EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2013-6906 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

THE UNITED KINGDOM

FROM 22 APRIL TO 03 MAY 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 the United Kingdom (UK), carried out from 22 April to 3 May 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 the UK (DG (SANCO)/2009/8128) in February 2009.

It is concluded that the elaboration of the RMP is carried out in a timely fashion, involves all relevant bodies, takes into account relevant data and covers all commodities and the respective substance groups to be tested with few exceptions . The number of samples to be taken at national level is in line with EU requirements, however, the distribution of samples to country and regional level in GB is not based on representative and up-to-date production data, which is important for risk-based sampling.

Overall the implementation of the RMP has largely been carried out in line with planned arrangements and the supervision of the implementation has been mostly effective. The effectiveness of the residue monitoring plan implementation is also to a very large extent guaranteed. It has however, been slightly weakened by some minor deficiencies with regard to suspect sampling and with regard to targeting of certain samples at slaughterhouses due to a lack of information, coordination and communication between some competent authorities about non-compliances found at other slaughterhouses and with regard to food chain information. The other residues control programmes operated in NI and GB increase confidence in competent authority guarantees on the residue status of food of animal origin in the UK.

Whilst veterinary medicinal treatment records on farms visited were complete, official controls cannot offer full assurances that medicines had been used in accordance with veterinary prescriptions and that treated animals complied with withdrawal periods.

There are well-established procedures in place to ensure that the causes of non-compliances detected in the RMP are investigated promptly which underpins the effectiveness of residue controls in the UK.

The programme to check the carcasses of all equines for the presence of phenylbutazone, in matrices where this substance is most likely to be found, prior to their release for human consumption, should eliminate any potential risk that those would end up in the food chain.
However, the fact that approximately 2% of carcasses (whilst not being signed out of the food chain) tested are found to contain such residues and that numerous deficiencies have been identified in the implementation of the horse passport scheme (i.e. deficiencies regarding identification requirements and keeping of medicinal treatment records; the completion of food chain information; the occasional issuance of a duplicate or replacement passport, where the horse is not signed out of the food chain; frequently not notifying the change of ownership of horses on the equine passport; the lack of policy on what sanctions to apply for wrong or missing information) highlights a need to strengthen official controls and the sanctions in place to deter non-compliances in this area.

The fact that the laboratories involved in the RMP are all accredited to ISO 17025, that methods used for the residues monitoring plan are validated in accordance with EU rules, that samples, apart from a small fraction, are split in line with EU rules, that the results of the majority of proficiency tests are satisfactory and the NRLs are discharging their responsibilities, gives the competent authority confidence in the reliability of laboratory performance underpinning guarantees on the residues status of food of animal origin.

Five out of 10 recommendations made during the 2009 residue audit (DG (SANCO /2009/8128) were fully and five were partially addressed.

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

Table of Contents

Abbreviations and definitions used in this report

Abbreviation	Explanation
AFBI	Agri-Food Biosciences Institute
AHVLA	Animal Health Veterinary Laboratories Agency
CCα / CCβ	Decision Limit / Detection Capability
CEFAS	Centre for Environment, Fisheries and Aquaculture Sciences
DARD	Department of Agriculture and Rural Development
DEFRA	Department for Environment, Food and Rural Affairs
DG(SANCO)	Health and Consumers Directorate General
EU	European Union
FERA	Food and Environment Research Agency
FSA	Food Standards Agency
FVO	Food and Veterinary Office
GB	Great Britain
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
LGC	Laboratory of the Government Chemist
LIMS	Laboratory Information Management System
ML	Maximum Levels
MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
MSS	Marine Scotland Science
NBU	National Bee Unit
NI	Northern Ireland
NRL	National Reference Laboratory
PIOs	Passport Issuing Organisations
RASFF	Rapid Alert System for Food and Feed
SOP	Standard Operating Procedure
UK	United Kingdom
UKAS	United Kingdom Accreditation Service
VMD	Veterinary Medicines Directorate

1 Introduction

The audit took place in the United Kingdom (UK) from 22nd April to 3rd May 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 the Veterinary Medicines Directorate (VMD) accompanied the audit team during the whole audit. An opening meeting was held on 22 ndApril 2013 with the central competent authority and other competent authorities 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 effectiveness of 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, regional and local levels, the legal and administrative measures in place to give effect to the relevant EU requirements, residue controls and the performance of the 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 the UK (DG (SANCO)/8128/2009) in February 2009. 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 Veterinary Medicines Directorate (VMD), the Food Standards Agency (FSA), the Animal Health Veterinary Laboratories Agency (AHVLA) and the Agri-Food and Biosciences Institute (AFBI) Veterinary Sciences Division.
	Regional	**3**	Meetings with representatives of the regional AHVLA offices in York (England), Inverurie (Scotland) and Gloucester (England).
	Local	**3**	Meetings with district/area authorities: in York (England), Inverurie (Scotland) and Gloucester (England).
Laboratories		**1**	A National Reference Laboratory (NRL) for Residues and Contaminants in the United Kingdom (UK), the Food and Environment Research Agency (FERA).
Farms		**7**	Two dairy farms, one pig farm, one egg packing station, one farmed game farm, one aquaculture farm, one horse trader.
Establishments		**4**	One slaughterhouse for cattle, one for pigs, one for cattle, pigs, wild and farmed game and one for horses, cattle, pigs and sheep.

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 last audited by the FVO in 2009 (DG (SANCO/2009/8128 MR Final). The report of this audit (henceforth referred to as the 2009 FVO audit) has been published on the website of the Directorate–General for Health and Consumers here: http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=2237 . The report concluded that a generally robust system of residues controls was in place and largely in line with EU requirements. However, the effectiveness of this system was undermined by: a.) Not testing goat/sheep milk and rabbit meat; b.) Omitting several substance groups compulsory for testing in horses and farmed game; c.) Inconsistencies between Northern Ireland (NI) and Great Britain (GB) regarding targeting of routine, suspect and follow-up samples; d.) Shortcomings in the laboratory network and lastly e.) Significant problems in relation to the residues status of *equidae* for slaughter for human consumption compounded by shortcomings regarding treatment record requirements in equine passports. The system of horse identification and equine passports was audited b y the FVO in 2011 (DG (SANCO) 2011/6056). The report found that organisation of the identification of *equidae* and the deficiencies in related official controls were such that the system could not ensure consistent and always correct application of the requirements laid down in Regulation (EC) No 504/2008.

5 Findings And Conclusions

5.1 Residue monitoring

5.1.1 Competent authorities involved

The Veterinary Medicines Directorate (VMD) is responsible for the implementation of the Residue Monitoring Plan (RMP). The RMP planning group comprises representatives from the VMD, the Agri Food Biosciences Institute (AFBI), the Animal Health and Veterinary Laboratory Agency (AHVLA), the Food Standards Agency (FSA), the Food and Environment Research Agency (FERA), Marine Scotland Science (MSS), the Centre for Environment, Fisheries and Aquaculture Science (CEFAS) and from the competent authority-independent Veterinary Residues Committee (VRC).

The responsibility for sampling and follow-up of non-compliant results is delegated by the VMD to several official implementing bodies in the UK. These delegations are specified through individual

memoranda of understanding. The AHVLA undertakes on-farm sampling of cattle, pigs, poultry, eggs and milk. In Scotland, egg samples are collected by the Scottish Government Egg Marketing Officers. The FSA has delegated controls related to meat hygiene, compliance checks with food chain information as well as suspect and RMP sampling for red meat, game and poultry in slaughterhouses, to two subcontracted companies of which one is active in England and Wales and the other in Scotland. The service level agreement between the FSA and these two companies is the same. CEFAS collects samples of aquaculture products in England and Wales, while in Scotland MSS is responsible for this task. DEFRA's National Bee Unit (NBU) collects samples of honey in England and Wales, whereas the Scottish government does so in Scotland.

In NI the Department of Agriculture and Rural Development (DARD) - Veterinary Service carries out on-farm sampling of cattle, pigs and poultry, while inspectors attached to the Veterinary Service's Veterinary Public Health Unit, authorised by the Food Standards Agency (NI), take samples in slaughterhouses. Inspectors from DARD Quality Assurance Branch collect egg, milk, fish and honey samples.

The competent authorities and the distribution of responsibilities have been described in more detail in the country profile for the UK, which can be found here: http://ec.europa.eu/food/fvo/controlsystems_en.cfm?co_id=GB

*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

An RMP document has been created by the VMD outlining who is involved in and responsible for the RMP planning, sampling and follow-up investigation activities. It further indicates which laboratories have been designated to be the NRL for the various substance groups, highlights the main RMP changes for the year concerned and states that detailed field instructions regarding sample collection have been prepared by all implementing bodies.

The members of the RMP planning group meet each year in September under the chairmanship of the VMD to plan the programme for the following year. The draft plan is presented to the VRC at its autumn meeting for comments, amendments and approval. The VRC is an independent advisory committee, appointed to assess and advise on the RMP and other residue surveillance programmes. In GB the sample requests are primarily sent quarterly by the VMD to the implementing bodies with the first quarterly sampling requests sent early enough to commence sampling in January.

In GB the VMD distributes slaughterhouse sample requests to the FSA for each individual slaughterhouse. On-farm samples for cattle, goat, sheep, farmed game as well as cow milk etc. are distributed quarterly to each AHVLA area. Aquaculture samples are distributed quarterly per country to CEFAS in England and Wales and to MSS. Egg and honey samples are distributed quarterly to the Egg Marketing Inspectorate in GB and yearly to the NBU. All implementing bodies, apart from the FSA, then subsequently break down the number of samples to individual food business operators where the samples are taken.

National sample numbers are based on the previous year's production data. For cattle, sheep, goat as well as for poultry, cow milk and hen eggs data come from DEFRA. Honey data come from the NBU based on volumes reported by the professional bee associations. For aquaculture, data come from CEFAS and the Crown Estate, the official government body in Scotland, and are based on the annual non-gutted weight of fish produced.

The audit team noted that:

- The planning process involves all relevant bodies and ensures that the RMP can be implemented from January.
- Relevant risks, such as non-compliances found in the UK and in other EU Member States, new veterinary medicinal products and new MRLs are documented and taken into account in the planning process.
- The results of all official residues programmes in the UK are taken into account when the RMP is planned (see section 5.1.4.).
- Past performance of food business operators is taken into account in general. In NI, all food business operators having had a non-compliant result will automatically be re-sampled in the following year. In GB, the VMD assesses each non-compliant result to decide if the respective food business operator will be re-sampled in the following year. This is in line with requirements laid down in Article 3(1)(b) of Regulation (EC) No 882/2004.
- Since the 2009 audit, testing for the substance groups A1, A3, A4 and A6 has been added for aquaculture products and testing for group A3 has been added for farmed game. The number of substance groups for *equidae* has been increased from two in 2009 (sedatives and non-steroidal anti-inflammatory substances (NSAIDs)) to 14. In 2012, e.g. 82 horse samples were tested for the NSAID phenylbutazone, 22 for antimicrobials and two for steroids. In this way **recommendation No. 1** of the 2009 FVO audit report has been fully addressed.
- The RMP largely 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 farms and the substances to analyse for. However, the 2012 RMP did not cover sheep milk and eggs from others species of poultry. The 2013 RMP does not include low volume commodities like goat milk and eggs from other species of poultry which is not in line with requirements laid down in Commission Decision 97/747/EC.

- Sheep and goat milk were not included in the RMP prior to 2009 (see the 2009 FVO audit report) as the producers of sheep and goat milk had not been known to the VMD. In 2009, several goat milk producing farms were identified by staff of the VMD and goat milk testing for all required substance groups commenced. Staff of the VMD informed the audit team that several sheep milk producers were identified in 2012, which subsequently led to testing of sheep milk in the 2013 RMP. The competent authority informed the audit team, that they did not plan sampling for goat milk in 2013, as tests during the three previous years had not indicated any non-compliance. Not testing goat milk in 2013 is not in line with requirements laid down in Chapter 1.2 in the Annex to Commission Decision 97/747/EC and thus **recommendation No. 2** of the 2009 FVO audit report has not been fully addressed.
- Rabbit meat was not included in the RMP as of end 2011, as it was not, according to the VMD, produced any more in the UK, thus **recommendation No. 3** of the 2009 FVO audit report no longer applies.
- Egg farms producing eggs from other poultry are not yet all known to the VMD and thus not included in RMP sampling activities.
- Up-to-date production data are not taken as available background information to target sampling at slaughterhouses or on-farm when allocating RMP samples across countries and regions/areas. The VMD informed the audit team that production data existed in the national database used to distribute samples across countries and regions, but the VMD did not know if those data had been updated since the database creation in 1998. They stated further that it was certain that data had not been updated in the database for the last four years. In one slaughterhouse visited, the number of RMP samples to be taken from sheep had not been adjusted for several years to the up-to-date number of animals slaughtered in that establishment, which was 10 times higher than the number originally used to calculate the number of samples for that establishment. This is not in line with requirements laid down in Annex III to Council Directive 96/23/EC. The VMD informed the audit team that they had started to update data in 2012 with regard to slaughtered animals and the resulting number of samples to be taken but that this process had not been finalised.

Conclusions on planning of the residue monitoring plan

It is concluded that the elaboration of the RMP is carried out in a timely fashion, involves all relevant bodies, takes into account relevant data and covers all commodities and the respective substance groups to be tested with few exceptions (milk from species other than bovine and eggs from species other than hens). The number of samples to be taken at national level is in line with EU requirements, however, the distribution of samples to country and regional level in GB is not based on representative and up-to-date production data, which is important for risk-based sampling.

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 coordinating the activities of all bodies involved in residues controls. General principles governing the co-ordination of activities and ensuring the cooperation 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 Regulation (EC) No

882/2004 deals with the general obligations with regard to the organisation of official controls and Article 8(3) of said Regulation 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 (EC) No 1883/2006 (dioxins and dioxin-like PCBs); Commission Regulation (EC) No 333/2007 (certain chemical elements); Commission Regulation (EC) No 401/2006 (mycotoxins).

Findings

The audit team noted that:

- Sample targets for 2012 for the whole of the UK were met as planned and regular checks are done by the VMD to ensure that sampling targets overall and for each official implementing body are fulfilled.
- Quarterly sampling plans (yearly for the NBU), accompanied by sampling forms and sample identification bar codes, are distributed from the VMD to the official implementing bodies in GB. The VMD selects and sends sampling requests directly to slaughterhouses, while all other sampling sites are selected by the official implementing bodies.
- Each month the VMD receives a monitoring report from the FSA and an update of all samples received and tested for from FERA and the AFBI including the number of non-assayable samples. It uses these data to generate reports which are forwarded to all implementing bodies each month apart from the AHVLA which is sent one quarterly to, for example, initiate additional sampling if the planned annual sample numbers are not reached and to supervise that sampling is carried out throughout the year. Thus **recommendation No. 5** of the 2009 FVO audit report has been addressed.
- The implementing bodies are responsible for drawing up and issuing sampling instructions, all of which have been elaborated in cooperation with the VMD.
- Sampling staff interviewed had been trained, training activities were documented and staff were well aware of the sampling requirements.
- On-farm RMP sampling is in general unannounced to the farmer while taking place in the context of other announced official visits.
- Appropriate sampling materials including tamper-proof bags, as required by point 2.6. of the Annex to Commission Decision 98/179/EC, and insulated boxes for sample transport were kept by sampling officials on-the-spot.
- The instructions regarding the selection of farms where on-farm samples are to be taken differ between NI and GB. For example, in NI the selection of farms is partially targeted at risk, as all farms testing non-compliant for Group A or any other unauthorised substances will be sampled again the following year. However, farms for the remainder of samples to be taken are selected at random by the Animal and Public Health Information System software. The latter is not in line with the requirements of Commission Decision 98/179/EC, thus **recommendation No. 4** of the 2009 FVO audit report has not been fully addressed. In GB the instructions from the AHVLA, NBU, CEFAS and MSS comprise risk-based selection criteria (e.g. type of fattening system, sex of animal, breeds kept, type of production system,

indication of the use of pharmacologically active substances, etc.) based on which individual farms are selected for sampling in accordance with Commission Decision 98/179/EC. However, AHVLA officials informed the audit team that in practice the selection of farms for RMP sampling, which keep livestock for meat or milk production, cannot be primarily based on using local knowledge or any other relevant information, as sampling almost always takes place in conjunction with other official visits, for example cross compliance checks or disease control programmes. The VMD informed the audit team that a review of regulatory burdens by Hampton had recommended that official visits to farms should be joined up as far as practicable. The VMD stated further that this meant no change to the practice of taking an unannounced residues sample when judged appropriate at a farm visited for another purpose. To not target controls based on risk is not in line with the requirements of Article 3 of Regulation (EC) No 882/2004 and not in line with the requirements laid down in point 2.3.2.1 of the Annex to Commission Decision 98/179/EC.

- Guidelines regarding the risk-based selection criteria to use for animals to be sampled for on-farm sampling or slaughterhouse sampling are included in instructions from DARD in NI and the official implementing bodies in GB, which are all largely in line with the requirements of Annex III to Council Directive 96/23/EC including guidance on avoiding multiple sampling from one producer in accordance with point 2.3.3.1. of the Annex to Commission Decision 98/179/EC.
- In GB and NI, clear instructions had been issued for the identification of animals for suspect sampling. However, in the slaughterhouses visited in England and Scotland, animals which could fall under the suspect category, based on the FSA staff instructions for RMP implementation and findings in the post-mortem register assessed by the audit team, were rarely sampled and detained as suspect animals in line with the instructions. The instructions were known to the official veterinarians met, but not followed. In 2012, 46 suspect samples were taken in GB and 204 in NI, while production in GB is much higher than in NI.
- Thus, suspect samples for the detection of pharmacologically active substances are not always taken where there are indications to suspect non-compliances regarding the residues status of an animal, as required by Article 24(1) and 24(2) of Council Directive 96/23/EC, in spite of specific national FSA staff instructions for RMP implementation. Thus **recommendation No. 6** of the 2009 FVO audit report has not been fully addressed.
- At an egg packing station visited by the audit team, RMP samples had been taken from hen eggs, with each sample consisting of 12 eggs. This egg packing station also packed eggs of other species of poultry like quail, duck, pheasant, geese and guinea-fowl.
- The laboratories involved in RMP testing inform both the VMD as well as the FSA Policy department about all non-compliances found on farm. The FSA Policy department however, does not forward all of these non-compliant results to the central FSA Operation department. In the event that a non-compliance is found at slaughterhouse level, the VMD requests the respective food chain information from the central FSA Operation staff. FSA Operation staff, in turn, request the food chain information from FSA staff at the slaughterhouse and forwards it to the VMD, which then asks the AHVLA to start an investigation on the farm indicated in the food chain information. It is up to the FSA staff responsible at the slaughterhouse to then decide if they want to take samples from animals coming for slaughter from that farm.
- FSA staff at two slaughterhouse visited by the audit team were not aware of non-compliant results (e.g. Group A compounds) from on-farm testing of farms not slaughtering at their establishment, which would allow them to sample animals from those farms, should these farms` animals be slaughtered at the establishment in question. Staff from the FSA Policy

department confirmed to the audit team that they do not inform the FSA Incident Team or FSA Operation staff at central or slaughterhouse level about non-compliant on-farm samples. This is not in accordance with Article 24 of Commission Directive 96/23/EC and with Article 3(1) and Article 4(5) of Regulation (EC) No 882/2004.

With regard to **food chain information, veterinary medicine treatment records** and **internal or external audits** the audit team noted that:

- **Food chain information**, in the form of standardised declarations made by the producers, was in place for all animal species slaughtered. However, those varied in content per species and country. Food chain information used by pig farmers in Scotland required the farmer to confirm that " *The required withdrawal period for all medicines has been adhered to* " and that *"No medicines have been administered in the last 28 days"*. Those two statements together might make it confusing for the farmer as to what to confirm, especially given that there are authorised veterinary medicinal products in the UK with a withdrawal period greater than 28 days and up to 75 days.
- According to DEFRA, food chain information is required for all horses slaughtered in GB but not in NI, where the equine passport is accepted as food chain information. This situation remains unchanged from that described in the 2009 FVO audit report. This is not in line with the requirements of Annex II, Section III, point 3(c) to Regulation (EC) No 853/2004 (as information is given on the passport only about treatments with medicines which require the animal to be excluded from the food chain or for which a six-month withdrawal period applies under Regulation (EC) No 1950/2006). Although there is currently no slaughter of horses in NI, as stated by the competent authority, the fact that horses are being sent for direct slaughter in GB with no accompanying food chain information from NI means that the presenter of the horse for slaughter in GB is not in a position to reliably complete the food chain information declaration.
- Compliance with food chain information requirements was checked on a daily basis by the official veterinarian in all slaughterhouses visited. The audit team saw for all species and in all slaughterhouses visited, that 93 to 99 per cent of all food chain information was correctly provided, however, one to seven per cent of food chain information documents were not signed or dated or the farmer or owner had not indicated if the withdrawal period was respected. This is not in compliance with point 3(c) and 4(b) of Section III of Annex II to Regulation (EC) No 853/2004. The official veterinarian at the slaughterhouses had not noted these shortcomings, although food chain information compliance checks were part of a regular internal audit that had to be done every five to eight months. Thus controls to check if requirements laid down in Article 5 of Regulation (EC) No 854/2004 were fulfilled, were not properly implemented. The shortcomings with regard to the effectiveness of official controls had also not been noted by the supervising hierarchy of the FSA subcontractor or the FSA, thus the FSA had failed to ensure and verify the effectiveness of official controls, which is not in line with Article 4 (2)(a) and Article 8(3) of Regulation (EC) 882/2004.
- In one slaughterhouse visited neither the signed original food chain information document nor a copy was kept at the slaughterhouse, but was immediately returned to the transport company. The VMD informed the audit team that in such a situation it would not be possible to obtain the original signed food chain information from animals, however, an unsigned electronic version sent to the slaughterhouse 24 hours before the animal's arrival was available and stored electronically at the slaughterhouse. The VMD informed the audit team that they request food chain information for all non-complaint cases within 24 hours and that

it would be rare for this information to be unavailable. In another slaughterhouse food chain information originals were kept for one year. The FSA informed the audit team that no written guidance existed on how long a slaughterhouse should retain originals or copies of food chain information, but that six months would be expected.

- **Veterinary medicine treatment records** and labelling of veterinary medicinal products at all farms visited were in compliance with EU requirements. Thus **recommendation No. 9** of the 2009 FVO audit report has been addressed.

- Staff of the AHVLA conduct regular controls on compliance of veterinary medicine treatment records using a RIM 15 control report. However, the audit team found that AHVLA staff carrying out RIM 15 inspections on farm were confirming that withdrawal periods had been recorded against drug treatment, but were not checking that this was the correct withdrawal period for the treatment used, if treatment and withdrawal period records were based on a respective veterinary prescription, or that animals sent for slaughter had complied with withdrawal times. This shortcoming had not been noted by the supervising competent authority.
- With regard to **internal and external audits**, the audit team found that the VMD underwent a first internal audit assessing its Standard Operating Procedures (SOPs) in 2011. No audits of implementing agencies had taken place between 2009 and 2011 but started again in 2012 and are planned to continue during 2013. Audits of implementing agencies will be repeated every two to three years. The VMD had applied for ISO 9001 certification to be received in September 2013 and an audit covering all processes of the VMD as well as an audit of the AFBI in NI is planned for January 2014.
- No audits have yet taken place to verify if the overall system of residue controls from farm to fork achieves the objectives of Regulation (EC) No 882/2004 and Council Directive 96/23/EC, e.g. verifying the effectiveness of the overall system when several departments within one authority or several authorities need to work together to exchange RMP-relevant data or for follow-up investigations (see also section 5.1.5).

Conclusions on implementation of the residue monitoring plan

Overall the implementation of the RMP has largely been carried out in line with planned arrangements and the supervision of the implementation has been mostly effective. The effectiveness of the residue monitoring plan implementation is also to a very large extend guaranteed. It has however, been slightly weakened by some smaller deficiencies with regard to suspect sampling and with regard to targeting of certain samples at slaughterhouses due to a lack of information, coordination and communication between some competent authorities about non-compliances found at other slaughterhouses and with regard to food chain information.

Whilst veterinary medicinal treatment records on farms visited were complete, official controls cannot offer full assurances that medicines had been used in accordance with veterinary prescriptions and that treated animals complied with withdrawal periods.

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 NI three extensive residue testing programmes outside the RMP are in place (the Meat Inspection Scheme, the Pig Assurance Scheme and the Bovine Quality Assurance Scheme). In GB the so-called non-statutory surveillance programme for residues covers only imported foodstuffs. In January 2013, GB also introduced a four-month surveillance programme for phenylbutazone testing in all slaughtered horses, which included also the samples to be taken as part of the European Commission's reinforced testing plan for phenylbutazone. In addition, several organisations and food business operators have their own surveillance programmes for residues. The VMD informed the audit team that these data will in future also be used to facilitate the risk-based planning of the RMP.

The audit team noted that:

- Under the NI Meat Inspection scheme, samples are taken from any animal presented for slaughter that the DARD official veterinarian or the meat inspector suspects has been treated, and it is detained at the plant, pending the results of analysis. In 2012, 204 suspect samples across all species were taken.
- The NI Pig Assurance Scheme is designed to detect antimicrobials. Each producer is tested at least five times each year. Any producer that has a non-compliant result is placed on intensive sampling, where batches of carcases are detained at slaughter pending laboratory results. After three batches of compliant results, the producer is taken off the intensive sampling list. Approximately 5,000 animals are tested each year.
- The Bovine Quality Assurance Scheme is designed to detect antimicrobials, antiparasitics and, in part, beta-agonists. Each year approximately 1,200 cattle are tested.
- The non-statutory surveillance scheme in GB targets imported food of animal origin looking for prohibited/unauthorised substances.
- During the four-month 100% phenylbutazone surveillance programme in 2013, around 2% of all horses slaughtered for human consumption tested non-compliant and were subsequently sent for destruction. In the UK very sensitive matrices (GB: kidney /NI: plasma) for phenylbutazone testing have been chosen and the majority of non-compliant samples had test results of under 2µg/kg. The FSA informed the audit team that the 100% phenylbutazone surveillance programme had been extended indefinitely as of April 2013.
- Food business operators are obliged to provide the competent authority with non-compliant residue results from their own control programmes to avoid placing unsafe food on the market in line with Article 14 (1) of Regulation (EC) No 178/2002.

Conclusions on other residues monitoring programmes

The other residues control programmes operated in NI and GB increase confidence in competent authority guarantees on the residue status of food of animal origin in the UK.

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 found in the RMP or in the other residue monitoring programmes is as described in the 2009 FVO audit report. In GB, the VMD is responsible for initiating and coordinating follow-up actions of non-compliant results from the food business operator level (e.g. slaughterhouse) back to the farm level. It`s Inspections and Investigations Team carries out follow-up investigations related to feed issues. The FSA performs tasks for follow-up actions from the food business operator level to the market place. The FSA is also responsible for issuing and responding to RASFF alerts.

In GB non-compliant results are sent directly from the relevant laboratories to the VMD and the FSA Policy department. In the case of the VMD, it will forward the results and a request for further investigation regarding red meat, poultry, egg, milk and game to the National Veterinary Advisor (Residues) at the AHVLA. Results and requests for sampling for aquaculture products are sent to CEFAS or MSS, while those for honey are sent to the NBU. If prosecution is anticipated for gross violations of the MRL or for the detection of unauthorised substances, an investigation officer from DEFRA's legal branch will take part in or lead the investigation.

The Veterinary Residues Team of the Chemical Contaminants Division of the FSA directly receives information concerning non-compliant residues test results and allocates the information to the relevant FSA Policy department. For example, non-compliances involving heavy metals are passed to the FSA Agricultural Contaminants Team. Each incidence of non-compliance is dealt with on a case-by-case basis and the FSA Operation department or Incident Team will be contacted as needed. Advice may be requested from the Toxicological Risk-Assessment Team, especially where a public campaign for the recall of products already purchased by consumers may be required. The FSA Operation department or Incident Team will request that Trading Standards in relevant Local Authorities carry out an investigation either alone or in conjunction with the VMD or other bodies. This may result in a request that products on the market are withdrawn from sale .

T he audit team noted that:

- According to the VMD, in the two year period from 2011 to 2012, a total of 298 non-compliant sample results were reported although all except 67 of these were subsequently attributed to natural causes (e.g. finding thiouracil in cattle which had consumed brassicas), sampling of the wrong animals (such as sampling pregnant cattle when checking for 17 beta-19- nor testosterone), or faecal contamination of urine samples.

- The procedures to be followed when non-compliant sample results are reported include those actions specified in Directive 96/23/EC. The VMD informed the audit team that the AHVLA are to publish a revised version of the field instructions, which will include information on non-compliant samples.
- The audit team examined 15 follow-up files, mostly for non-compliances detected in the RMP, but also including several relating to findings of phenylbutazone in the UK's 100% phenylbutazone surveillance programme for horse carcases (see section 5.2). The procedures followed were similar in each case, with the VMD initiating the follow-up investigations with input from the National Veterinary Adviser (Residues). The AHVLA carried out investigations on-farm promptly in collaboration with the Local Authorities, where appropriate. In three out of four cases where the cause of the residue was thought to be contaminated feed, a specialist VMD investigations unit had been involved. In each case, a report of the investigation was provided to the VMD.
- In many of the cases examined, the AHVLA had identified factors, which could have caused the residue and required corrective measures to prevent a recurrence. Where there had been a non-compliance with the requirements for medicinal treatment records, or the withdrawal periods had not been respected, the Rural Payments Agency was informed with a view to reducing payments made under the cross-compliance scheme. Information was provided showing that payments had been reduced by 3% in a few cases in 2011/12 and in two cases of repeated non-compliance the payments were reduced by up to 9%.
- The VMD is responsible for specifying if any samples should be taken during follow-up investigations and the audit team observed that this was rarely done in GB, even in cases where they could have been useful in supporting the hypothesis that certain findings of prohibited substances had arisen as a result of natural contamination rather than through illegal treatments. As noted in the 2009 FVO report, there is also no mechanism in place in GB whereby animals from far ms which have been the subject of non-compliant sample results could be "flagged" for further sampling in any slaughterhouse. The situation in NI differed considerably in that follow-up samples were routinely taken and, under the Animal and Public Health Information System, animals from farms that have been the subject of non-compliances are 'flagged' for further investigation.
- The investigations carried out by the AHVLA, often in conjunction with the Local Authorities, in cases where phenylbutazone was detected in the 100% phenylbutazone surveillance programme followed the standard procedures for RMP non-compliances. In several cases, it was problematic to identify who had administered the treatment as the previous owners of the animals were not always recorded on the equine passports (see section 5.2.). In other cases, the owner or veterinary practitioner treating the horse had not, as required, signed it out of the food chain by completing the relevant part of Section IX of the passport.
- Two out of six 2012 RASFF notification cases related to phenylbutazone were not notified in a timely manner. Some were classified as having a serious impact and others as having no impact for human health. The competent authority provided evidence to the audit team that all 2012 RASFF notifications had been followed up in a timely manner, with only two notified later, and that after adoption of a risk classification guideline in November 2012 all Group A and unauthorised substance non-compliances were classified as having a serious impact on human health. All 2013 RASFF notifications related to phenylbutazone in horse meat were classified as having a serious impact on human health and were also notified in a timely manner.

Conclusions on follow-up investigations/actions

There are well-established procedures in place to ensure that the causes of non-compliances detected in the RMP are investigated promptly which underpins the effectiveness of residue controls in the UK.

5.2 Identification of *equidae* and medicines records requirements

Legal Requirements

Equidae must be identified by an identification document (passport) as established in Commission Regulation (EC) No 504/2008.

Commission Regulation (EC) No 1950/2006 lists certain pharmacologically active substances which are deemed to be essential for the treatment of *equidae* and even though they are not listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010, these substances may be used to treat *equidae* intended for human consumption. The corollary of this is that if *equidae* are treated with a substance which is neither listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 nor defined as an essential substance by Commission Regulation (EC) No 1950/2006, such a treatment permanently excludes the animal from the food chain. Exclusion from the food chain must be declared by the owner under Part 2 of Section IX of the passport.

For those *equidae* which are eligible for human consumption, treatment with pharmacologically active substances listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 must be recorded in a medicines record kept on the farm as required by Article 10 of Council Directive 96/23/EC and Annex I, Part A, III, point 8(b) to Regulation (EC) No 852/2004. Annex II, Section III, point 3(c) to Regulation (EC) No 853/2004 lays down the content of food chain information as regards records of treatment with veterinary medicinal products and other substances which have to be checked by food business operators at slaughterhouses.

For those *equidae* which are eligible for human consumption, treatment with any of the essential pharmacologically active substances listed in Commission Regulation (EC) No 1950/2006 must be recorded in Part 3 of Section IX of the equine passport and a period of six months from the date of last treatment to time of slaughter must be observed.

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 is considered as part of the food chain information for *equidae* as in this section the horse may be permanently or temporarily excluded from the food chain.

Findings

- The responsibility for the implementation and enforcement of the identification system for *equidae* in the UK lies with DEFRA as the central competent authority and with the FSA and Local Authority Trading Standards staff responsible for checking compliance with the equine passport requirements. Responsibility is devolved to the administration in Scotland, Wales and NI. There are currently 75 passport issuing organisations (PIOs), most of which are breeding organisations. Since the 2009 FVO audit, the requirements of Regulation (EC) No 504/2008 have been fully enacted into the legislation of the devolved administrations of the UK. The Horse Passports Regulations 2009 (England) require that any passport re-issued

for a horse (as a replacement or a duplicate) is automatically excluded from the food chain and supporting guidance has been provided to PIOs. The competent authority informed the audit team that equivalent arrangements are in place in Scotland, Wales and NI.

- The Horse Passports Regulations 2009 (England) and the parallel legislation in Scotland, Wales and NI require wild or domesticated solipeds within the genus equus of the family *equidae*, and their crosses, to have a passport. A number of derogations for Dartmoor, Exmoor and New Forest semi-wild populations exist, as allowed under Article 7 of Regulation (EC) No 504/2008. These include requirements to identify and microchip an animal if it receives veterinary treatment or is moved. A horse that has been treated with a veterinary medicinal product not authorised for use in food producing animals must be signed out of the food chain.
- Equine passports must be available, inter alia, when horses are sold, transported or submitted for slaughter. Section IX (medical treatment) must be included in the passport and completed. Equine passports are checked by staff of the Local Authority Trading Standards Departments to ensure that *equidae* have identity documents, inter alia,when sold and transported. Equine passports, in particular the proper completion of Section IX confirming that the animal has not been excluded from the food chain, are also checked by official veterinarians at slaughter.
- According to DEFRA, a central National Equine Database was established in 2008 based on data provided by the PIOs. The competent authority informed the audit team that a review in 2011/12 concluded that the database did not directly contribute to the core aims of the horse Passport Regime, (i.e. to protect the food chain) and that arguments in favour of funding a database in the future did not justify the benefits, especially at a time of significant budgetary pressure. Since this time, the database has not been updated, although DEFRA is considering developing a revised system taking account of on-going discussions at European level.
- Detailed guidance setting out the requirement s for equine passports and recording use of veterinary medicinal products is available on the VMD and GOV.UK website. In addition, the Chief Veterinary Officer recently issued a reminder to veterinary practitioners regarding these requirements. Most, but not all, veterinary practitioners met during this audit who were administering treatments to horses were aware of which treatments should be recorded in Section IX of the equine passports and would be able to correctly ascertain the equine animal's status as either intended for slaughter for human consumption or not, as set out in Part II of Section IX of the identification document and as required by Article 20 of Regulation (EC) No 504/2008.
- All horses arriving at the horse slaughterhouse visited were accompanied by a passport which contained all relevant information required by Regulation (EC) No 504/2004. It was noted that around 60 UK passports seen by the audit team and issued from 2005 onwards included Section IX. The audit team also confirmed that around 20 horses present on the farm and at a horse dealer's holding had passports which contained these sections.
- Food business operators and an official veterinarian responsible for checking passports at slaughter met by the audit team were well aware of the relevant requirements for horse passports. They highlighted considerable variations in the layouts of the passports and a number of inconsistencies in the presentation of information in particular in one or two cases where it was unclear what some stamps applied by the PIOs in Section IX meant with regard to the eligibility of the horses for slaughter for human consumption. In each case, the food business operator and official vet had contacted the relevant PIO to seek clarification.

- There was an additional source of potential confusion relating to the time between date of birth and the date on which the passport was issued. In several passports seen by the audit team, the dates included in the passports raised the possibility that the PIOs did not respect the relevant time periods for animals being identified, as set down in Regulation (EC) No 504/2008, which could mean that the animals were not eligible to receive a passport. The audit team was informed by the competent authority that such delays were routinely caused by the PIOs, which e.g. needed a long time for DNA testing. In such cases, the horse dealer, slaughterhouse operator and the official veterinarian had contacted the relevant PIO to obtain written confirmation that the passport had been applied for within the time periods set down in Article 5 of Regulation (EC) No 504/2008.
- One passport seen by the audit team at a dealer visited, where the horse had been born in 2002 was issued as a replacement passport in 2012. This horse was not signed out of the food chain in Annex IX, nor was there a date of commencement for the six-month suspension period in line with requirements of Article 16(2) of Regulation (EC) No 504/2008. This does not comply with requirements laid down in Article 16(1) of Regulation (EC) No 504/2008, as the horse should have been signed out of the food chain. Thus **recommendation No. 10** of the 2009 FVO audit report has not been fully addressed. This had also been found during an audit by the FVO in 2011 (DG (SANCO) 2011/6056 MR).
- A few equine passports were seen by the audit team where the previous owners of the animals were not always recorded (see also section 5.1.5.).
- Local Authority Trading Standards staff met by the audit team, responsible for checking compliance with the equine passport requirements, acknowledged that the priority given to this task is generally low, although specific campaigns are carried out at major competitions and in areas where large numbers of horses are kept. This was also found during the 2011 FVO audit. According to one official met from Trading Standards, the checks have identified a number of incorrect passport formats (e.g. no or wrong format for section IX) and that change of ownership is not always recorded. Of around 80 equine passports evaluated by the audit team, section IX was in the correct format but several passports were seen in which the change of ownership had not been recorded.
- In one slaughterhouse visited, where 200-300 horses are slaughtered per month, the official veterinarian checked all equine passports before horses were accepted for slaughter for human consumption in line with the requirements of Article 5 and Annex I, chapter IIA point 1 of Regulation (EC) No 854/2004. In particular, section IX was checked to ensure that the horse was declared as intended for human consumption. Food chain information documents were available for all horses and followed a standard format including a declaration which required the seller to declare: " *To the best of my knowledge the withdrawal periods have been respected and no substances leading to the horse being signed out of the food chain have been used"*.
- However, food chain information documents were often completed by the food business operator (Slaughterhouse), as many horses were supplied by private owners who were not familiar with the specific provisions of the relevant legislation. In other cases seen by the audit team, it was clear that a dealer supplying the horses had filled and signed the food chain information document although he had very little knowledge of the treatment history of the horses, because he had only had them for one or two days and where subsequently the horse tested non-compliant for presence of phenylbutazone. Where animals were delivered to the slaughterhouse through a livestock market, the market had received food chain information documents from the previous owner, which was presented to the food business operator before slaughter.

- The results of investigations carried out by the AHVLA and Local Authorities following the detection of residues of phenylbutazone in horse carcasses highlighted many shortcomings in the practical implementation of the equine passports. In particular, the change in ownership of horses is often not recorded making it difficult to trace previous owners. This is not in line with requirements of Section III of Regulation (EC) No 504/2008. In addition, the audit team was informed by the AHVLA and the Local Authority Trading Standards staff met, that owners and veterinary practitioners responsible for treating the horses are sometimes unaware of the requirement to exclude an animal from the food chain following treatment with phenylbutazone or they may deliberately disregard this requirement. This is not fully in line with requirements of Article 20 of Regulation (EC) No 504/2008.
- According to the VMD, sanctions to be applied to the range of infringements identified in connection with horse identification and medicines records required by Regulation (EC) No 504/2008 are currently being evaluated. Thus, official sanctions and measures are not yet fully implemented for these infringements detected, which is not in line with Article 55 of Regulation (EC) No 882/2004.

Conclusions on the identification of *equidae* and medicines records requirements

The programme to check the carcasses of all equines for the presence of phenylbutazone, in matrices where this substance is most likely to be found, prior to their release for human consumption, should eliminate any potential risk that those would end up in the food chain.
However, the fact that approximately 2% of carcasses (whilst not being signed out of the food chain) tested are found to contain such residues and that numerous deficiencies have been identified in the implementation of the horse passport scheme (i.e. deficiencies regarding identification requirements and keeping of medicinal treatment records; the completion of food chain information; the occasional issuance of a duplicate or replacement passport, where the horse is not signed out of the food chain; frequently not notifying the change of ownership of horses on the equine passport; the lack of policy on what sanctions to apply for wrong or missing information) highlights a need to strengthen official controls and the sanctions in place to deter non-compliances in this area.

5.3 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).

5.3.1 General description

Findings

FERA is nominated as routine laboratory for all samples taken in GB. The AFBI is nominated as the routine laboratory for all samples taken in NI. Both conduct analysis both for the government and for private bodies.

The three laboratories listed above are nominated as NRLs according the following distribution:

- AFBI: A1, A2, A3, A4, A5, A6 (nitrofurans except honey), A6 (nitroimidazoles), B2b (nicarbazin), B2f

- FERA: A6 (chloramphenicol), A6 (honey), A6 (dapsone), B1, B2a, B2b (ionophores)

- Laboratory of the Government Chemist (LGC): A6 (chlorpromazine), B2c, B2d, B2e, B3a, B3b, B3c, B3d, B3e. Thus **recommendation No. 7** of the 2009 FVO audit report has been addressed.

The audit team noted that:

- The AFBI and FERA contribute to the drafting of the UK's RMP during the RMP September planning meeting.
- The AFBI and FERA were accredited to ISO/IEC 17025 certified by the national accreditation body UKAS (United Kingdom Accreditation Service). The AFBI and FERA SOPs and methods used for conducting analysis within the RMP were included in the scope of accreditation.
- FERA analysis approximately 90% of all UK samples (England, Wales, Scotland) and AFBI the remainder (NI).

5.3.2 On the spot visit of the FERA laboratory

The audit team noted that:

- Written documents (SOPs and instructions, in particular for validation) were in place.
- Staff were trained and randomly selected training records were found to be satisfactory.
- Facilities and equipment were adequate for the analyses carried out.
- The samples arrived in insulated boxes containing sufficient cooling elements. The samples in the boxes were sealed. The required sampling reports accompanied the samples evaluated by the audit team and the samples were correctly labelled.
- The laboratory implemented a Laboratory Information Management System (LIMS) for the registration of samples. The information about the origin of the samples is stored in the LIMS. However, staff analysing the samples do not have access to these data. After storing the data of the samples in the LIMS, all samples were labelled with unique LIMS numbers.
- Sample preparation was performed in a separate room. Staff in charge of the sample reception and initial preparation of the samples performed their tasks satisfactorily avoiding cross contamination.
- Aliquots of samples needed for a first line screening were taken from the original samples and directly weighed into one-way extraction tubes. The main specimen of the sample was stored in a freezer. In case of a non-compliant screening result, the stored sample specimen would be portioned into three samples of equal quality: two sample specimens be used for the confirmatory analysis and the third sample specimen would be stored in a freezer in case

of requests by the owners of the animals, who have been informed about their right to an independent analysis by information included in the non-compliance report issued by FERA.

- Compliant samples will be stored for another 14 days after submitting the results. Non-compliant samples will be stored until the follow-up investigation is closed by the VMD or the FSA.
- The audit team checked two randomly selected non-compliant samples. One sample of milk contained 51 µg/kg of nitroxynil and the other sample was a kidney from a calf containing 210 µg/kg of gamithromycin. Sample handling and receipt were acceptable and full traceability was ensured. The contractually defined target times were met and all relevant data for both cases were timely reported to the VMD and the FSA Policy department.
- The SOP for validation was checked. The validation of confirmatory methods follows the classical approach as described in Chapter 3.1.2 of the Annex to Commission Decision 2002/657/EC. Laboratory experiments were performed according to sections 3.1.2.1 and 3.1.2.2 (seven replicates per level and validation experiment). The results were evaluated according to sections 3.1.2.5 (CC-alpha) and 3.1.2.6 (CC-beta) using an excel sheet also used by UKAS.
- The validation data of the confirmatory methods for nitroxynil and gamithromycin (LC-MS/MS) and tetracyclines (LC-MS/MS) were checked by the audit team. The practical experiments as well as the evaluation of data were well described. On request, all raw data including the chromatograms were shown to the audit team. The validation was performed as described in the SOP for validation. A shortcoming regarding not having reliable data for the applicability and ruggedness was found in an audit conducted by the VMD in November 2012 and rectified by FERA in March 2013.
- The validation of a microbiological test used for screening of antibiotics was checked. The validation followed Commission Decision 2002/657/EC in combination with the guidelines of the European Union Reference Laboratory for qualitative screening methodology. The data shown to the mission team showed that t he test used for screening was fit for purpose.
- Between 2010 and 2012, FERA participated in a wide spectrum of proficiency tests for various analyte/matrix combinations and achieved in most cases a satisfactory result (within a z-score of +/- 2.0). When the results were questionable or unsatisfactory, a follow-up programme was carried out to eliminate potential shortcomings. All UK NRLs share and discuss in regular meetings the outcome of proficiency tests.
- UKAS carries out audits in the context of FERA´s accreditation. In addition, seven FERA internal audits are planned for 2013. The mission team checked the UKAS and FERA internal audit reports from the last two years and found that a few non-critical shortcomings had been identified and that these were quickly resolved.
- FERA in its function as an NRL, has trained staff from other laboratories and offers methods for the other national laboratories on request. FERA has aquired a multi-method for Group A1, A3 and A4 from AFBI, which is the NRL for these groups. The AFBI trained staff from FERA in using the method.

5.3.3 Findings from the AFBI laboratory

While the AFBI laboratory was not visited by the audit team, it received and assessed several documents from AFBI.

The audit team noted that:

- RMP samples received at the AFBI are split into two equivalent sub-sample specimens ("A" and "B" sample specimen) each allowing the complete analytical procedure for certain Group A substances (beta-agonists, nitrofurans, nitroimidazoles and chloramphenicol) . The "A" sample specimen is used for testing and the "B" sample specimen is held elsewhere in the laboratory. If the "A" sample specimen tests compliant the "B" sample specimen is disposed of. If the "A" sample specimen is non-compliant, the "B" sample specimen is retained indefinitely and can be requested by the food business operator to be used for a supplementary expert opinion. This complies with the requirements of Article 11(5) of Regulation (EC) No 882/2004 and point 2.5 of the Annex to Commission Decision 98/179/EC.
- RMP samples received for the testing of steroids and thyrostats and Group B substances are not split into two equivalent sub-sample specimens, each allowing the complete analytical procedure, and the laboratory SOPs for sampling do not indicate whether this is done at any later stage during the analytical procedure. This does not comply with the requirements of point 2.5 of the Annex to Commission Decision 98/179/EC.
- Laboratory SOPs or other documents do not indicate how the competent authority can ensure that the food business operator can "obtain sufficient numbers of samples for a supplementary expert opinion", as required by Article 11(6) of Regulation (EC) No 882/2004. However, the audit team was informed by laboratory staff that if an FBO required a sample specimen for a supplementary expert opinion, that this could be taken from the remainder of the first sample specimen which would be sent directly to the laboratory selected by the FBO.

Conclusions on laboratories

The fact that the laboratories involved in the RMP are all accredited to ISO 17025, that methods used for the residues monitoring plan are validated in accordance with EU rules, that samples, apart from a small fraction in one laboratory, are split in line with EU rules, that the results of the majority of proficiency tests are satisfactory and the NRLs are discharging their responsibilities, gives the competent authority confidence in the reliability of laboratory performance underpinning guarantees on the residues status of food of animal origin.

5.4 Follow-up of relevant recommendations made in previous FVO report on residues (DG SANCO 2009-8128 MR Final)

No	Recommendation	Findings
1	Ensure that *equidae* and farmed game are also sampled under the National Residue Control Plan for all mandatory substance groups required under Article 5(2) of Council Directive 96/23/EC.	*Equidae* and farmed game are now tested for all mandatory substance groups, thus this recommendation has been addressed (see section 5.1.2.).

2	Ensure that milk from other species (goat and sheep) is sampled under the National Residue Control Plan, in addition to bovine milk, in line with the requirements in Chapter 1.2 in the Annex to Commission Decision 97/747/EC	Sheep milk has been added to the RMP in 2013, however goat milk is not sampled in 2013. Thus this recommendation has only been partially addressed (see section 5.1.2.). (See recommendation No. 1 of the current audit report)
3	Ensure that rabbits, if slaughtered for human consumption in the UK, are sampled under the National Residue Control Plan in line with the requirements in Chapter 3 in the Annex to Commission Decision 97/747/EC.	No slaughterhouses for rabbits are active in the UK. This 2009 recommendation no longer applies (see section 5.1.2.).
4	Ensure that the implementation of the sampling for the National Residue Control Plan, in particular targeting of farms for routine sampling is consistent throughout the United Kingdom as required under point 2.3.2. in the Annex to Commission Decision 98/179/EC and Article 4(4) of Regulation (EC) No 882/2004, respectively.	This recommendation has not been fully addressed, as inconsistencies in targeting of on-farm samples between NI and GB still exist (see section 5.1.3). (See recommendation No. 2 of the current audit report)
5	Ensure that the central competent authority has sufficient information, as required under Article 4(2) (c) of Council Directive 96/23/EC, about the sampling in all regions and sectors to guarantee that sampling is carried out throughout the sampling year in accordance with the National Residue Control Plan and in line with point 2.1. of the Annex to Commission Decision 98/179/EC.	This recommendation has been addressed, as the central competent authority receives timely and monthly sample reports to guarantee that sampling is carried out throughout the sampling year (see section 5.1.3).
6	Ensure that suspect sampling, and detention of sampled carcasses, is carried out in line with national instructions and as required under Article 24 (1) of Council Directive 96/23/EC.	This recommendation has not been fully addressed, as suspect sampling is, in GB at least: a.) not always carried out when there are indications to suspect non-compliances with regard to the residue status of an animal and b.) not in line with national instructions (see section 5.1.3). (See recommendation No. 3 of the current audit report)
7	Designate a NRL for substance group B2e (non-steroidal anti-inflammatory drugs) as required by Article 14 of Council Directive 96/23/EC.	This recommendation has been addressed as an NRL has also been designated for group B2e (see section 5.3.)
8	Ensure that all methods used for analysis of samples under the National Residue Control Plan are validated in accordance with the requirements of Commission Decision 2002/657/EC.	This recommendation is not relevant as it referred to a laboratory which is not any-more involved in routine RMP testing.
9	Ensure that the required retention time for treatment records on farm is in line with the requirements of Article 69 of Directive 2001/82/EC.	This recommendation has been addressed (see section 5.1.3.).

10	Ensure that Section IX in the identification document (passport) for *equidae* is implemented in line with the requirements of Commission Decision 93/623/EEC as amended by Commission Decision 2000/68/EC and that by 1 July 2009 all issuing bodies for identification documents fulfil the criteria under Article 4 of Commission Regulation (EC) No 504/2008.	This recommendation has not been fully addressed (see section 5.3). (See recommendations No. 7, 8, 9 and 10 of the current audit report)

6 Overall Conclusions

It is concluded that the elaboration of the RMP is carried out in a timely fashion, involves all relevant bodies, takes into account relevant data and covers all commodities and the respective substances groups to be tested with few exceptions . The number of samples to be taken at national level is in line with EU requirements, however, the distribution of samples to country and regional level in GB is not based on representative and up-to-date production data, which is important for risk-based sampling.

Overall the implementation of the RMP has largely been carried out in line with planned arrangements and the supervision of the implementation has been mostly effective. The effectiveness of the residue monitoring plan implementation is also to a very large extend guaranteed. It has however, been slightly weakened by some smaller deficiencies with regard to suspect sampling and with regard to targeting of certain samples at slaughterhouses due to a lack of information, coordination and communication between some competent authorities about non-compliances found at other slaughterhouses and with regard to food chain information. The other residues control programmes operated in NI and GB increase confidence in competent authority guarantees on the residue status of food of animal origin in the UK.

Whilst veterinary medicinal treatment records on farms visited were complete, official controls cannot offer full assurances that medicines had been used in accordance with veterinary prescriptions and that treated animals complied with withdrawal periods.

There are well-established procedures in place to ensure that the causes of non-compliances detected in the RMP are investigated promptly which underpins the effectiveness of residue controls in the UK.

The programme to check the carcasses of all equines for the presence of phenylbutazone, in matrices where this substance is most likely to be found, prior to their release for human consumption, should eliminate any potential risk that those would end up in the food chain.
However, the fact that approximately 2% of carcasses (whilst not being signed out of the food chain) tested are found to contain such residues and that numerous deficiencies have been identified in the implementation of the horse passport scheme (i.e. deficiencies regarding identification requirements and keeping of medicinal treatment records; the completion of food chain information; the occasional issuance of a duplicate or replacement passport, where the horse is not signed out of the food chain; frequently not notifying the change of ownership of horses on the equine passport; the lack of policy on what sanctions to apply for wrong or missing information) highlights a need to strengthen official controls and the sanctions in place to deter non-compliances in this area.

The fact that the laboratories involved in the RMP are all accredited to ISO 17025, that methods used for the residues monitoring plan are validated in accordance with EU rules, that samples, apart from a small fraction, are split in line with EU rules, that the results of the majority of proficiency tests are satisfactory and the NRLs are discharging their responsibilities, gives the competent

authority confidence in the reliability of laboratory performance underpinning guarantees on the residues status of food of animal origin.

7 Closing Meeting

A closing meeting was held on 3rd May 2013 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 presented findings and preliminary conclusions.

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.	Ensure that milk from other species (goat) as required in Chapter 1.2 as well as eggs from other species as required in Chapter 2.2 of the Annex to Commission Decision 97/747/EC are included in the RMP.
2.	Ensure that the official RMP controls on farms are carried out on a risk basis taking account of identified risks when choosing farms to be sampled as required by Article 3(1) of Regulation (EC) No 882/2004, and ensure in addition that the implementation of the RMP, in particular targeting of farms for routine sampling, is consistent throughout the UK as required by Article 4(4) of Regulation (EC) No 882/2004.
3.	Ensure that suspect samples for the detection of pharmacologically active substances are taken: a.) when there are indications to suspect non-compliances with regard the residue status of an animal, as required by Article 24(1) of Council Directive 96/23/EC, and b.) in line with the FSA staff instructions for implementation of the RMP, as required by point 2.3.2.2. of Commission Decision 98/179/EC.
4.	Ensure effective and efficient coordination and cooperation between different competent authorities as required by Article 4(5) of Regulation (EC) No 882/2004 to allow that official controls in slaughterhouses are carried out on a risk basis (taking account of information which might indicate non-compliance), as required by Article 3(1) of Regulation (EC) No 882/2004 and point 2.3.3.1. of Commission Decision 98/179/EC in order to comply with requirements laid down in Article 24 of Council Directive 96/23/EC.

N°.	Recommendation
5.	Ensure and verify the effectiveness and appropriateness of official controls in relation to food chain information, as required by Article 4(2) (a) and Article 8(3) of Regulation (EC) No 882/2004 in all slaughterhouses.
6.	Ensure that official controls regarding on-farm veterinary medicinal treatment records are fully effective and appropriate, as required by Article 4(2)(a) of Regulation (EC) No 882/2004.
7.	Ensure that the responsible veterinary practitioners and horse owners correctly ascertain the equine animal´s status as either intended for slaughter for human consumption or not, as set out in Part II of Section IX of the identification document and as required by Article 20 of Regulation (EC) No 504/2008.
8.	Ensure that equine passports are issued within the time periods set down in Article 5 of Regulation (EC) No 504/2008, and that measures to implement sanctions applicable to infringements of the cited Regulation are fully in place, as required by Article 55 of Regulation (EC) No 882/2004.
9.	Ensure that the passport issuing organisations take appropriate measures when issuing a replacement or duplicate identification document to sign the respective horse out of the food chain, following the requirements laid down in Articles 16 and 17 of the Regulation (EC) No 504/2008, and that on change of ownership of equidae, passports are immediately lodged with these organisations, giving the name and address of the new owner, for re-registration and forwarding to the new owner, as required in Section III of the Annex to the cited Regulation.
10.	Ensure that all RMP samples are divided into at least two equivalent sub-samples, as required in point 2.5 of the Annex to Commission Decision 98/179/EC.

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=2013-6906

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
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
Monitoring and sampling of residues in food of animal origin		

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
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