EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2012-6530 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

GERMANY

FROM 05 TO 15 NOVEMBER 2012

IN ORDER TO EVALUATE THE MONITORING 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 Germany, carried out from 5 to15 November 2012, 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 Germany(DG (SANCO)/2008/7775) in September 2008.

It is concluded that the elaboration of the residue monitoring plan is carried out in a timely manner, involves all relevant parties and takes into account relevant data at federal and *Länder* level, thus fulfilling EU requirements. Overall the implementation of the residue monitoring plan, which is the responsibility of the *Länder*, has been largely carried out in line with planned arrangements and supervision of implementation has been mostly effective. Timely and comprehensive follow-up investigations in case of residue infringements have been carried out and corresponding measures have been taken. However, in a few cases the effectiveness of the residue control system has been slightly weakened by some factors including: lack of supervision at *Länder* level resulting in under-sampling, having inadequate checks on food chain information and a lack of audits regarding the effectiveness of competent authorities at *Länder* level in the area of residue controls of Directive 96/23/EC.

The fact that the visited laboratories involved are all accredited to ISO 17025, that methods used for the residues monitoring plan are 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.

Recommendations made during the 2008 residue audit (DG(SANCO/2008/7775) were, based on the assessment at federal level and the two *Länder* level visited, satisfactorily addressed.

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

Table of Contents

Abbreviations and definitions used in this report

AKS	*Staatliche Akkreditierungsstelle Hannover (Accreditation body Hannover)*
BfR	*Bundesinstitut für Risikobewertung* (Federal Institute for Risk-Assessment)
BMELV	*Bundesministerium für Verbraucherschutz, Landwirtschaft und Ernährung* (Federal Ministry for Food, Agriculture and Consumer Protection)
BVL	*Bundesamt für Verbraucherschutz und Lebensmittelsicherheit* (Federal Office of Consumer Protection and Food Safety)
CCα / CCβ	Decision Limit / Detection Capability
CVUA-OWL	*Chemisches- und Veterinäruntersuchungssamt Ostwestfalen-Lippe* (Chemical and Veterinary office East-Westphalia-Lippe)
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
LANUV	*Landesamt für Natur, Umwelt und Verbraucherschutz des Landes Nordrhein Westfalen* (State Office of Nature, the Environment, and Consumer Protection of the *Land* North Rhine-Westphalia)
LAVES	*Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit* (Lower Saxony State Office of Consumer Protection and Food Safety)
LC-MS/MS	Liquid Chromatography-(Tandem) Mass Spectrometry
MKULNV	*Ministerium für Klimaschutz, Umwelt, Landwirtschaft, Natur- und Verbraucherschutz des Landes Nordrhein-Westfalen* (Ministry of the Climate Protection, Environment and Nature Conservation, Agriculture, nature and Consumer Protection in North Rhine-Westphalia)
ML	Maximum Level
MLOD	National minimum limits of determination

MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
NIML	*Niedersächsisches Ministerium für Ernährung, Landwirtschaft, Verbraucherschutz und Landesentwicklung* (Lower Saxony Ministry of Food, Agriculture, Consumer protection and Rural Development)
NOKO	*Norddeutsche Kooperation* (North German cooperation)
NRL	National Reference Laboratory
NRW	Nordrhein-Westfalen (North Rhine-Westphalia)
RASFF	Rapid Alert System for Food and Feed
RMP	Residue Monitoring Plan
SAL	*Die Staatliche Anerkennungsstelle der Lebensmittelüberwachung*
SOP	Standard Operating Procedure
VIHLS	*Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit – Veterinärinstitut Hannover* - (Veterinary institute Hannover of the Lower Saxony Office of Consumer protection and Food safety)

1 INTRODUCTION

The audit took place in Germany from 5th to 15th November 2012. 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 5th November 2012 with the central competent authority 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, 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 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 Germany (DG (SANCO)/7775/2008) in September 2012. 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 Federal Ministry of Food, Agriculture and consumer Protection (BMELV), the Federal Office of Consumer Protection and Food Safety (BVL) as well as the *Länder NRW and Lower Saxony.*
	Regional	**2**	Meetings with federal state authorities: 1). "Ministry of Food, Agriculture, Consumer Protection and Rural Development" (NIML) and the "State Office of Consumer Protection and Food Safety" (LAVES) of Lower Saxony; 2.) "Ministry of the Climate Protection, Environment and Nature Conservation (MKULNV), Agriculture, Nature and Consumer Protection" and the "State Office of Nature, the Environment and Consumer Protection of the *Land* NRW" (LANUV) of NRW.
	Local	**3**	Meetings with district authorities: the District Competent Authority of Osnabrück in Lower Saxony and of Warendorf and Hamm in NRW.
LABORATORIES		**3**	National Reference Laboratory for Contaminants and Residues (NRL); Veterinary Institute Hannover of the Lower Saxony Offices of Consumer Protection and Food safety (VIHLS), Chemical and Veterinary office East-Westphalia-Lippe (CVUA-OWL)
FARMS		**3**	One dairy farm, one pig farm and one bee keeper
ESTABLISHMENTS		**2**	One slaughterhouse for bovines and one for pigs

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 2001 (DG(SANCO/2001-3267 – MR-Final); 2005 (DG(SANCO/2005-7510 – MR-Final) and in 2008 (DG(SANCO/2008/7775 – MR – Final). These reports (hereafter referred to as the 2001, 2005 and 2008 FVO audits respectively) have been published on the website of the Health and Consumers Directorate – General here: http://ec.europa.eu/food/fvo/ir_search_en.cfm. The most recent report concluded that there was a robust system of residues controls in place, which was generally in line with EU requirements. However, the effectiveness of this system was undermined by shortcomings in the laboratory network and in the ability of the central competent authority to monitor the follow–up procedures carried out in each of the *Länder* (federal states).

5 Findings And Conclusions

5.1 Residue monitoring

5.1.1 Competent authorities involved

At federal level the Federal Ministry for Food, Agriculture and Consumer Protection (BMELV) is the central competent authority for veterinary drug residues. Unit 106 of the Federal Office of Consumer Protection and Food Safety (BVL) carries out specific tasks on veterinary drug residues, sets up the *Nationaler Rückstandskontroll und Import Kontrollplan* (National Residue Control and Import Control Plan - hereafter referred to as RMP), collects and analyses the data of the results of the *Länder*, summarises the data, reports them to the European Commission and publishes the data.

In one *Land* (federal state) visited, Lower Saxony, the RMP is implemented by the Lower Saxony Ministry of Food, Agriculture, Consumer Protection and Rural

Development (NIML) in cooperation with the Lower Saxony State Office of Consumer Protection and Food Safety (LAVES). In the other *Land* visited*:* North Rhine-Westphalia *(*NRW*),* the RMP is implemented by the Ministry of Climate Protection, Environment and Nature Conservation, Agriculture, Nature and Consumer Protection of North Rhine-Westphalia (MKULNV) and by the State Office of Nature, the Environment, and Consumer Protection of the *Land* North Rhine-Westphalia (LANUV). In both *Länder* the Veterinary and Food Supervisory Offices at district level are responsible for sampling.

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

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 RMP planning process is led by Unit 106 of the BVL. Each September, a working meeting is organised in which representatives of all the *Länder*, the BMELV, the Federal Institute for Risk-Assessment (*Bundesinstitut für Risikobewertung*) (BfR) and the National Reference laboratory (NRL) participate to agree the RMP for the following year. Relevant factors are taken into account and discussed including: previous RMP results; the outcome of controls on the use of veterinary medicines; Rapid Alert System for Food and Feed notifications (RASFF); annual production/slaughter data and other relevant risk factors. The BVL breaks down the plan to the *Länder* level, which subsequently distributes them to the district level which is responsible for sampling. Each *Land* then inserts its final plan in a federal database, the Consumer Protection and Food Safety Technical Information System

(*Fachinformationssystem Verbraucherschutz und Lebensmittelsicherheit*) which is accessible to the BVL.

A comprehensive RMP document has been created by the BVL in cooperation with other bodies involved in its planning and implementation which *inter alia* provides instructions regarding factors to be taken into account by the *Länder* when preparing their RMPs and, the risk-criteria and procedures for sampling taking into account the relevant EU requirements. This document also specifies the requirements for screening and confirmatory tests carried out by the laboratories and the maximum time (maximum six weeks) to complete the analysis and procedures on how to act/report in case of confirmed non-compliances.

The audit team noted that:

- all relevant bodies are involved in the planning of the RMP and there was documented evidence showing this (e.g. Agenda of the annual September RMP working meeting). This is in line with Article 14 of Council Directive 96/23/EC and Article 4(3) of Regulation EC No 882/2004;
- the planning of the residue monitoring program at *Länder* and district level was largely carried out in a timely fashion and in line with the deadlines foreseen in the RMP;
- comments made by the EU Reference Laboratories (EURLs) and the Commission services were generally taken into account in the elaboration of the RMP and this could be seen in the increased scope of testing with the inclusion of nitrofurans, nitroimidazoes and anticoccidials in the RMP since the 2008 FVO report. In addition, previous non–compliant residue results were taken into account in designing the RMP, as required by Article 3 of Regulation (EC) No 882/2004. In this way **recommendations No 1, 2 and 8** of the 2008 FVO audit report have been addressed;
- in both *Länder* visited, the federal level RMP had been broken down on the basis of local production data (for all except a few low production commodities in one of the *Länder*) and the sampling strategies and frequencies laid down in the requirements of Annex III-IV to Council Directive 96/23EC and Commission Decision 97/747/EC were followed. In this way **recommendation No. 4** of the 2008 report has been addressed.

Conclusions on planning of the residue monitoring plan
The elaboration of the RMP is carried out in a timely fashion, involving all relevant bodies and taking into account relevant data at federal level and overall *Länder* level, thus fulfilling 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 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).

The veterinary medicines record-keeping requirements of stockowners 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.

Findings

While the central competent authority is responsible for the co-ordination of the RMP in accordance with Article 4 (2)b of Directive 96/23/EC and Article 4 (3) of Regulation 882/2004/EC, responsibility for the organisation and supervision of the implementation of the RMP lies primarily with the competent authorities in the 16 *Länder*. To facilitate this, the RMP requires the *Länder* to provide the BVL with their overall sampling results every six months and also at the annual RMP working meeting described in the section 5.1.2 above.

The RMP includes detailed instructions and procedures to be followed for the implementation of sampling activities.

The audit team noted that:

- the sample targets for 2011 for the whole of Germany were met as planned. This was also generally the case in the *Länder* visited, although some under-sampling was noted for commodities with low production volumes and for certain substance groups;
- according to the annual sampling data for 2011 which was provided to the BVL by the *Länder*, in Lower Saxony, less than 65% of the samples planned for horses and sheep for substance group A&B were taken. In NRW some under-sampling of certain substance groups was noted in live bovines, turkeys, fish and wild game. Both competent authorities of these *Länder* informed the audit team that they do not routinely check throughout the year that the sampling

targets of the districts or laboratories are fulfilled. This is not in compliance with Article 4 (2) to Regulation (EC) 882/2004, which requires that the competent authority shall ensure the effectiveness and appropriateness of official controls;

- all samples are collected by official staff and sampling is generally carried out without prior warning as required by Article 12 of Council Directive 96/23/EC and Article 3(2) of Regulation (EC) No 882/2004. Training has been provided for officials responsible for collecting samples for the RMP through workshops and regular meetings, or on-the-job training;
- instructions to avoid sample clustering, in accordance with point 2.3.3.1. of the Annex to Commission Decision 98/179/EC, are included in the RMP and were in place in the slaughterhouses and farms visited. Both laboratories visited and LAVES officials met carried out checks to ensure clustering did not occur and, evidence was provided to show that, where this did happen, re-sampling had been ordered
- veterinary inspectors met in slaughterhouses, farms and district offices were aware of targeting criteria for sampling. In one district visited, individual establishments and farms had been assigned a "risk point score", on the basis of an elaborate risk assessment system, which was used to target controls. In another district, risk factors including production type, size and previous non-compliances were taken into account when targeting sampling. In the slaughterhouses visited, relevant criteria were used to identify animals to be sampled and to target suspect sampling, which took place regularly;
- appropriate sampling materials including tamper-proof bags and seals, 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 RMP foresees a maximum of seven days from sampling to arrival at the lab, which was mostly met. However, in one *Land* NRW and slaughterhouse visited this period was regularly lasting up to 20 days, thus exceeding the required seven days;
- food chain information, in the form of standardised declarations made by the producers, was in place for all slaughter animal species. However, approximately 10% of the copies kept in the slaughterhouses which were checked by the audit team had not been signed by the animal owners/producers. This is not in compliance with point 4(b) of section III of Annex II to Regulation (EC) No 853/2004. The officials in charge of controls in the slaughterhouse had not notified this shortcoming
- treatment records at all the farms visited were in compliance with EU requirements;
- a quality control system has been implemented in the BVL and an internal audit carried out as part of this, in November 2012, found that the RMP procedures were largely fit for purpose. In Lower Saxony a comprehensive quality control system exists, but no audits covering compliance with requirements of Directive 96/23/EC have been conducted at district level. In NRW a quality control and internal audit system is currently being created so internal audits foreseen in Article 4.6 of Regulation 882/2004 have not yet been carried out.

Conclusions on implementation of the residue monitoring plan

Sampling under the RMP has been carried out in line with planned arrangements and the supervision of implementation is mostly effective. However, the effectiveness of this system in some few cases slightly weakened by factors like: lack of supervision

at *Länder* level resulting in undersampling, having non-compliant food chain information and not to audit the effectiveness of competent authorities at *Länder* level with regards to implementation of controls regarding Directive 96/23/EC.[1]

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 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, a number of other official residue monitoring programmes have been implemented in Germany. These include *inter alia* a requirement under the German Regulation on Monitoring of Food of Animal Origin for at least 2% of all commercially slaughtered calves and at least 0.5% of all other commercially slaughtered ungulates to be tested for residues of antimicrobials using the three-plate inhibitor substance test. Any screening positive tests under this monitoring programme are subject to qualitative and quantitative confirmation by chemical methods to identify and confirm the substance detected. The audit team also noted that:

- treatment records at all the farms visited were in compliance with EU requirements;
- in 2009 and 2010 (under the auspices of a federal programme) the *Länder* visited had participated in an additional programme monitoring heavy metals (lead, cadmium and mercury) in 24 month old cattle;
- since 2009 another federal programme prescribed that RMP samples in aquaculture should be tested in parallel for malachite green, due to previous non-compliant results being reported for this substance;
- in one of the *Länder* visited by the audit team (Lower Saxony), due to previous non-compliant results additional monitoring programmes were put in place in 2012 to analyse National Residue Control Plan cattle samples for dexamethasone and to test the drinking water on turkey farms for metronidazole;
- the audit team saw that results from these other official residue monitoring programmes are taken into account in the planning and implementation of the National Residue Control Plan (including the targeting of sampling). Any non-compliant results are also subject to official follow-up (see section 5.1.5);
- the food business operators visited had own control programs in place as required which, in the dairy included checks for residues of antimicrobials. The competent authority must be notified of non-compliant residues test results from own control

1 *In its response to the draft report, the competent authority noted that the annual samples numbers in NRW are planned by the federal state authority and then broken down and requested weekly by the laboratory, which sends reminders when samples have not been received. It noted further that in NRW a new integrated consumer protection data processing system is currently in development. This will, once fully operational, provide the federal state authority with a simple way to supervise the fulfillment of planned sample numbers.*

programmes to avoid placing unsafe food on the market in line with article 14(1) of Regulation (EC) 178/2002.

Conclusions on other residues monitoring programmes
Other official residue monitoring programmes are in place, thus providing additional assurances about the residue status of animals and 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 RMP sets out the general procedures to be followed in case of non-compliant results. Section 41 of the German Food and Feed Code establishes the overall framework for measures to be taken relating to the farm of origin, with furthermore detailed operating procedures in place at *Länder* level. Testing laboratories transmit non-compliant results to the responsible *Länder* and official staff in the establishment where sampling took place. The BVL is also informed of all non-compliant results. The *Länder* competent authorities are primarily responsible for the implementation of follow-up actions when non-compliant results are reported.

The audit team noted that:

- in the two *Länder* visited by the audit team detailed manuals were in place on the procedures to be followed in case of non-compliant results and staff were trained accordingly. In one *Land* (Lower Saxony) the *Länder* competent authorities performed the follow-up investigation concerning the veterinarian attending or pharmacy supplying the farm, while district authorities performed the follow-up investigations on the farm itself. In the second *Land* NRW visited all investigations were performed by district level, whether covering the farm in question, the attending veterinarian or the supplying pharmacy. The audit team saw evidence of effective coordination between the *Länder* and districts in performing these follow-up investigations;
- standard forms are used both for the reporting of non-compliant results by laboratories and also communicating the outcome of follow-up investigations performed, including any sanctions applied. The BVL receives copies of these reporting forms and maintains a database of non-compliant results and the follow-up procedures implemented in the *Länder*. In this way **recommendation No. 5** of the 2008 FVO audit report has been addressed;
- the RMP establishes a target of 6 weeks at the latest from the reporting of non-compliant results to the submission of reports of follow-up investigations carried out. In Lower Saxony the audit team saw that this target was generally met. Reminders were sent by NRW and Lower Saxony to the responsible districts in cases where reports were not submitted within this period;

- with regard to the 2011 and 2012 RMP non-compliances results, in the *Länder* visited, follow-up investigations were well-documented, timely and effective;
- in the case of animals originating from a farm in one *Länd*er but being slaughtered and sampled in another *Länd*er, the audit team saw that there was effective communication and coordination between the *Länd*er as regards informing of the non-compliant result and performing the appropriate follow-up investigations;
- non-compliant results from other official residue monitoring programmes were subject to the same follow-up actions as non-compliant RMP samples. In the cases examined by the audit team appropriate and timely follow-up actions were taken and some of the farms in question were also targeted for subsequent sampling under the RMP;
- follow-up files for a number of RASFF alerts were examined by the audit team. Measures following the notifications were implemented promptly and were well-documented.

Conclusions on follow-up investigations/actions

Follow-up investigations performed at *Länder* and district levels are generally timely and effective and the central competent authority BVL is kept informed of the progress and outcome of these investigations.

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

Germany has one NRL for all commodities and all substance groups listed in Annex I to Council Directive 96/23/EC. The NRL resides under the BVL, which reports to the federal ministry BMELV. The NRL is also designated as an EU-RL and is tasked to implement the requirements outlined in Article 14 to Council Directive 96/23. In this context, the NRL among many other activities also conducts every two years a survey regarding the validation of methods in the *Länder* laboratories.

There are 27 national routine testing laboratories in Germany performing residue analysis under the scope of the RMP. They are all accredited according to ISO 17025. Within each *Land* visited, a number of laboratories are responsible for the analysis of a portion of the RMP based on compound group, species, matrix and whether the test is screening or confirmation.

Lower Saxony has three laboratories based in Hanover; Oldenburg and Cuxhaven which are also part of the North German Laboratory Cooperation (NOKO), which came into force in 2005. It has the objective to share and rationalise residue analytical work of the *Länder* Berlin, Brandenburg, Mecklenburg-Western Pomerania, Lower Saxony, Schleswig-Holstein, Bremen and Hamburg.

NRW has four laboratories based in Krefeld; Münster; Arnsberg and Detmold and each laboratory specializes in a particular compound group or groups.

5.2.2 On the spot visits in the laboratories

The audit team visited three laboratories. The audit team noted that:

- the laboratories had suitably qualified and well trained staff. Training records were checked and found to be satisfactory and staff had attended conferences organised by the BVL;
- the laboratories were very well equipped e.g. with LC-MS/MS and other instruments which were state of the art and properly maintained with a service contract in place;
- Standard Operation Procedures (SOP) were available for method procedures and the method of validation was according to Commission Decision 2002/657/EC;
- samples received in the laboratories visited were properly sealed, identified and stored as required by the RMP instructions. Procedures for the dispersion of relevant samples to the appropriate laboratories were available;
- a national overview of Group A/B substance CCα from February 2011, provided by the NRL, showed that the MRLs, the MRPL and national minimum limits of determination (MLOD) specified in the 2012 RMP were in line with EU legislation and were followed by the laboratories. In this way **recommendations No. 3 and 6** of the 2008 report have been addressed;
- MRPLs and MRLs assessed were in line with EU requirements

5.2.2.1 National Reference Laboratory (Nationales Referenzlabor für Kontaminanten und Rückstände, inklusive pharmakologisch aktiver Substanzen)

Findings
The audit team noted that:

- the NRL role executes its tasks in accordance with Article 14 of Council Directive 96/23/EC;
- between 2010 and 2012 the NRL participated in a wide spectrum of proficiency tests for various analyte/matrix combinations available worldwide and achieved fully satisfactory results;
- since the 2008 FVO audit, the NRL has introduced analytical methods for

sedatives (B2d), organophosphorus compounds (B3b) and chemical elements (B3c). The validation file for sedatives (B2d) and penicillin and cephlasporin (B1) were checked and found to be compliant with Commission Decision 2002/657/EC. The penicillin and cephalosporin (B1) method is planned to be introduced in 2012 into the catalogue of analytical methods available to other laboratories;

- on request, the audit team was informed by the NRL that they have overall sufficient resources to execute their tasks as a NRL, however this will not be the case as of next year for the group B3c (chemical elements) due to resource cuts. The NRL had notified the BVL of this;[2]
- the NRL stated that in general laboratories participating in NRL organized proficiency tests achieve good results. If a proficiency test result is unsatisfactory for a participating laboratory, the NRL offers help to remedy the situation and informs the central competent authority and the competent authority in the *Land* concerned;
- the NRL does not perform analysis of samples from the RMP and is asked in very few cases to act as an arbiter for non-compliant samples found by the national control laboratories;
- the 2010 NRL validation status survey found in some *Länder* laboratories, that very few methods for some substance matrix combinations (e.g.A1,3,4; B2a,b,e in chicken, or B2e in bovines etc.) had no or pending validation status. A 2012 study will be completed at the end of the year. The audit team was informed by the central competent authority that only validated methods are to be used for screening and confirmatory methods and that this was always followed in the past. They stated further that in a case where a confirmatory method for a non-compliant screening result, was not yet validated, that the laboratory concerned, would validate this method or send the sample to a laboratory with a validated confirmatory method. In this way **recommendation No. 7** of the 2008 report has been fully addressed.

5.2.2.2 Laboratory in Lower Saxony (Lebensmittel und Veterinärinstitut Braunsschweig, Hannover)

Findings

The audit team noted that:

- the 2009 accreditation body audit report found several deficiencies leading to the following recommendations: to create a system of data backup in the area of analysis of residues; to participate in ring trials and proficiency tests in the area of residues and to store analytical standards according to the supplier's instructions. The audit team found that data backup and storage of standards had been addressed. They also found that proficiency tests inspected were satisfactory including those for antimicrobial screening and confirmation. However the laboratory had not participated in proficiency tests for some compound groups e.g.

2 *In its response to the draft report, the competent authority noted that meanwhile funds were provided which allow that the NRL can exercise their tasks also for group B3c substances.*

ractopamine/zilpaterol; chloramphenicol in milk and coccidiostats, although such tests were available.

- the SOP for determination of tetracyclines (B1) in milk by LC-MS/MS was checked and analytical data of one batch of respective samples. Quality assurance samples were included in the 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;
- two validation files were checked by the audit team, i.e. nitroimidazoles (A6) in plasma and penicillins (B1) in tissue and milk, both by LC-MS/MS analysis. Necessary validation parameters were properly evaluated according to the validation SOP.
- staff in charge of the sample reception and initial preparation of the samples performed tasks satisfactorily avoiding cross-contamination. However, the respective standard operation procedures (SOP) were not detailed enough (e.g. no step by step instructions like when or if to change gloves, trays, disinfect instruments used etc.) to exclude the possibility of cross-contamination.

5.2.2.3 Laboratory in NRW (Chemisches und Veterinäruntersuchungsamt Ostwestfalen-Lippe (CVUA-OWL)

- in the outcome of the last accreditation body audit, minor non-conformances found were rectified immediately and that the audit was overall satisfactory, however, one recommendation concerned the creation of a SOP on how to deal with samples;
- samples transported by an externally contracted courier were properly sealed, however, they contained the name of the farmer and farm where the sample was taken. In addition, this data accompanied the sample into the laboratory analytical area, beyond the sample reception area;
- the validation file for sedatives (B2d) in porcine kidney by LC-MS/MS analysis was checked. The validation parameters were properly evaluated according to the validation SOP;
- the laboratory had participated regularly in proficiency tests covering relevant substance /matrix combinations. They had achieved satisfactory results in each case;
- participation in proficiency tests was successful. The proficiency tests covered all RMP relevant substance groups analysed in this laboratory and were of regular frequency;
- the SOP for determination of nitroimidazoles (A6) in plasma by LC-MS/MS was checked along with the analytical data for one batch of samples. Quality assurance samples were included in the 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;
- staff in charge of the sample reception and initial preparation of the samples performed their tasks satisfactorily avoiding cross-contamination.

However, the respective SOP were not detailed enough (e.g. no step-by-step instructions such as when to change gloves, trays, disinfect instruments used etc) to exclude the possibility of cross contamination.

Conclusions on laboratories

The fact that the visited laboratories involved are all accredited to ISO 17025, that methods used for the residues monitoring plan are validated in accordance with EU rules and that proficiency tests have been mostly conducted, gives the competent authority confidence in the reliability of laboratory performance underpinning guarantees on the residues status of food of animal origin.

5.3 Follow-up of relevant recommendations made in previous FVO report on residues (DG SANCO 7775-2008 MR Final

1	Ensure that testing for illegal substances such as nitrofurans and nitroimidazoles is included in the RMP for those commodities where the use of these substances is more likely to occur, e.g. nitroimidazoles in farmed game, horses and rabbits.	Testing for nitrofurans and nitroimidazoles has been included in the RMP and covers also testing in farmed game, horses and rabbits. This recommendation has been addressed (See section 5.1.2)
2	Expand the scope of the RMP for residues of authorised pharmacologically active substances and feed additives (anticoccidials) taking account of the availability of such substances and the recommendations made by the Community Reference Laboratory in Berlin concerning the scope of the RMP.	Testing for anticoccidials has been included in the RMP. This recommendation has been addressed (See section 5.1.2).
3	Ensure that the National Reference Laboratory fulfils all functions as laid down in Article 14 of Council Directive 96/23/EC to coordinate the work of the national laboratories and to ensure that these laboratories observe the Community limits (MRPLs) and national minimum limits of determination (MLODs) laid down in the RMP.	The NRL fulfills all tasks with regard to co-ordinating the work of the national laboratories in line with article 14 of Council Directive 96/23/EC. The audit team also found that, (apart from one substance in one lab), national laboratories observed the Community limits (MRPLs) and MLODs laid down in the RMP. This recommendation has been addressed (See section 5.2.2)**.**
4	Ensure geographical distribution of the RMP sampling per certain commodities (e.g. farmed game, aquaculture, honey) also in *Länder* with small animal production in order to detect any possible violation or misuse in line with Article 3(1) of Regulation (EC) No 882/2004.	Samples are distributed across all *Länder* according to production and slaughter numbers covering also e.g. farmed game, aquaculture and honey production. In the two *Länder* visited samples were taken from small production commodities like farmed game, aquaculture and honey. This recommendation has been addressed (See section 5.1.2)**.**
5	In relation to the follow-up of non-compliant	The central competent authority is informed and

	residues results, for Germany to meet its obligations in respect of consistency in the application of official controls as required by Article 4(4) of Regulation (EC) No 882/2004, the central competent authority should have an overview of the procedures followed in each of the *Länder*.	maintains a database of the procedures followed by all *Länd*er in relation to the follow-up of non-compliant residues results. This recommendation has been addressed (see section 5.1.5).
6	Review national minimum limits of determination (MLODs) established for Group A substances and ensure that these are commensurate with the detection of abuse. The central competent authority is reminded that target values have been recommended by the Community Reference Laboratories.	National laboratories, observed the Community Union limits (MRPLs) and MLODs laid down in the RMP. This recommendation has been addressed (See section 5.2.2).
7	Ensure that all laboratories meet national and Community requirements with respect to validation of analytical methods (Articles 3, 4, 5 and 6 of Commission Decision 2002/657/EC, Commission Regulation (EC) No 333/2007, Commission Regulation (EC) No 1883/2006, Commission Regulation (EC) No 401/2006) in particular demonstrating fitness for purpose.	National laboratories used validated screening methods and for all non-compliant samples validated confirmatory methods. In case a national laboratory has for a certain substance/matrix combination no validated confirmatory method, it needs to validate it or send it to another laboratory having the required validated method. This recommendation has been addressed (See section 5.2.2.1)
8	Co-ordinate the risk-based approaches applied for the geographical distribution of the RMP samples and for controls on the use of veterinary medicinal products on farms to ensure that all sectors in all *Länder* are covered by adequate controls in line with requirements of Article 11 (1.c.) of Council Directive 96/23/EC and Article 3 (1) of Regulation (EC) No 882/2004.	Results from controls on the use of veterinary medicinal products were used as information for a risk-based approach regarding the RMP and official sampling was geographically distributed among the *Länder* based on production data for all relevant commodities. This recommendation has been addressed. (See section 5.1.2)

6 Overall Conclusions

It is concluded that the elaboration of the residue monitoring plan is carried out in a timely manner, involves all relevant parties and takes into account relevant data at federal and *Länder* level, thus fulfilling EU requirements. Overall, it has the implementation of the residue monitoring plan, which is the responsibility of the *Länder*, has been largely carried out in line with planned arrangement and supervision of implementation has been mostly effective. Timely and comprehensive follow-up investigations in the case of residue infringements have been carried out and corresponding measures have been taken.

However, in a few cases the effectiveness of the residue control system has been slightly weakened by some factors including: lack of supervision at *Länder* level resulting in undersampling, having inadequate checks on food chain information and a lack of audits regarding the effectiveness of competent authorities at *Länder* level in the area of residue controls of Directive 96/23/EC.

The fact that the visited laboratories involved are all accredited to ISO 17025, that methods used for the residues monitoring plan are validated in accordance with EU rules and that proficiency tests have been mostly conducted, 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 15th November 2012 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 twenty five working days of receipt of this audit report.

N°.	Recommendation
1.	Ensure that the competent authorities at Länder level ensure that the RMP sampling targets are fulfilled effectively, in accordance with article 4(2) of Regulation (EC) 882/2004.
2.	Ensure that, where standard declarations are used for food chain information, that they are signed by the producers in line with the requirements stipulated in Annex 2 section III to Regulation (EC) No 853/2004.
3.	Ensure that officials in charge of controls in slaughterhouses carry out inspection tasks related to food chain information as required by Article 5 of Regulation (EC) No 854/2004.
4.	Ensure that the competent authorities responsible for 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 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=2012-6530

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
Sampling methods and methods of analysis for contaminants in foodstuffs		

Legal Reference	Official Journal	Title
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
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