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FINAL REPORT OF A SPECIFIC AUDIT

CARRIED OUT IN

FRANCE

FROM 22 FEBRUARY TO 01 MARCH 2010

IN ORDER TO EVALUATE THE CONTROL OF RESIDUES AND CONTAMINANTS AND THE USE OF VETERINARY MEDICINAL PRODUCTS IN FOOD PRODUCING ANIMALS

IN THE CONTEXT OF A GENERAL AUDIT

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) specific audit in France, carried out from 22 February to 1 March 2010, as part of the general audit of France carried out under the provisions of Regulation (EC) No 882/2004 on official food and feed controls.

The objective of the specific audit was to check that official controls to ensure the verification of compliance with feed and food law, animal health and animal welfare rules laid down in Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 are carried out in accordance with the principles of that Regulation and in line with the multi-annual national control plan as specified in Article 41 of the above Regulation. In order to achieve that overall objective the specific audit evaluated the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products in accordance with the requirements of Council Directive 96/23/EC. Controls on the use of veterinary medicinal products in food producing animals were also evaluated.

It is concluded that in general the system of residues controls and controls on the use of veterinary medicinal products is in compliance with EU rules. Strong points of the control system include the comprehensive legal framework in place, the work instructions issued to staff, the formal system of staff training, the provision of appropriate materials for sampling, the information and communication technology tools available for reporting and real-time monitoring of implementation of controls, the accreditation of laboratories to ISO 17025 and satisfactory analytical performance of the laboratory network. However, the effectiveness of the control system is compromised by several factors including the clustering of sampling, the notification of farmers in advance of inspections, not using food chain information, the long time span between an infringement and the start of an investigation and the low probability of an infringement leading to any sanctions.

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

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Abbreviations and definitions used in this report

Abbreviation	Explanation
AFSSA	French Agency for Food Safety *Agence française de sécurité sanitaire des aliments*
ANMV	French Agency for Veterinary Medicinal Products *Agence Nationale du Médicament Vétérinaire*
BISPE	Office for input and public health in livestock *Bureau des intrant et de la santé publique en élevage*
BLA	Office for food law *Bureau de la législation alimentaire*
BNEVP	National Brigade for Veterinary and Plant Health Investigations *Brigade nationale d'enquêtes vétérinaires et phytosanitaires*
CC alpha / CC beta	Decision Limit / Detection Capability
COFRAC	*Comité Français d'Accréditation (France)* (National accreditation body)
CRL	Community Reference Laboratory
DDCSPP	Departmental Directorate for social cohesion and protection of the population *Direction Départementale de la Cohésion Sociale et de la Protection des Populations*
DDPP	Departmental Directorate for the protection of the population *Direction Départementale de la Protection des Populations*
DG SANCO	Health and Consumers Directorate-General
DGAL	Directorate-General for Food *Direction Générale de l´Alimentation*
DRAAF	Regional Directorates of food and feed, agriculture and forestry *Direction régionale de l'alimentation, de l'agriculture et de la forêt*
EC	European Community
EU	European Union
FVO	Food and Veterinary Office
GC-MS	Gas chromatography – Mass Spectrometry
GC-MS/MS	Gas Chromatography-(Tandem) Mass Spectrometry
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC
HPLC –DAD/FL/UV	High Performance Liquid Chromatography with Diode Array Detector / Fluorescence Detector / Ultraviolet wavelength detector
INvS	National Institute for Public Health Surveillance *L'Institut national de veille sanitaire*
ISO	International Organisation for Standardisation
LABERCA	Laboratory for the study of residues and contaminants in food *LABoratoire d'Etude des Résidus et Contaminants dans les Aliments*

LC-MS/MS	Liquid Chromatography-(Tandem) Mass Spectrometry
MAAP	Ministry of Agriculture and Fisheries *Ministère de l'agriculture et de la pêche*
MANCP	Single Integrated Multi-Annual National Control Plan
MEIE	Ministry of Economy, Industry and Employment *Ministère de l'Economie, de l'Industrie et de l'Emploi*
MHS	Ministry of Health and Sport *Ministère de la Santé et des Sports*
ML	Maximum Level
MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
MUS	Mission for health emergencies
NRL	National Reference Laboratory
RASFF	Rapid Alert System for Food and Feed
SIGAL	Information system of the Directorate-General for Food *Système d'Information de la Direction Générale de l'Alimentation*
SIRE	*Système de gestion des populations de chevaux* (National database for *equidae*)
SOP	Standard Operating Procedure

1 Introduction

The Specific Audit formed part of the FVO's planned mission programme and was carried out as a component of a General Audit, as prescribed in Article 45 of 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.

The specific audit took place in France from 22 February to 1 March 2010. The audit team comprised 4 inspectors from the Food and Veterinary Office (FVO). Representatives from the central competent authority accompanied the audit team for the duration of the audit. An opening meeting was held on 22 February 2010 with the central competent authority. At this meeting, the objectives of, and itinerary for, the specific audit were confirmed by the audit team and the control systems were described by the authorities.

2 Objectives Of The Mission

The objective of the specific audit was to check that official controls to ensure the verification of compliance with feed and food law, animal health and animal welfare rules laid down in Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 are carried out in accordance with the principles of that Regulation and the multi-annual national control plan as specified in Article 41 of the above Regulation. In order to achieve that overall objective the specific audit evaluated the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products in accordance with the requirements of Council Directive 96/23/EC. Controls on the use of veterinary medicinal products in food producing animals were also evaluated. Attention was paid to examining the implementation of corrective actions promised in response to recommendations made in the report of a previous FVO residues mission to France (DG (SANCO)/7506/2005) in June/July 2005, henceforth referred to as the 2005 FVO mission.

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 meetings with DGAL, the competent central authority for the national residue control plan. Meetings at the *Département* Competent Authority office in Quimper (*Département* 29), Limoges (*Département* 87) and Rodez (*Département* 12).
	Regional	**3**	
LABORATORIES		**4**	Governmental laboratories in Fougères (AFS35), Limoges (LVD87), Tulle (LVD19) and Rodez (LVD12).
FARMS		**7**	Farms keeping fattening pigs, laying hens, beef cattle, dairy cattle, milk sheep, rabbits and honey bees.
ESTABLISHMENTS		**4**	Slaughterhouses for cattle, veal calves, pigs and small ruminants and a dairy plant.

3 Legal Basis for the Mission

The mission was carried out under the general provisions of Community legislation, and in particular:

- 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;

- 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.

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

4 Background

4.1 Contribution to the General Audit

Article 45 of Regulation (EC) No 882/2004 requires the Commission to carry out general and specific audits in member States. The main purpose of such audits is to verify that, overall, official controls take place in Member States in accordance with the multi-national national control plans (MANCP) referred to in Article 41 and in compliance with Community law.

This Specific Audit was carried out as a component of a General Audit to France. Section 5 below contains findings and conclusions relating to the implementation of Regulation (EC) No 882/2004; Section 6 below contains findings and conclusions relating to sector specific issues.

4.2 Summary of previous FVO mission results

The 2005 FVO mission resulted in 14 recommendations. The December 2009 version of the country profile of France (DG(SANCO)/8104-2009-CP-FINAL) which has been published on the website of the Commission's Health and Consumers Directorate-General here: http://ec.europa.eu/food/fvo/country_profiles/CP_france.pdf (and henceforth referred to as the country profile), indicates that action on one recommendation was outstanding by the end of 2009. This recommendation related to the accreditation of laboratories.

5 Findings And Conclusions related to implementation of Regulation (EC) no 882/2004

5.1 Competent Authorities

5.1.1 Designation of Competent Authorities

Legal Requirements

Article 4(1) of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for official controls.

Findings

The designation of authorities and the distribution of responsibilities are described in the country profile. The Directorate-General for Food (DGAL) of the Ministry of Agriculture and Fisheries (MAAP) is the competent authority responsible for the national residue control plan and for controls on the use of veterinary medicinal products in food producing animals. The audit team noted that:

- the reorganisation of the French civil service came into effect on 1 January 2010. As a consequence the name of certain services has changed, the coordinating role of the region has been enforced and veterinary services at *Départemental* level have merged with other inspection services into either the *Direction Départementale de la Protection des Populations* (DDPP) or *Direction Départementale de la Cohésion Sociale et de la Protection des Populations* (DDCSPP) (depending on the structure of the individual

Département). The veterinary services in the *Départements* visited have become separate units within their respective DDPP or DDCSPP and continue to receive their instructions from MAAP, either from the central level (DGAL) or the regional level (*Direction régionale de l'alimentation, de l'agriculture et de la forêt* - DRAAF);

- *les Haras Nationaux* is the body responsible for the identification of horses.

5.1.2 Co-operation between Competent Authorities

Legal Requirements

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective co-ordination and co-operation between competent authorities.

Findings

The connection between competent authorities is described in the country profile. The audit team noted that:

- communication takes place between DGAL and residue laboratories, between DGAL and the risk evaluation bodies *Agence française de sécurité sanitaire des aliments (*AFSSA) and *l'Institut national de veille sanitaire* (InVS), between *Départements*, as well as between different services at *Départemental* level;
- DGAL organises a coordination meeting with other control services and AFSSA and InVS for the planning of the national residue control plan.

5.1.3 Co-operation within Competent Authorities

Legal Requirements

Article 4(5) of Regulation (EC) No 882/2004 requires that, when, within a competent authority, more than one unit is competent to carry out official controls, efficient and effective co-ordination and co-operation shall be ensured between the different units.

Findings

The structure of the competent authority at central, regional and *Départemental* level is described in the country profile. The audit team noted that:

- there was evidence of cooperation between the different levels in the organisational structure in MAAP, as well as between units at the same level with regard to the national residue control plan and controls on the use of veterinary medicinal products.

5.1.4 Delegation of specific tasks related to official controls

Legal Requirements

Article 5 of Regulation (EC) No 882/2004 sets out the scope of possible delegation to control bodies, the criteria for delegation, and the minimum criteria which must be met by control bodies. Where such delegation takes place, the delegating competent authority must organise audits or inspections of the control bodies as necessary. The Commission must be notified about any intended delegation.

Findings

The audit team noted that:

- no delegated control bodies have been assigned in the framework of the national residue control plan or controls on the use veterinary medicinal products.

5.1.5 Contingency planning

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 also requires that competent authorities have contingency plans in place, and are prepared to operate such plans in the event of an emergency. Article 13 of Regulation (EC) No 882/2004 requires Member States to draw up operational contingency plans setting out measures to be implemented without delay when feed or food is found to present a serious risk.

Findings

The audit team noted that:

- three ministries (MAAP, the Ministry of Economy, Industry and Employment – MEIE and the Ministry of Health and Sport – MHS) have produced a common guide on the management of food alerts. A dedicated unit (Mission for health emergencies - MUS) is responsible within DGAL for contingency planning and management of emergencies and acts as contact point for the Rapid Alert System for Food and Feed (RASFF);
- in 2007, the French authorities introduced a written procedure for field inspectors and the management of non-compliance on account of dioxin-like substances. There is also a general procedure for other contaminants covered by Regulation (EC) No 1881/2006.

Conclusions on Competent Authorities

With regard to Article 4.1, 4.2(f), 4.3 and 4.5 of Regulation (EC) No 882/2004, the requirements of the regulation have been met.

5.2 Resources for performance of controls

5.2.1 Legal basis for controls

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires that the necessary legal powers to carry out controls are in place and that there is an obligation on food business operators to undergo inspection by the competent authorities. Article 8 of the above Regulation requires that competent authorities have the necessary powers of access to food business premises and documentation.

Findings

The audit team noted that:

- controls in the framework of the national residue control plan are based on the Rural Code. Controls on the use of veterinary medicinal products are carried out on the basis of the Rural Code and the Public Health Code. *Notes de Service* give detailed instructions for the implementation in a certain year, such as the required sample numbers and targeting criteria;
- powers to carry out controls, to enter premises, to obtain information, to check the administration, to take samples and to take corrective measures are conferred by the Codes.

5.2.2 Staffing provision and facilities

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires the competent authority to ensure that they have access to a sufficient number of suitably qualified and experienced staff; that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are free of any conflict of interest.

Findings

The DGAL Quality Manual includes provisions on the management and competence of staff and addresses issues of confidentiality, independence, integrity and impartiality. Article 25 of Law No 83-634 of 13 July 1983 on the rights and obligations of civil servants sets out conditions to be respected by staff, including the avoidance of conflicts of interest.

The audit team noted that:

- there was a sufficient number of staff for the implementation of the national residue control plan as well as controls on the use of veterinary medicinal products on farms;
- there is a comprehensive information and communication technology system in place, the *Système d'Information de la Direction Générale de l'Alimentation* (SIGAL), which facilitates the communication, collation and analysis of data pertinent to residue controls;
- materials and equipment for sampling in the framework of the national residue control plan are adequate;
- private veterinarians are contracted by the *Départements* to carry out checks on their clients` farms, including checks on matters in relation to the use of veterinary medicinal products. The competent authority has not ensured that in this context contracted veterinarians are free from conflict of interest. However, the competent authority explained that these checks do not constitute nor replace official controls.

5.2.3 Staff qualifications and training

Legal Requirements

Article 6 of Regulation (EC) No 882/2004 requires competent authorities to ensure that staff receive appropriate training, and are kept up-to-date in their competencies.

Findings

The audit team noted that:

- in respect of staff taking and analysing samples for the national residue control plan, mechanisms for training and maintenance of competence were in place and were documented.

Conclusions on Resources for Performance of Controls

The relevant requirements of Regulation (EC) No 882/2004 in relation to resources for the performance of controls have in general been met.

5.3 Organisation and implementation of official controls

5.3.1 Registration / approval of food business operators

Legal Requirements

Article 31 of Regulation (EC) No 882/2004 requires Member States to establish procedures for the registration/approval of food and feed business operators, for reviewing compliance with conditions of registration and for the withdrawal of approvals.

Findings

The registration of food and feed business establishments was not checked during this mission.

5.3.2 Prioritisation of official controls

Legal Requirements

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. Controls shall be carried out at any of the stages of the production and processing chain and, in general, are to be carried out without prior warning. Controls shall be applied with the same care to exports from the Community, imports into the Community and to product placed on the Community market.

Findings

Notes de Service and the Quality Manual of DGAL include provisions on the planning of inspections.

The audit team noted that:

- there was evidence that risk factors were taken into consideration for the planning and implementation of official controls in the framework of the national residue control plan and for veterinary medicinal product controls.

5.3.3 Control activities, methods and techniques

Legal Requirements

Article 10 of Regulation (EC) No 882/2004 specifies the control activities, methods and techniques that should be deployed.

Findings

The audit team noted that:

- as regards controls on residues and use of veterinary medicinal products on farms the methods used included all relevant aspects required by Article 10(1) of Regulation (EC) No 882/2004.

5.3.4 Sampling and Laboratory analysis

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires competent authorities to have, or to have access to, adequate laboratory capacity. Article 11 of the Regulation establishes requirements for sampling and analysis and Article 12 requires the competent authority to designate laboratories that may carry out analysis of samples taken during official controls. It also lays down accreditation criteria for

laboratories so designated.

Findings

A detailed description of the laboratory network is given in section 6.2. The audit team noted that:

- with regard to the designation of laboratories, the adequacy of the laboratories and the requirements for sampling and analysis, the requirements of Article 4, 11 and 12 of Regulation (EC) No 882/2004 have in general been met;
- in relation to samples taken on-farm under the national residue control plan, the farmer's name and address were identified on the sampling form which accompanied the sample throughout the laboratory.

5.3.5 Procedures for performance and reporting of control activities

Legal Requirements

Article 8 of Regulation (EC) No 882/2004 requires that competent authorities carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

Article 9 of the above Regulation requires competent authorities to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned.

Findings

The operations of DGAL are covered by a Quality Manual which includes provisions on the management of national instructions, inspection methods and inspection reporting. *Notes de Service* provide for detailed instructions for sampling including targeting, analysis and reporting in the framework of the national residue control plan. In addition the competent authority has defined operating procedures relating to the management of sampling and storage materials, the management of samples and the monitoring of storage vessels. Furthermore, a general inspection guide provides general instructions on how to carry out inspections

Controls on the use of veterinary medicines are covered by *Notes de Service* in relation to cross-compliance and inspection manuals specific to controls throughout the pharmaceutical distribution chain.

Notes de Service, quality manuals, procedures and circular letters are disseminated from the central level to the regions and *Départements*. The competent authority reports the results of the national residue control plan to the European Commission.

The audit team noted that:

- at local level relevant instructions such as *Notes de Service* and circular letters are distributed to staff;
- staff involved in controls was aware of the applicable procedures. In various places staff has developed work instructions appropriate to the local situation;
- files were kept of follow-up actions on non-compliant test results.

5.3.6 Transparency and confidentially

Legal Requirements

Article 7 of Regulation (EC) No 882/2004 requires that competent authorities carry out their

activities with a high degree of transparency, in particular by giving relevant information to the public as soon as possible. However, information covered by professional secrecy and personal data protection is not to be disclosed.

Findings

The audit team noted that:

- the Provisions on transparency and confidentiality are included in general texts on the status of civil servants and other state officials.

Conclusions on Organisation and Implementation of Official Controls

The relevant requirements of Regulation (EC) No 882/2004 in relation to the organisation and implementation of official controls have in general been met. However, the fact that the identity of the farm from which a sample has been taken is known to the analyst in the laboratory, could bias the result of analysis. Consequently the competent authority can not guarantee the impartiality of laboratory testing as required by Article 4 (4) of Regulation (EC) No 882/2004 and this has the potential to reduce the effectiveness of official controls.

5.4 Enforcement Measures

5.4.1 Measures in the case of non-compliance

Legal Requirements

Article 54 of Regulation (EC) No 882/2004 requires a competent authority which identifies a non-compliance to take appropriate action to ensure that the operator remedies the situation.

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 procedure for follow-up on non compliant results in the national residue control plan is described in *Notes de Service* (N2009-8238 and N2003-8078) based on the Rural Code. The Rural Code and the Health Code provide the legal basis for follow-up on non-compliances detected during controls on the use veterinary medicinal products. Measures can be taken following cross-compliance controls or specific controls on the use of veterinary medicinal products.

In the case of a non-compliant result the *Département* sends an e-mail to MUS and DGAL. An exchange of information may take place between MUS and the *Bureau des intrant et de la santé publique en élevage* (BISPE) or the *Bureau de la législation alimentaire* (BLA). Consequently MUS sends instructions by e-mail to the *Département*. In general these instructions will at the least include an investigation on the farm of origin. Once the investigation is finished and possible sanctions have been applied, the *Département* will send its conclusions to MUS and BISPE or BLA and the dossier is closed. In the case of forbidden substances DGAL and MUS must inform the *Brigade nationale d'enquêtes vétérinaires et phytosanitaires* (BNEVP). The BNEVP takes charge of the investigation and the *Département* cannot launch an investigation without consulting the BNEVP.

The audit team noted that:

- following the deadlines set in the *Note de Service*, the period between sampling and

initiation of follow-up on a non-compliant result in the national residue control plan can legitimately be up to 130 days;

- out of 68 non-compliant results for forbidden substances in 2008, by 1 June 2009, 43 investigations had been concluded, 24 investigations were still ongoing, and for one case it was not clear whether an investigation had been initiated. All closed cases related to the possible feeding of *Brassicaceae* and feed contaminated with mycotoxins which may result in positive test results for thiorucil and zeranol respectively. The pending investigations related, however, to substances such as chloramphenicol and nitroimidazoles;
- information was provided on the follow-up on 154 non-compliances for other substances in 2008. The main measures consisted of advice to the farmers to observe the withdrawal periods and an increased likelihood of the farm to be sampled in 2009;
- from 12 randomly selected follow-up files on non compliant results for 2008 and 2009 at three *Département* offices it appeared that follow-up is not always prompt and appropriate. The time span between the date of sampling and the date when action was initiated varied between two and 24 months;
- in one case a slaughter animal was sampled in June 2008. In January 2009 the test result (non compliant for the corticosteroid prednisolone) was communicated to the DDCSPP. Follow-up action was initiated in June 2009 and in September 2009 animals from the farm were sampled. These samples were not tested for prednisolone because the use of this substance was not noted in the medicines records on the farm. It was therefore assumed that prednisolone had not been used. The samples were tested for chloramphenicol instead which is completely unrelated to the original violation.

5.4.2 Sanctions

Legal Requirements

Article 55 of Regulation (EC) No 882/2004 states that Member States shall lay down the rules on sanctions applicable to infringements of feed and food law and other Community provisions relating to the protection of animal health and welfare and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

Findings

Note de Service N2008-8078 dated 2 April 2008 sets out the procedures to be followed following inspections (warnings, formal notice and judicial actions). In case of judicial actions, the file is passed to the State prosecutor.

Articles L231-2 of the Rural Code provides for penal sanctions. Articles L231-2 provide for the imposition of administrative sanctions. Article L237 makes it an offence to place unsafe food on the market. Penal sanctions may be initiated on request to the courts. There are five classes of contravention in addition to the range of criminal sanctions. Financial sanctions can be applied in relation to Community direct support schemes for farmers following cross-compliance checks (circular letter C2009-8004).

The audit team noted that:

- in 2008, 4332 inspections were carried out in relation to the use of veterinary medicinal products and 5743 inspections regarding the farm register. This resulted in 397 administrative warnings, nine warnings with and absolute deadline for compliance and six notifications to the public prosecutor;

- in one case an on-farm inspection revealed that were no medicine records or prescriptions at all on the farm. The farmer was sent a written request to correct the situation or face the threat of sanctions. This case is still ongoing and consequently sanctions have not yet been applied;
- in another case a sample was taken at slaughter in April 2009. The result (non-compliant for avermectin) was sent in August 2009 and follow-up was initiated one month later. This comprised of an inquiry by telephone and a request to the farmer to send copies of the treatment records. The farmer explained that he had forgotten about the withdrawal period when he sent the animal for emergency slaughter. The farmer was issued a warning;
- although figures indicated that in one *Département* visited 25% of the cross-compliance checks had resulted in changes to payments, it could not be established what proportion of these were related non-compliances concerning the use of veterinary medicinal products.

Conclusions on Enforcement Measures

There is a comprehensive legal framework for the application of administrative and penal sanctions. However, the effectiveness of enforcement is compromised by the long time span between sampling, reporting of the infringement and the start of an investigation, and the absence of evidence that sanctions had been applied in a number of cases where infringements had been confirmed.

5.5 Verification and review of official controls and procedures

5.5.1 Verification procedures

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires the competent authorities to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls. Article 8 states that they must have procedures in place to verify the effectiveness of official controls, to ensure effectiveness of corrective action and to update documentation where needed.

Findings

As part of the quality system, supervision of inspection takes place in line with standard ISO/IEC 17020. It comprises supervision based on documentation and based on-site visits. Document supervision focuses on the quality of the inspection reports, the management of samples, the use of methodological tools, the use of the information system and the quality of follow-up. On-site supervision is geared to assessing the means and methods used, knowledge and inter-personal skills of inspectors. The procedures are set out in DGAL quality manual. The audit team noted that:

- standardised sampling under the national residue control plan and for inspections on farms is in place. Standardised forms are available in SIGAL;
- there are well documented procedures in place for the training and supervision of staff at all stages of controls, e.g. sampling and laboratory analysis;
- the accreditation of laboratories and the requirement to participate in proficiency tests ensures the quality of residue testing;
- the analyte-matrix combinations specified by DGAL are appropriate to maximise the possibility of detecting illegal use of veterinary medicinal products;
- laboratory performance is regularly audited and there are procedures in place that corrective

actions are taken when required.

5.5.2 Audit

Legal Requirements

Under Article 4 of Regulation (EC) No 882/2004 competent authorities are required to carry out internal audits, or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner.

Findings

The audit team noted that:

- internal audits are in place. The national French accreditation body (*Comité Français d'Accréditation (France*) - COFRAC) audited DGAL's work in relation to the national residue control plan and controls on the use of veterinary medicinal products at the end of 2009 according to norm NF EN ISO/CEI 17020.

Conclusions on Verification Procedures

The relevant requirements of Regulation (EC) No 882/2004 in relation to verification procedures have in general been met.

5.6 Multi Annual National Control Plan

Legal Requirements

Article 41 of Regulation (EC) No 882/2004 requires that each Member State prepares a single integrated MANCP. According to Article 42 it should be implemented for the first time no later than 1 January 2007 and be regularly updated in light of developments. Details on the type of general information on the structure and organisation of the systems of feed and food control and of animal health and welfare control in the Member State concerned are provided.

Findings

The audit team noted that:

- the national residue control plan and controls on veterinary medicinal products are included in the current MANCP, which has been recently reviewed. The relationships between competent authorities have been described.

Conclusions on the Multi-Annual National Control Plan

The requirements of Article 41 and 42 of Regulation (EC) No 882/2004 have been met.

6 Sector Specific findings and conclusions

6.1 RESIDUE CONTROL PROGRAMMES

6.1.1 Planning of the national residue control plan

Legal Requirements

Article 5 of Council Directive 96/23/EC provides that MSs 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, MSs shall submit any update of 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 national residue control 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

Notes de Service and the Quality Manual of DGAL include provisions on the planning of inspections.

The audit team noted that:

- planning takes place from April to September for the following year. The process takes into account the need for developing new methods, results from the previous year testing and other factors. In September there is a meeting between DGAL and AFSSA and InVS. Production data are collected by DGAL for the 26 regions. The instructions for the next year are prepared in October. Official instructions are put in SIGAL and verified in November. The plan runs from February to December;

- sector specific *Notes de Service* providing instructions for the national residue control plan in the following year are published in December. The regions consequently allocate sampling numbers to the *Départements*. The *Départements* in turn distribute sampling amongst establishments. Depending on the policy of the *Département*, either the DDPP (or DDCSPP) office or the official veterinarian at the slaughterhouse allocates samples temporally. As a result ready-to-use sampling plans are available at the earliest at the beginning of February;

- at one slaughterhouse sampling for steroids and beta-agonists was according to the local distribution plan in 2009 and 2010 clustered in a limited number of months. No sampling for any substance was scheduled for November or December. This reason for this policy was to facilitate testing efficiency and to avoid the busy end-of-year period in the laboratory;

- implementing rules for cross-compliance checks in the framework of Regulation (EC) No 1122/2009, which include aspects of veterinary medicinal product use, are published in the course of the inspection year. Cross-compliance checks were for this reason not carried out during the first months of 2009 and 2010. For the year 2009 in one *Département* cross-compliance checks had not been carried out before June of that year. This had also a bearing on the on-farm sampling for forbidden substances in the framework of the national residue control plan, where sampling has been aligned with cross-compliance checks by the *Départments*.

Conclusions on planning of the national residue control plan

Planning of the national residue control plan includes all relevant actors and takes into account relevant risks. However, the effectiveness of the plan is compromised by the fact that the plans are disseminated by DGAL relatively late in the year. Therefore sampling does not take place before February. The effectiveness is furthermore comprised by the fact that planning of sampling is in some cases limited to a number of months, either to facilitate testing efficiency in the laboratory or as a result of aligning sampling with cross-compliance checks.

6.1.2 Implementation of the national residue control plan

Legal Requirements

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

Notes de Service and the Quality Manual of DGAL include provisions on the implementation of inspections. In relation to the implementation of the 2009 national residue control plan the audit team noted that:

- samples are taken by official staff. Instructions which include targeting criteria are available in the SIGAL database. Sampling forms, also available in SIGAL, contain a section where the reasons for targeting the particular animal should be filled in. The completion of this information was inconsistent between establishments;
- adequate sampling material is provided by the *Départements*;
- a warning may be given up to 48 hours in advance of an on-farm visit. The competent authority stated that the farmer is not notified of the purpose of the visit;
- samples are taken in accordance with the plan. *Départements* had real time information on the number of samples taken. Progress in sampling is monitored by DGAL as the *Départements* have to meet and report set targets in June and September.

Conclusions on implementation of the national residue control plan

All samples were taken in accordance with the plan. The provision of appropriate sampling materials, instructions for sampling, the information and communication technology tools available to facilitate supervision of sampling, allied with training of sampling staff, underpin the effectiveness of the residue control system.

Notwithstanding the fact that the purpose of on farm inspections are not disclosed to the farmer in

advance, the possibility of giving up to 48 hours notice of on farm visits could compromise the objective of detecting the use of illegal substances.

6.1.3 Other residues control programmes

Legal Requirements

In addition to the national residue control plan, Article 11 of Council Directive 96/23/EC 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 Council Directive 96/23/EC 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. Article 19 of Regulation (EC) No 178/2002 obliges food business operators to inform the relevant competent authorities when non-compliances are detected, which may pose a risk to the consumers..

Findings

The audit team noted that:

- own checks on residues had been carried on the following premises visited: the veal slaughterhouse, the dairy plant, the layer hen farm and the apiary. The competent authority had access to the outcome of these checks;
- own controls were carried out by the dairy plant and apiary with respect to antibiotics. The packing station receiving eggs from the layer farm carried out controls in relation to antibiotics and contaminants. Approximately 25% of the farms supplying the veal slaughterhouse were sampled and tested annually for the use of forbidden substances;
- a case where an animal for slaughter had been tested positive for a forbidden substance in the company's own control program had been reported to the competent authority;
- in the case of non-compliant results following antibiotic residue testing performed by the dairy plant, the competent authority had taken action with regard to the destruction of the milk.

6.2 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).

Findings

6.2.1 General description

The national legal basis for the designation of laboratories for residue testing under the national residue control plan is the Rural Code, articles L.202-1 to L.202.5 and the Ministerial Order of 19 December 2007 fixing the conditions for the approval of all laboratories analysing samples in the field of veterinary public health.

There are three NRLs in France covering all of the substance groups listed in Council Directive 96/23/EC. For the 2010 national residue control plan, there are 43 routine laboratories carrying out analyses under the national residue control plan in addition to the three NRLs. (In 2009 33 routine laboratories were used). All of the laboratories are state-funded.

All methods used in the national residue control plan are developed by the respective NRLs and disseminated to the routine field laboratories. The laboratories must use these methods (which have the status of 'approved' methods) and are not free to develop or use other methods.

All laboratories involved in the national residue control plan are required to be accredited to ISO 17025. The national accreditation body COFRAC has published a list of all of the analytical methods included in each laboratories accreditation scopes. This is publicly available on the COFRAC web site http://www.cofrac.fr/fr/recherche/default.htm

Not all methods listed in the national residue control plan are necessarily included in the accreditation scope. However this is permitted by DGAL under a provisional arrangement (of 18 months duration which is non-renewable) whereby laboratories commit themselves to apply to have those methods included in the accreditation scope.

The audit team noted that:

- for the 2010 plan a total of six such provisional arrangements are in place, having been issued in late 2009. In general the agreements cover one or two methods per laboratory and in one case, accreditation had been granted for the method in question in the period since issuing the provisional arrangement;
- one laboratory in the network – AFSSA LERPRA (Sophia-Antipolis) whilst accredited to ISO 17025 for serological testing is neither accredited for any residues methods (it currently analyses pesticides in honey) nor is it included in the provisional arrangements from DGAL. This laboratory had been the only laboratory in the network testing antimicrobials and heavy metals in honey prior to October 2009. For the 2010 national residue control plan, antimicrobials and heavy metals in honey will be tested by the NRLs AFSSA LERMVD (Fougères) and AFSSA LERQAP (Maisons-Alfort) respectively;
- AFSSA LERVMD Fougères is also not included in the provisional arrangement with DGAL even though the methods for which it functions as a routine field laboratory (anticoccidials in muscle and eggs, non-steroidal anti-inflammatory drugs in milk and antibiotics in honey) are not included in the accreditation scope to ISO 17025;
- target turnaround times for the sending of samples and from sample receipt to reporting of a result are established by DGAL. Samplers are allowed one month to submit a sample, once taken. Screening laboratories are allowed one month in which to generate a screening result. If it screens positive, the laboratory is given a further month in which to confirm the result – whether this takes place in the screening laboratory or in one of the NRLs;
- it was seen that in 2008, DGAL had written to 16 laboratories with a warning about delays in the reporting of screening and confirmatory results. There was no evidence that this exercise had been repeated in 2009 even though the proportion of delayed results had increased in one of the laboratories visited.

6.2.2 On-the-spot visits in the laboratories

The audit team visited four laboratories – one NRL (AFSSA LERMVD in Fougères) and three routine field laboratories in *Département* Nos 19, 87 and 12. The audit team noted that:

- all laboratories were well equipped with modern, state of the art equipment including LC-MS/MS, GC-MS/MS, GC-MS and HPLC with DAD, FL and UV detectors;
- the number of staff in each laboratory was commensurate with the tasks to be performed;
- comprehensive staff training files were available in each laboratory and all of the staff interviewed were knowledgeable on issues such as method validation and quality control;
- COFRAC had regularly performed audits – roughly every 15 months - on each of the laboratories and the outcome of these audits was favourable. On those occasions where shortcomings were detected, actions had been taken to rectify the problems and COFRAC had accepted these actions prior to the reissuing of the accreditation certificate;
- internal audit programmes were in place in each of the laboratories and, as for the COFRAC audits, where shortcomings had been found (which occasionally had not been remarked upon by COFRAC) rectifying actions had been carried out and verified by the quality management team carrying out the audits;
- with the exception of AFSSA LERVMD which organises proficiency tests, each of the routine laboratories visited had participated in the relevant proficiency tests organised by the French NRLs. In all cases performance was satisfactory;
- each of the laboratories was performing in a manner consistent with ISO 17025 accreditation;
- with the exception of AFSSA LERVMD, all of the laboratories had direct access to the SIGAL database for entry of screening and (if applicable) confirmatory results.

6.2.2.1 AFSSA LERVMD Fougères - NRL

Findings

AFSSA Fougères is the NRL for the following substance groups listed in the Annex to Council Directive 96/23/EC: A6, B1, B2e, B2f (carbadox, olaquindox but excluding corticosteroids) and B3e.

The laboratory – which is also a CRL - functions principally as an NRL, however it also carries out a limited number of tests as a routine field laboratory – for example it is the only laboratory in the network carrying out tests for anticoccidials in eggs, non-steroidal anti-inflammatory drugs in milk and antibiotics in honey.

The audit team noted that:

- the laboratory carried out all of its NRL functions as required by Article 14 of Directive 96/23/EC;
- the laboratory organised six proficiency tests since 2008 to date covering a range of the substance groups for which it has NRL responsibilities. A number of other proficiency tests are scheduled for 2010. The laboratory is currently seeking accreditation as a provider of proficiency tests;

- the laboratory has developed and disseminated a number of analytical methods to the routine field laboratories. Training in the implementation of methods is held on-site and attendance lists could be reconciled with training records of staff in the routine field laboratories visited;
- out of 32 analytical methods for residues of veterinary drugs in place, 13 are currently within the scope of accreditation;
- the laboratory carried out approximately 300 analyses in 2009. In several cases selected at random by the audit team, turnaround times from sampling to analysis were in line with the 30 day target figure specified by DGAL;
- analytical methods examined by the audit team (e.g. nitroimidazoles in animal tissues and eggs by LC-MS/MS) were well validated in accordance to Commission Decision 2002/657/EC, were run with appropriate quality controls and were fit for purpose. However, the methods for antibiotics in honey are not yet validated though there are plans to do so before the first honey samples for 2010 are delivered to the laboratory later in the year.

6.2.2.2 Laboratoire Départemental de la Haute-Vienne, Limoges

Findings

Under the national residue control plan this laboratory is responsible for testing inter alia thyrostats (A2), steroids (A3), resorcylic acid lactones (A4), beta agonists (A5) and a number of A6, B1, B2f (corticosteroids only), B3a, B3b and B3c compounds in a range of matrices. The methods used have all been developed in the respective NRLs and been transferred.

The audit team noted that:

- of the 74 approved methods in place (for residues of veterinary medicinal products, pesticides and contaminants) used in the national residue control plan, 42 are currently within the scope of accreditation of the laboratory and 27 are foreseen to be added to the scope in 2010. Methods are not used for the national residue control plan until they have been validated in-house first. For example, the laboratory received the protocol for a new LC-MS/MS method for quinolones in animal tissues in December 2009 from AFSSA LERVMD. This method will not be used until validation (which is under way) is completed and it is also one of the methods which will be presented to COFRAC during the next audit of the laboratory which is foreseen for June 2010;
- the laboratory receives approximately 2500 samples per annum from 18 different *Départements*;
- in contrast to the other laboratories visited, there was no validation SOP in place. The person responsible for running the method (who will have received training in the respective NRL) can decide on a method-by-method basis which performance parameters in Commission Decision 2002/657/EC will be assessed;
- several methods examined by the audit team (corticosteroids in hair by LC-MS/MS, nitroimidazoles in muscle and feedingstuffs by LC-MS/MS and chloramphenicol by GC-MS (NCI)) had been validated according to Commission Decision 2002/657/EC and estimates for CC alpha (for the methods in confirmatory mode) and CC beta (for the methods in screening mode) satisfied the Community Reference Laboratory (CRL)-recommended concentrations and MRPLs where applicable. Not all of the requirements of Commission Decision 2002/657/EC (e.g. analyte stability and within-laboratory reproducibility) had been included in the validation files and as noted in the Corrèze laboratory, in the case of tissues

(e.g. muscle, liver etc), validation had been carried out on a mixed range of 'representative' animal tissues and a formal statistical analysis had not been performed to assess any matrix interactions;

- in the raw data file selected at random for a sample tested for chloramphenicol in bovine muscle, the calibration curve had been made up in shrimp muscle. However the recovery of the internal standard (d5 chloramphenicol), the positive control spike (0.2 µg/kg) and a certified reference material (assigned concentration of 7 µg/kg) run in this assay were all acceptable, thus the validity of the result (which was compliant for the sample) could be demonstrated.

6.2.2.3 Corrèze Laboratoire Départemental d'analyses, Le Treuil, Tulle

Findings

Under the national residue control plan this laboratory is responsible for testing inter alia thyrostats (A2), steroids (A3) and beta agonists (A5) and a number of B1, A6, B3a and B3b compounds in a range of matrices. The methods used have all been developed in the respective NRLs and been transferred.

The audit team noted that:

- all methods used in the national residue control plan, with the exception of the method for organophosphate pesticide residues (B3b) are included in the scope of accreditation;
- the laboratory receives approximately 2500 samples per annum from 16 different *Départements*;
- a log of sample turnaround times is maintained. It was seen in 2008 and 2009 that 8% and 19% of samples took longer than 70 days to process from receipt to reporting (i.e. in excess of DGAL targets). These data are difficult to interpret since a screening positive sample has to be confirmed by the NRL and the file is only closed once the result is received from the NRL. Therefore it was not possible to identify whether the delays were necessarily caused by problems in the Corrèze laboratory. It was noted that the majority of delays were for natural steroids. These are confirmed in the NRL using several approaches including isotope ration GC-MS and this machine had broken down during 2009. Recent results generated by the Corrèze laboratory were within DGAL target times;
- there was a comprehensive validation SOP in place in line with Commission Decision 2002/657/EC (with the exception of analyte stability which was not included) and, for the methods examined by the audit team (beta-agonists and stanozolol in urine by LC-MS/MS, beta-agonists in lung tissue by LC-MS/MS, thyrostats in urine, tissues and feedingstuffs by LC-MS/MS and steroids in urine, animal tissues and hair by LC-MS/MS), all had been validated according to the protocol. It was noted that in the case of tissues (e.g. muscle, liver etc), validation had been carried out on a mixed range of 'representative' tissues (e.g. the 20 samples chosen for the estimation of CC alpha and CC beta had been comprised of five bovine muscles, five porcine muscles etc.). Possible tissue-analyte interactions had not been considered (for example by performing a multi-factorial experiment with analysis of variance);
- estimates for CC alpha (for the methods in confirmatory mode) and CC beta (for the methods in screening mode) satisfied the CRL-recommended concentrations for the wide range of analytes tested. Any particular problems (e.g. extraction) encountered with certain analytes were reported in the validation files;

- raw data files for several analytical runs selected at random from the above methods were examined by the audit team. In each case samples were analysed and calibrated against a five-point spiked-matrix-extracted standard curve with appropriate internal standards and blank and spiked quality control samples. The results for the requisite quality control samples demonstrated that the methods had performed as expected and were fit for purpose. For those methods for which quality control charts are maintained, long term performance of the methods was seen to be satisfactory.

6.2.2.4 Aveyron Labo, Rodez

Findings

Under the national residue control plan this laboratory is responsible for testing inter alia steroids and beta agonists and a number of A6 and B1 compounds in a range of matrices. The methods used have all been developed in the respective NRL and been transferred. The audit team noted that:

- all methods used in the national residue control plan (18) are included in the scope of accreditation;
- the laboratory receives approximately 500 samples per annum from six different *Départements*;.
- while a log of sample turnaround times is not maintained, examination of the raw data for approximately 100 samples selected at random by the audit team demonstrated that target turnaround times had been met in every case;
- in the (rare) event of a received sample not being suitable for analysis, formal procedures were in place to reject the sample and request resubmission;
- there was a comprehensive validation SOP in place and all methods examined (chloramphenicol in muscle by LC-MS/MS and sulphonamides in animal tissues by HPLC-UV) had been validated in-house according to this protocol which is in line with Commission Decision 2002/657/EC. All of the validation parameters required by this Decision had been estimated, including stability of the analyte;
- raw data files for several analytical runs for the above methods were selected at random examined by the audit team and the results for the requisite quality control samples demonstrated that the methods had performed as expected and were fit for purpose;
- only one method has not been validated – the TLC screening method for sulphonamides. The method has been in place in the laboratory since 1992 and performance in proficiency tests for the method has been satisfactory over the years. Nevertheless, the absence of in-house validation data had been identified in the most recent internal audit carried out and the method is scheduled to be validated in accordance with the in-house protocol.

Conclusions on laboratories

The performance of each of the laboratories visited by the audit team was consistent with that expected of laboratories accredited to ISO 17025. The comprehensive system of proficiency tests organised by the NRLs and the mode of dissemination of NRL-developed methods to the laboratory network helps to assure consistent laboratory performance. Notwithstanding some differences in the approach taken to validation of transferred analytical methods in the different laboratories, it is concluded that the competent authorities can have confidence in the analytical results generated by these laboratories, thus underpinning guarantees on the residue status of food of animal origin.

6.3 Veterinary medicinal products and feeding stuffs

6.3.1 Distribution and use of veterinary medicinal products

Legal Requirements

Conditions governing the distribution and use of veterinary medicinal products are laid down in Articles 65-71 of Directive 2001/82/EC. Article 67(aa) of Directive 2001/82/EC requires that veterinary medicinal products for food producing animals are only dispensed to the public under a veterinary prescription unless exempted under the conditions laid down in Article 2 of Commission Directive 2006/130/EC.

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

With regard to the use of certain hormones and beta-agonists for zootechnical and/or therapeutic purposes, the conditions governing such use are laid down in Articles 4, 5, 6, 8 and 9 of Council Directive 96/22/EC.

Findings

The country profile describes the organisations responsible for the authorisation of veterinary medicinal products and for the authorisation and control of manufacturers, wholesalers and retailers. Although the names of organisations at regional and *Départemental* level have changed since the reorganisation of 1 January 2010, the system operates as before.

Information on the number and type of veterinary medicinal products authorised nationally and on the number of manufacturers and wholesalers of veterinary medicinal products is available on the following website: www.anmv.afssa.fr

Veterinary medicinal products are sold to farmers by veterinary practitioners and producer associations, called *groupements*, and dispensary pharmacists.

Most veterinary medicinal products for food producing animals are scheduled as prescription-only. Minimum requirements for a prescription are laid down in national legislation. Where applicable, the withdrawal period should be mentioned on the prescription. Repeat prescriptions may be issued without the need to examine the animals, for a year following the initial prescription, depending on the class of drug and the agreement between the veterinarian and the farmer.

The audit team noted that:

- the medicines stocks seen at the farms visited contained only substances that could be rightfully in the possession of the farmer. Stocks were in accordance with the records;
- according to national rules copies of prescriptions retained by the veterinarian must state the batch number of the veterinary medicinal product. There is, however, no requirement that a batch number is indicated on the prescription given to the farmer;
- not all veterinarians note batch numbers on prescription copies. This issue has now been included in the post academic pharmacy training for veterinary practitioners.

Conclusions on distribution and use of veterinary medicinal products

In general the requirements of Articles 65-71 of Directive 2001/82/EC, Article 2 of Commission Directive 2006/130/EC, Articles 2, 8 and 9 of Council Directive 90/167/EEC, Articles 9, 10, 11 and 13 of Regulation (EC) No 183/2005 and articles 4, 5, 6, 8 and 9 of Council Directive 96/22/EC have been met. Thus the system for distribution and use of veterinary medicinal products underpins guarantees on food safety.

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

Legal Requirements

Competent authorities have a general obligation under Article 80(1) of the Community code relating to veterinary medicinal products (Directive 2001/82/EC) to carry out inspections throughout the distribution chain of veterinary medicinal products in order to verify compliance with the provisions of the Directive 2001/82/EC. Specific obligations for competent authorities are laid down in Articles 65, 66, 68, 69 of the above Directive. With regard to ensuring that the production of medicated feeding stuffs is in accordance with Council Directive 90/167/EEC, the rules governing control functions by the competent authorities are laid down in Articles 4, 9 and 13 of said Directive.

The veterinary medicines record keeping requirements of stock owners are laid down in Article 69 of Directive 2001/82/EC, Article 10 of Council Directive 96/23/EC and Annex I, Part A III, point 8(b) to Regulation (EC) No 852/2004. The requirements for food chain information accompanying animals submitted for slaughter for human consumption are laid down in Annex II, Section III, point 3(c) to Regulation (EC) No 853/2004.

Findings

Of all farms keeping food producing animals, 1% is inspected annually in the framework of cross-compliance. Additionally there was a target to inspect 5% of pig farms specifically for antibiotic use. There are also (bi)annual checks on cattle farms by private veterinarians contracted by the competent authority. These checks are not considered to constitute or replace official controls. The contracted veterinarians are nevertheless obliged to report non-compliant findings.

The audit team noted that:

- adequate instructions and check lists are available and used for checks on the use of veterinary medicinal products;
- in 2008, 4332 inspections were carried out in relation to the use of veterinary medicinal products and 5743 inspections regarding the farm register. This resulted in 397 administrative warnings, nine warnings with an absolute deadline for compliance and six notifications to the public prosecutor;
- a veterinary practitioner, contracted to carry out health checks, was not aware of the obligation to report non-compliant findings although a contract had been signed to this effect. Notwithstanding that these health checks are not considered official controls, the practice of performing checks on own clients represents a conflict of interest;
- food chain information was collected at the rabbit farm in order to be sent with the animals to the slaughterhouse;
- for adult cattle and veal calves a declaration on food chain information has been introduced in the form of an attachment to the cattle passport. It was seen in three slaughterhouses that declarations were not checked because no instructions had been received from DGAL in this regard. Thus animals arriving without a declaration or with an unsigned declaration were accepted for slaughter;

- for pigs and small ruminants the competent authority did not require the operator of the slaughterhouse to receive food chain information with the animals for slaughter. No instructions on this subject had been issued by the DGAL and official veterinarians and technicians were not aware of this requirement of Regulation (EC) No 853/2004. At one slaughterhouse food chain information for pigs was required by the establishment operator but this information was not verified by the competent authority.

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

Official controls on the use of veterinary medicinal products are generally in line with EU requirements. However, the fact that the requirement of Regulation (EC) No 853/2004 Annex II Section III to deliver food chain information with the animals for slaughter is not being enforced does not facilitate targeting of animals in the context of the national residue control plan. The checks carried out by private practitioners contracted by the state, although not considered official controls, have limited value in relation to detecting and remedying non-compliances in the use of veterinary medicinal products.

6.4 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 for the food chain.

Findings

The National Stud (*Les Haras Nationaux*) is a designated public agency responsible *inter alia* for the identification of equine animals. This agency operates under the authority of MAAP and has its branches in all *Départements* of France. Identification of equine animals can also be done by private veterinary practitioners who have been authorised by the National Stud to carry out this procedure on its behalf.

According to the national legislation, identification of all equine animals has been compulsory since 2001 and since 1 January 2008 all equine animals have to be chipped with an electronic transponder. An equine animal is considered identified when the identification document and the accompanying registration card (attesting the ownership) has been issued, an electronic transponder has been implanted in the animal and the animal has been registered in the national database (SIRE), managed by the National Stud.

According to the national requirements, the time limit for the owner to identify a newborn equine animal is six months and a change of ownership has to be reported within eight days.

If the owner applies for a duplicate of the identification document, the animal will not be automatically excluded from the food chain. The owner will be given the opportunity to prove (via the veterinarian) that no medical treatment which would result in the exclusion of the animal from the food chain has been administered. The absence of previous identification of the animal will be checked through the SIRE database.

DGAL informed the audit team that controls on the identification of equines are carried out by veterinary officials from the *Départements* on occasions such as visits to stables, controls of public events (horse fairs, markets etc.) and upon arrival of animals at the slaughterhouse. The access to the SIRE database has been granted to these veterinary officials by letter (No. 02587 of 20 November 2008).

The audit team noted that:

- several types of identification documents are in place for different categories of equine animals - depending on the sport discipline, animal species and origin. Some documents published on the website of *Les Haras Nationaux* are not in accordance with the model document set out in Annex I to Commission Regulation (EC) No 504/2008. All identification documents include a section for the registration of medical treatments;
- adult *equidae* which have not been identified before in accordance with Commission Regulation (EC) No 504/2008 or Decisions 93/623/EEC or 2000/68/EC, are eligible for slaughter for human consumption even though such animals could have been treated with phenylbutazone. Medical treatments in the relevant section of their identification documents would only be recorded for the period after the identification.

Conclusions on identification of *equidae* and medicines records requirements

In general the requirements of Commission Regulation (EC) No 504/2008 have been met. However, the fact that *equidae* with an unknown treatment history are identified beyond the deadline set in that Regulation (31 December in the year of birth or six months after birth, whichever comes later), and that these horses can consequently be sent for slaughter for human consumption, means that the competent authority can not have confidence in residue/contaminant status of meat derived from such animals.

7 Overall Conclusion

In general the system of residues controls and controls on the use of veterinary medicinal products

is in compliance with EU rules. Strong points of the control system include the comprehensive legal framework in place, the work instructions issued to staff, the formal system of staff training, the provision of appropriate materials for sampling, the information and communication technology tools available for reporting and real-time monitoring of implementation of controls, the accreditation of laboratories to ISO 17025 and satisfactory analytical performance of the laboratory network. However, the effectiveness of the control system is compromised by several factors including the clustering of sampling, the notification of farmers in advance of inspections, not using food chain information, the long time span between an infringement and the start of an investigation and the low probability of an infringement leading to any sanctions.

8 Closing Meeting

A closing meeting was held on 1 March 2010 with representatives of the central competent authority and *Les Haras Nationaux*. At this meeting, the audit team presented the main findings and preliminary conclusions of the mission. The authorities did not express disagreement with the findings and explained that:

- the implementation of food chain information is being discussed with the stakeholders and that it will be required for cattle and pigs during the course of 2010 and for small ruminants in 2011;
- laboratories had been reminded recently to observe the sample turnaround time stipulated in the relevant *Note de Service*;
- as a policy decision on-farm sampling has been combined with cross-compliance checks for which instructions are usually only available later in the year. This is the reason why samples have not been taken at the start of the year. It is unlikely that this policy will be changed;
- at present only horse identification documents are issued in accordance with Commission Regulation (EC) No 504/2008.

9 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 specific audit report.

N°.	**Recommendation**
1.	Ensure that food business operators operating slaughterhouses do no not accept animals (other than wild game) for slaughter unless they have been provided with relevant food chain information, in accordance with Section III of Annex II to Regulation (EC) No 853/2004, and in this context, ensure that available information shall be taken into consideration when choosing samples, in accordance with point 2.1. of the Annex to Commission Decision 98/179/EC.
2.	Ensure that whenever official samples are taken, sampling is unforeseen, unexpected and effected at no fixed time and on no particular day of the week and that all precautions necessary to ensure that the element of surprise in the checks is constantly

N°.	Recommendation
	maintained, in accordance with point 2.1. of the Annex to Commission Decision 98/179/EC.
3.	Ensure that follow-up of all non-compliant results is carried out by the competent authority, in line with the requirements of Articles 12, 13, 16-18, 23 and 24 of Council Directive 96/23/EC and Article 54 of Regulation (EC) No 882/2004.
4.	Ensure that in residue laboratories samples are not directly identifiable to the farm of origin in order to guarantee impartiality in the implementation of this official control in accordance with Article 4.4 of Regulation (EC) No 882/2004.

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

http://ec.europa.eu/food/fvo/ap/ap_fr_2010-8435.pdf

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
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		
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.	98/179/EC: Commission Decision of 23 February

Legal Reference	Official Journal	Title
	31-34	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		
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.	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005

Legal Reference	Official Journal	Title
	1-16	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
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

Legal Reference	Official Journal	Title
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
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		

Legal Reference	Official Journal	Title
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