 CC α values for some group A and prohibited group B substances which are significantly higher than the European Union Reference Laboratories (EURL) recommended values. (e.g. Andalucia/ Laboratorio de Salud Publica de Granada: Group A 5 Clenbuterol in liver: CC α 0.4 μ g/kg vs. recommended value of 0.2 μ g/kg; La Rioja/Laboratorio Regional de la Car: B2e Phenylbutazone in milk and plasma: CC α 120 μ g/kg vs. 5 μ g/kg; Castilla La-Mancha/Laboratorio Regional Cuenca: Group A5 Cimaterol in urine: CC α 50.5 μ g/kg vs. 0.5 μ g/kg, Group A1 Dienestrol in urine: CC α 3.85 μ g/kg vs 2 μ g/kg and Group A4 Zeranol in urine: CC α 5.76 μ g/kg vs. 2 μ g/kg; Castilla La-Mancha/Laboratorio de Salud Publica de Guadalajara: Group A2 Thiouracil in urine: CC α 80 μ g/kg vs. 10 μ g/kg).

5.2.2.2 Laboratorio de Produccion y Sanidad Animal de Cordoba

Findings

The audit team noted that:

- With the exception of beta-agonists, nitrofurans and nitroimidazoles in feed, all the other analyte/matrix combinations the laboratory was analysing (e.g. Group A1, A2 and A3 substances in urine and group A5 substances in water, urine, hair, etc.) were not included in the scope of laboratory accreditation.
- This laboratory analysed RMP samples obtained from four other regions.
- On the basis of a number of methods examined by the audit team almost all of the methods used for the RMP, were fully validated according to Commission Decision 2002/657/EC. However, the audit team noted that validation of the Group A1 (stilbenes) method was not finished and the validation file was not yet available.¹

5.2.2.3 Laboratorio de de Salud Publica de Toledo

Findings

The audit team noted that:

- This laboratory is in charge of analysis of group A6 (chloramphenicol and nitrofurans) in muscle, eggs, milk and honey, B1 substances in eggs, milk, honey, muscle and kidney and B2b substances in eggs and muscle.
- In the scope of the accreditation, the method for chloramphenicol and Group B1 substances is included. All other methods are validated, but are not yet accredited.
- The 2012 accreditation body audit report found two minor deficiencies, which subsequently were rectified.
- The SOPs for the determination of chloramphenicol in biological matrices and bound residues of nitrofurans by LC-MS/MS were checked. Quality assurance samples were included in a sample batch and four identification points were used for determination, which is in line with Commission Decision 2002/657/EC. Moreover, analytical acceptance criteria for approval of samples were also adhered to.

¹ In their response to the draft report the Competent Authority noted that the experimental part of the validation was complete but the final version of the validation file not available.

- The validation files for the determination of chloramphenicol were checked by the audit team, i.e. determination in pig muscle and in eggs, both by LC-MS/MS analysis. Most validation parameters were properly evaluated according to the validation SOP. Stability in matrix and sample extracts was not (yet) studied.
- The method mentioned above was also used for the analysis of chloramphenicol in milk and honey samples. No additional (limited) validation was performed for these matrices. Based on this and other findings regarding incomplete validation, **recommendation No. 8** of the 2008 FVO audit report has been largely but not yet fully addressed.
- The laboratory had not participated in proficiency tests since January 2012. The laboratory management present stated that this was due to lack of financial resources.
- The audit team found that the LC-MS/MS method for screening and confirmation for group B1 substances in milk did not include important substances like penicillins and aminoglycosides that are widely used in treatment against mastitis. However, on a national basis these compounds are included in the RMP.

Conclusions on laboratories

The fact that laboratories are now all accredited to ISO 17025 and that methods used for the RMP are to a very large extent validated in accordance with EU rules gives the competent authority confidence in the reliability of laboratory performance and underpins guarantees on the residues status of food of animal origin. This is also supported by the good progress made regarding the inclusion of methods in the laboratories' respective scopes of accreditation (66% included) and the undertakings to progressively include all methods in the laboratories scopes of accreditation.

The performance of the NRL is to a large extent in line with the requirements of Article 14 of Council Directive 96/23/EC. However, the overall effectiveness of the laboratory network is weakened by the fact that a few decision limits are substantially greater than the EURL recommended values, an issue which has not been addressed by the NRL as part of its task to co-ordinate standards and methods of analyses. This shortcoming compromises the capability to detect the potential abuse of the substances in question.

5.3 FOLLOW-UP OF RELEVANT RECOMMENDATIONS MADE IN PREVIOUS FVO REPORT ON RESIDUES (DG SANCO 2008-7781 MR FINAL)

N	Recommendation	Findings
1	Ensure that each Autonomous Community residue control plan complies with Council Directive 96/23/EC with regard to the number of samples taken, the substance groups tested, the scheduling of sampling throughout the year were appropriate and the analytical methods used for both screening and confirmation.	This recommendation has been largely addressed (see section 5.1.3) though there are still shortcomings regarding the even spread of sampling throughout the year, multiple sampling from individual producers and selection of matrices for on-farm sampling of cattle (in one Autonomous Community). (See recommendation No. 1 of the current

		<p>audit report).</p> <p>Appropriate analytical methods have been largely used for both screening and confirmation.</p>
2	<p>Review the current practice of sampling for residues of Group B substances in live animals on farm at the expense of testing for residues of such substances in the slaughterhouse in order to better ensure that edible products of animal origin comply with Community MRLs.</p>	<p>Sampling for B substances has been taken in slaughterhouses in line with requirements of Council Directive 96/23/EC.</p> <p>This recommendation has been addressed (see section 5.1.3).</p>
3	<p>Ensure that sampling and analysis are carried out in a timely fashion in order to guarantee the stability of any residues in such samples and, if results are non-compliant, optimise the effectiveness of follow-up investigations as laid out in Article 16 of Council Directive 96/23/EC.</p>	<p>The time from sampling to the result of the analysis of samples is sometimes too long to ensure compliance with requirements laid down in Article 16 of Council Directive 96/23/EC regarding follow-up of positive results. (See recommendation No. 5 of the current audit report).</p> <p>This recommendation has not been addressed, (see section 5.1.5).</p>
4	<p>Ensure that residues of authorised substances which on the basis of screening tests, putatively exceed Community MRLs, are subject to chemical confirmation in accordance with Article 6 of Commission Decision 2002/657/EC.</p>	<p>Samples which have exceeded MRLs in screening tests have been subject to confirmatory tests as required by Article 6 of Commission Decision 2002/657/EC.</p> <p>This recommendation has been addressed (see section 5.1.3).</p>
5	<p>Improve co-ordination of the RMP by the central competent authority in order to ensure that the plan is being implemented as foreseen throughout the national territory thereby satisfying those requirements laid down in Article 4 of Council Directive 96/23/EC and Articles 4.3, 4.4 and 4.5 of Regulation (EC) No 882/2004. When problems in implementation are identified the central competent authority should ensure that corrective actions are taken as required by Article 8.3 (b) of Regulation (EC) No 882/2004.</p>	<p>The central competent authority through and as part of the National Commission, which contains members of each Autonomous Community and the NRL, co-ordinates the fulfilment of requirements of the mentioned legislation. (see section 5.1.2). The central competent authority is also always informed and co-ordinates if required, corrective actions (see section 5.1.5).</p> <p>This recommendation has been addressed.</p>
6	<p>Ensure that all laboratories carrying out testing under the RMP are accredited to ISO 17025 in accordance with the requirements laid down in</p>	<p>All laboratories have been accredited to ISO 17025 (see section 5.2.1).</p>

	Point 1.2. of the Annex to Commission Decision 98/179/EC and in Article 12(2) and (3) of Regulation (EC) No 882/2004.	This recommendation has been addressed.
7	Ensure that the NRLs fulfil all of their functions as laid down in Article 14 of Council Directive 96/23/EC, particularly in relation to the co-ordination of the work of private laboratories designated by the Autonomous Communities to perform testing under the RMP.	Private laboratories are no longer responsible for the analysis of RMP samples (see section 5.2.1). This recommendation has been addressed.
8	Ensure that analytical methods for residues of pharmacologically active substances and certain contaminants are validated in accordance with the requirements laid down in Articles 3, 4, 5 and 6 of Commission Decision 2002/657/EC.	All methods are now in place and most are validated (see section 5.2.). Thus, the recommendation has been largely addressed. (See recommendation 8 of the current audit report).
12	Implement Commission Decision 2000/68/EC (horse passport) without delay.	No evidence was seen that could dispute the competent authorities assertion that all equine animals in Spain are identified in accordance with Regulation (EC) No 504/2008. Thus, this recommendation has been addressed.

6 OVERALL CONCLUSIONS

Comprehensive instructions are in place for planning of the national residue monitoring plan (RMP) and the elaboration of individual Autonomous Community plans are carried out in a timely manner, involving all relevant parties and taking into account relevant data. Nationally, the plan covers all required species and substance group/matrix combinations. With regard to implementation, at national level, the negligible shortfall in samples taken vs planned indicates that supervision of implementation has been effective. However, this masks differences in the performance of individual Autonomous Communities with regards to the Autonomous Community residue monitoring plan (AC-RMP) implementation like the clustering of sampling and sampling not being spread evenly through the year, which undermines the effectiveness of residues controls. With regard to food chain information, it is recognised that improvements have been made relative to the 2008 FVO audit. Nevertheless, its current format could give a false impression of the residues status of slaughtered animals. Furthermore, shortcomings in identification of incomplete/incorrect food chain information undermine confidence in the implementation of controls and, the absence of audits to verify the effectiveness of the implementation of residue controls by the Department of Health in the Autonomous communities visited, may have contributed to the fact that these shortcomings had not been detected. Also no audits to verify the effectiveness of the residue controls tasks carried out by the central competent authority had taken place.

With regard to the identification of *equidae*, again, improvements have been made relative to the previous FVO residues audit in 2008. Notwithstanding the relatively small number of samples taken nationally, particularly in light of the substantial increase in the number of horses being slaughtered, the regular checks on the use of veterinary medicinal products carried out on horse farms and

actions taken where non-compliances were detected, gives some confidence in the residues status of horse meat.

The system in place for the follow-up of non-compliant results is comprehensive and, in general, well co-ordinated and executed. However, in some cases its effectiveness has been undermined by delays in initiating actions, and by actions which have been insufficient to protect consumers from exposure to potentially contaminated product.

The fact that laboratories are now all accredited to ISO 17025 and that methods used for the RMP are to a very large extent validated in accordance with EU rules gives the competent authorities confidence in the reliability of laboratory performance and underpins guarantees on the residues status of food of animal origin. This is also supported by the good progress made regarding the inclusion of methods in the laboratories respective scopes of accreditation and the undertakings to progressively include all methods in the laboratories' scopes of accreditation. The performance of the NRL is to a large extent in line with the requirements of Article 14 of Council Directive 96/23/EC. However, the overall effectiveness of the laboratory network is weakened by the fact that a few decision limits are substantially greater than the EURL recommended values, an issue which has not been addressed by the NRL as part of its task to co-ordinate the standards and methods of analyses used. Thus the capability to detect the potential abuse of the substances in question is compromised.

7 CLOSING MEETING

A closing meeting was held on 31 January 2013 with representatives of the central competent authority, several Autonomous Communities and the NRL. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities did not express disagreement and stated that they would take whatever actions were necessary in order to address the recommendations made.

8 RECOMMENDATIONS

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

N°.	Recommendation
1.	Ensure that residues sampling is evenly spread over the whole year and that multiple sampling from individual producers is avoided as required by point 2 of the Annex to Commission Decision 98/179/EC.
2.	Ensure that food chain information is structured in such a way to guarantee that when properly completed and signed by the producer in line with the requirements stipulated in Annex 2, section III to Regulation (EC) No 853/2004, animals cannot be sent for slaughter within veterinary medicinal product withdrawal periods.

N°.	Recommendation
3.	Ensure that officials in charge of controls in slaughterhouses always carry out inspection tasks related to food chain information as required by Article 5 of Regulation (EC) No 854/2004.
4.	Ensure that all relevant competent authorities involved in the implementation of the RMP carry out internal audits or have external audits carried out, and take appropriate measures in the light of their results as required by Article 4.6 of Regulation (EC) No 882/2004.
5.	Ensure that sampling and analysis are carried out in a timely fashion and that when non-compliances are detected there is effective and efficient co-operation and co-ordination between relevant competent authorities, as required by Article 4(5) of Regulation (EC) No 882/2004, so that effective follow-up actions in accordance with the relevant requirements of Council Directive 96/23/EC can be implemented in a timely manner.
6.	Ensure that follow-up actions are sufficient to prevent products which potentially contain residues of veterinary medicinal products from being placed on the market, as required by Article 14 of Regulation (EC) No 178/2002.
7.	Ensure that the NRLs fulfil all of their functions as laid down in Article 14 of Council Directive 96/23/EC, particularly in relation to co-ordinating the standards and methods of analyses for each residue regarding all laboratories performing RMP testing and ensuring that the methods used in the Autonomous Community laboratories are sufficiently sensitive to detect abuse of illegal substances in line with EURL recommended values.
8.	Ensure that all remaining analytical laboratory methods are validated as laid down in Article 3 of Commission Decision 2002/657/EC and included in the scope of accreditation for all analyte/matrix combination as laid down in Article 12 of Regulation (EC) No 882/2004.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6760

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
<i>Audits by the Commission Services</i>		
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
<i>Food Law</i>		
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
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
<i>Monitoring and sampling of residues in food of animal origin</i>		

Legal Reference	Official Journal	Title
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
Dec. 97/747/EC	OJ L 303, 6.11.1997, p. 12-15	97/747/EC: Commission Decision of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products
Dec. 98/179/EC	OJ L 65, 5.3.1998, p. 31-34	98/179/EC: Commission Decision of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products
<i>Validation of analytical methods for residues and Minimum Required Performance Limits</i>		
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
<i>Bans on the use of hormones and beta-agonists for growth promotion in food producing animals</i>		
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 β -agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
<i>Maximum Residue Limits for veterinary medicinal products in food of animal origin</i>		

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
<i>Maximum Residue Levels for pesticide residues in food of animal origin</i>		
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
<i>Maximum Levels for contaminants in food</i>		
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
<i>Authorisation of veterinary medicinal products</i>		
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
<i>Medicated feedingstuffs and additives</i>		
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
<i>Sampling methods and methods of analysis for contaminants in foodstuffs</i>		
Reg. 333/2007	OJ L 88, 29.3.2007, p. 29-38	Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs
Reg. 401/2006	OJ L 70, 9.3.2006, p. 12-34	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs

Legal Reference	Official Journal	Title
Reg. 252/2012	OJ L 84, 23.3.2012, p. 1-22	Commission Regulation (EU) No 252/2012 of 21 March 2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006
<i>Sampling methods for pesticides in foodstuffs</i>		
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
<i>Horse identification (passport)</i>		
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
<i>Medicines essential for the treatment of equidae</i>		
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