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FINAL REPORT OF A SPECIFIC AUDIT

CARRIED OUT IN

THE CZECH REPUBLIC

FROM 26 APRIL TO 03 MAY 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

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) specific audit in the Czech Republic, which took place between 26 April to 3 May 2010, as part of the general audit of the Czech Republic carried out under the provisions of Regulation (EC) No 882/2004 on official food and feed controls.

The specific audit evaluated the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, including the controls on the distribution and use of veterinary medicinal products and feed additives, the use of which may give rise to residues in such products. The evaluation was based on the standards set out in Council Directive 96/23/EC, and other relevant European Union (EU) legislation in this field, including legislation on the control and distribution of veterinary medicinal products. The mission assessed the performance of the competent authorities and other officially authorised entities involved in residues and veterinary medicinal product controls and the legal and administrative measures put in place to give effect to the relevant EU requirements.

It is therefore concluded that the national residues control plan is designed in line with EU requirements. An effective flow of sampling information between all levels of the competent authority and the laboratories provides for adequate supervision. Effective follow-up actions are carried out after non-compliant residue results. The effectiveness of residue controls could be further strengthened by including certain commonly used substances in the scope of testing. All laboratories involved in residues analyses are accredited to ISO 17025 and in general, the competent authority can have confidence in the laboratory results. Overall, conditions governing the distribution and the use of veterinary medicinal products comply with the EU requirements. However, some shortcomings with regard to marketing authorisation and controls on the use of veterinary medicinal products undermine the overall effectiveness of the residues control system. Requirements of Regulation (EC) No 882/2004 relevant to this specific audit are complied with, except in relation to shortcomings in official controls on the use of veterinary medicinal products. The report makes a number of recommendations to the Czech Republic 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
CAI	Czech Accreditation Institute
CBI	Czech Breeding Inspectorate
CCα / CCβ	Decision Limit / Detection Capability
CISTA	Central Institute for Supervising and Testing in Agriculture
CRL	Community Reference Laboratory
CZK	Czech Crown (the official currency of the Czech Republic)
DICT	Department for Information and Communication Technologies
DG(SANCO)	Health and Consumers Directorate-General
DVI	District Veterinary Inspectorate
EC	European Community
ELISA	Enzyme-linked immuno-sorbent assay
EU	European Union
FVO	Food and Veterinary Office
GC-MS	Gas Chromatography-Mass Spectrometry
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC
HACCP	Hazard Analysis Critical Control Point system
HPLC –DAD/FL	High Performance Liquid Chromatography with Diode Array Detector / Fluorescence Detector
HPLC –UV/Vis	High Performance Liquid Chromatography with Ultraviolet / visible light wavelength detector
ISCVBM	Institute for State Control of Veterinary Biologicals and Medicaments
ISO	International Organisation for Standardisation
IS SVA	State Veterinary Administration Information System
LC-MS/MS	Liquid Chromatography-(Tandem) Mass Spectrometry
LIMS	Laboratory Management Information System
MANCP	Single Integrated Multi-Annual National Control Plan
MG/LMG	Malachite Green/Leucomalachite Green
ML	Maximum Level
MoA	Ministry of Agriculture
MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
NRCP	National Residue Control Plan
NRL	National Reference Laboratory

PCBs	Polychlorinated biphenyls
PHD	Public Health, Veterinary Hygiene and Ecology Department
PT	Proficiency Testing
RASFF	Rapid Alert System for Food and Feed
RL	Routine Laboratory
RVA	Regional Veterinary Administration
SOP	Standard Operating Procedure
SVA	State Veterinary Administration
SVI	State Veterinary Institute

1 Introduction

The Specific Audit formed part of the FVO's planned mission programme. It took place in the Czech Republic from 26 April to 3 May 2010. The audit team comprised two inspectors from the Food and Veterinary Office (FVO) and one expert from a European Union (EU) Member State. Representatives from the central competent authority accompanied the audit team for the duration of the audit. An opening meeting was held on 26 April 2010 with the competent authorities. 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 objectives of the specific audit were to:

- verify that official controls are organised and carried out in accordance with relevant provisions of Regulation (EC) No 882/2004, and the multi-annual national control plan (MANCP) prepared by the Czech Republic;

- to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, including the controls on the distribution and use of veterinary medicinal products and feed additives, the use of which may give rise to residues in such products. The mission was based on Council Directive 96/23/EC and other relevant EU legislation in this field, including legislation on the control and distribution of veterinary medicinal products.

In terms of scope, the audit concentrated primarily on:

- Regulation (EC) No 882/2004 - the organisation of official controls (Artt. 3-7), control and verification procedures and methods (Artt. 8-10), enforcement (Artt. 54-55), and MANCP (Artt. 41-42);

- the roles of the competent authorities at central and regional levels, the legal and administrative measures in place to give effect to the relevant EU requirements, controls with regard to residues and veterinary medicinal products and their operation, and the performance of residue laboratories.

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 the State Veterinary Administration of the Czech Republic (SVA) at central level
	Regional	**3**	Meetings at the Regional Veterinary Administration (RVA) offices in Brno and Ceske Budejovice and meeting at the District Veterinary Inspectorate (DVI) office in Blansko
LABORATORIES		**2**	Institute for State Control of Veterinary Biologicals and Medicaments and State Veterinary Institute Jihlava (National Reference Laboratories)
FARMS		**3**	Fish (trout), pig and poultry (hen) farms
ESTABLISHMENTS		**1**	Slaughterhouse

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.

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 control plans 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 the Czech Republic. 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

This was the first residues mission carried out in the Czech Republic since its accession to the EU in 2004.

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

A description of the competent authorities with responsibility for topics falling within the scope of this audit is given in the Country Profile for the Czech Republic (DG(SANCO)/8101/2009-Final CP), hereafter referred to as the Country Profile, which can be accessed at: http://ec.europa.eu/food/fvo/country_profiles_en.cfm.

The audit team noted that:

- the State Veterinary Administration (SVA) of the Ministry of Agriculture and its services at regional and district levels are responsible for the development and implementation of the National Residue Control Plan (NRCP) and certain controls on the use of veterinary medicinal products by veterinary practitioners and on farms;

- the Institute for State Control of Veterinary Biologicals and Medicaments (ISCVBM) of the SVA is responsible for, amongst others: the licensing of manufacturers and distributors of veterinary medicinal products including medicated feed; the authorisation of veterinary medicines; market surveillance and controls throughout the distribution chain of veterinary medicinal products, including veterinary practitioners and farmers. A laboratory of the ISCVBM also performs analyses of official samples for the NRCP;

- the Czech Breeding Inspectorate (CBI) and the SVA are responsible for controlling the identification and registration of equine animals.

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 arrangements in place to provide for co-ordination and co-operation between the competent authorities relevant for this Specific Audit are described in the Country Profile.

According to the SVA, mechanisms are in place to ensure effective co-operation and co-ordination between relevant competent authorities in the event of non-compliances being identified. In particular, there is an information exchange system in place between the laboratories and the various levels of the SVA which also includes the Central Institute for Supervising and Testing in Agriculture (CISTA), when problems are detected in feed. The co-operation with CISTA is based on an agreement on mutual co-operation (see Section 6.1.3.1).

The audit team noted that:

- in the regions visited, the audit team checked files describing the actions taken when laboratories detected non-compliances in NRCP samples. It could be seen that the arrangements for ensuring effective co-ordination and co-operation between the relevant competent authorities had been followed in practice;

- there has been an agreement in place between the SVA and the laboratories analysing samples taken for the NRCP since 1995 which provides for regular communication of results, including notification when a non-compliant result is detected. According to the SVA and representatives of the laboratories met, e-mail and telephone is used to communicate the results of analyses and it was possible to confirm that this is being done.

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

According to the SVA, co-ordination and co-operation between the central, regional and district levels (and laboratories) is ensured by various means including: regular meetings within and between the different levels; the provision of detailed instructions and guidance and; by regular reports regarding the implementation of official controls and any problems encountered.

The audit team noted that:

- in the regions visited it was possible to confirm that there is a regular routine flow of information between the different levels of the competent authorities regarding the implementation of the NRCP and the actions taken in the event of a non-compliance;

- the SVA is currently putting in place a sophisticated database within their information system intended to enhance co-ordination between the various levels of the SVA by providing up-to-date information on the controls to be performed and their results. This system was being used in the regions visited and is expected to be fully operational in all regions during this year;

- there are various types of controls carried out on the use of veterinary medicinal products. In the RVAs visited the majority of these controls were not co-ordinated (see Sections 5.3.2 and 6.3.2).

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

According to the SVA, no tasks related to official controls have been delegated within the meaning of Article 5 of Regulation (EC) No 882/2004.

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

According to the SVA, plans are in place for actions to be taken in the event that feed or food is found to present a serious risk, particularly in relation to rapid alerts issued through Rapid Alert System for Food and Feed (RASFF). There are requirements for co-operation and co-ordination of activities between and within the competent authorities involved (see Section 5.1.2).

The audit team noted that:

- in one case seen which involved the issuing of an alert under the RASFF (leucomalachite green in imported fish), action had been taken to prevent the sale of potentially contaminated products and arrangements put in place to withdraw and destroy products.

Conclusions on Competent Authorities

Competent authorities with responsibilities for topics within the scope of this audit have been designated and arrangements are in place to ensure that there is adequate co-operation and co-ordination between and within the relevant authorities, both on a routine basis and also in case of non-compliances and in the event that the contingency plan for dealing with serious issues in food or feed is implemented. However, co-ordination is not always taking place with regard to controls on the use of veterinary medicinal products.

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:

- according to the SVA, there are a number of national legal provisions which provide a general basis for controls by all competent authorities, including: Act No 552/1991 on State Control (amended); the Administrative Procedure Code (Act No 500/2004) and; Act No 106/1999 on Free Access to Information. Additional Acts set down specific obligations related to different sectors and those most relevant to the scope of this audit include the Act on the Protection of Animal Health and Eradication of Animal Infectious Diseases; the Veterinary Act (No 166/1999) and; the Pharmaceutical Act (No 378/2007).

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 audit team noted that:

- a document 'Conflict of the ISCVBM Employees' addresses the issue of potential conflict of interest. According to representatives of the SVA, there are no specific measures in place to ensure that officials are free from conflict of interest but, officials must ask permission to carry out any private work;

- according to the officials met, there are sufficient resources available to enable the tasks within the scope of the audit to be implemented as required;

- in the regions visited, it was confirmed that sufficient equipment is provided to enable samples to be collected, stored and transported appropriately. However, it was noted that the means used to seal samples were not always sufficient to ensure their legal validity (see section 6.2.2).

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 the regions visited, the educational status for officials implementing the NRCP and performing controls on farms were described, which included post graduate or professional qualifications appropriate for the tasks being performed;

- according to the SVA, regular training is provided to officials responsible for carrying out controls within the scope of this audit either through participation in relevant courses or by providing instructions and guidance. A cascade system should ensure that certain relevant information can be passed onto colleagues at the district level. It was possible to verify that all officials met who were collecting samples for the NRCP had participated in relevant training, but no evidence was provided to show that officials responsible for carrying out controls on the use of veterinary medicinal products on farms or at private veterinarians had received appropriate training. On the fish farm visited, officials carrying out regular controls had not identified that treatment records were not maintained by the operator;

- through its periodic journal, the ISCVBM provides up-to-date information on a number of relevant topics including any changes in the authorisation status for veterinary medicinal products and a summary of market consumption data for certain key groups of veterinary medicines (active substances).

Conclusions on Resources for Performance of Controls

There is sufficient staff available and arrangements in place to ensure they have the necessary legal powers to perform their tasks impartially, in accordance with the relevant requirements of Article 4 of Regulation (EC) No 882/2004. Whilst officials implementing the NRCP have been trained, in relation to controls on veterinary medicinal products there was a lack of awareness of certain EU requirements concerning the use of veterinary medicinal products on farms which has the potential to weaken the overall effectiveness of the residues control system.

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

This topic was not covered during this audit.

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

The risk criteria to be taken into account when taking targeted or suspect samples as part of the NRCP are set down in instructions included in the NRCP. It is required that sampling is carried out without prior notification.

The ISCVBM collects data relating to the distribution of veterinary medicinal products which may be used for the planning and targeting of controls. The Regional Veterinary Administrations (RVAs) are required to provide summarised production data which can be taken into account when planning controls.

The audit team noted that:

- officials met were aware of the relevant risk criteria which should be taken into account when collecting samples under the NRCP and it was possible to see that sites with a previous history of non-compliance are subject to intensified sampling;

- according to representatives of the ISCVBM, their controls of veterinary practitioners and farms are carried out mainly where problems have been identified or on the basis of particular patterns in distribution data for veterinary medicinal products. There are Standard Operating Procedures (SOPs) in place for carrying out these controls. The criteria to be

followed include market data and complaints. In one case seen by the mission team, a private veterinarian was controlled by the ISCVBM as a result of market data showing that a particular veterinary medicinal product was being used which was subject to prudent use requirements;

- during 2009, a total of 186 controls on farms were carried out specifically to check on veterinary medicinal products use. Out of these, 85 were 'planned' centrally by the SVA, with the farms to be checked identified by computer analyses based on relevant risk criteria. The remaining 101 'unplanned' controls were carried out on farms selected by the local inspectors. No clear or consistent explanation of the factors taken into account for targeting these controls was provided. Inspectors met in one district gave priority to larger farms while a representative of the SVA stated that an inspection would be performed following a complaint or tip. According to the SVA, it is not obligatory to carry out such 'unplanned' controls on veterinary medicinal products use and data provided showed that the number carried out in each region during 2009 varied between zero and 26;

- according to officials met in two regions visited, random checks on the use of veterinary medicinal products may also be carried out on farms during controls for animal welfare. No data could be provided to show the number or scope of these controls on veterinary medicinal products carried out although, one inspector met stated that a locally produced check-list of relevant points is completed during approximately 10% of animal welfare controls;

- the regional veterinary inspectors met in two regions, stated that the Animal Health and Welfare Department systematically checks 20% of veterinary practitioners each year during on farm controls relating to specific animal disease control programmes;

- a representative of the SVA stated that methodical guidelines for the performance of controls on the use of veterinary medicinal products are being prepared in consultation with the ISCVBM;

- during 2009, no routine controls on veterinary medicinal products use were planned or carried out on farms keeping: bees, rabbits, game or fish. According to the SVA, it is not planned to target any such farms in 2010 despite a number of non-compliant results for fish samples collected under the NRCP in 2009 and before.

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:

- the control activities, methods and techniques specified in Article 10 of Regulation (EC) No 882/2004 were used.

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 the laboratories visited, after the receipt of samples they are codified and the code accompanies the sample throughout the laboratory. However, the identity of a sample (farm of origin) could be seen by analysts in a laboratory computer database as the samples are generally not anonymous upon receipt in 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 audit team noted that:

- comprehensive instructions and documented procedures have been put in place for the implementation of the NRCP and a standard protocol was used to accompany all samples sent for laboratory analyses;

- check-lists have been put in place for controls of veterinary practitioners and the use of veterinary medicinal products on farms with the exception of those carried out as part of animal welfare controls. In two regions visited, the inspectors carrying out such controls had developed their own aide memoires or check-lists;

- in the regions visited, reports of the official controls carried out were prepared and a copy provided to the operator. The check-lists completed during the 'planned' and 'unplanned'

controls on veterinary medicinal products use on farms were also entered into the SVA Information System (IS SVA). Corrective actions were required where appropriate and operators (or their representatives) are required to sign the report to acknowledge the results;

- a national non-compulsory template for food chain information has been made available on the SVA website and was being used in the slaughterhouse visited.

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:

- annual results on residues controls are published on the SVA website in their Information Bulletin. In one of the RVAs visited the regional annual report of official controls was published on its website;

- the ISCVBM publishes a summary of its activities on the website and in a Bulletin.

Conclusions on Organisation and Implementation of Official Controls

The organisation and planning of the NRCP and 'planned' controls on the use of veterinary medicinal products generally fulfill the relevant requirements of Regulation (EC) No 882/2004 as they are based on documented procedures which take into account relevant risk criteria which are followed in practice, using appropriate methods and techniques, and there is sufficient laboratory capacity to ensure the plans can be implemented and the results recorded and summaries published. However, the fact that the majority of controls on the use of veterinary medicinal products are carried out outside the scope of the planned arrangements and there are no procedures in place to ensure a consistent and risk-based approach means that the relevant requirements of Articles 3, 4 and 8 of Regulation (EC) No 882/2004 are not fulfilled for these particular controls. In addition, the fact that the identity of the farm from which a sample has been taken is available to the analyst in the laboratory means that the competent authority can not guarantee the impartiality of laboratory testing as required by Article 4 (4) of Regulation (EC) No 882/2004.

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.

Findings

General instructions for follow-up procedures are included in the NRCP. All steps of the procedure should be documented, including any legal action taken. Measures to be taken are laid down in national legislation i.e. the Veterinary Act No. 166/1999 and the Decree of the Ministry of Agriculture No. 291/2003. Laboratories shall immediately, and no later than within 24 hours, inform via phone and e-mail the SVA and the RVA where the sample was taken. SVA further notifies all 14 RVA coordinators through the internal system of rapid warning (e-mail communication) and recommends to RVA in question the follow-up procedures and measures to be taken in order to protect public health. Follow-up investigations are carried out by District Veterinary Inspectorate (DVI) inspectors under the RVA co-ordination or jointly by DVI and RVA inspectors. According to SVA, in case of non-compliant results for Group A and Group B1 substances the participation of an ISCVBM inspection team in follow-up investigation is required. Similarly, in case of non-compliant results for Group B2 and B3 substances, the presence of an inspection team from the SVA is foreseen. Participation of these inspection teams depends on the seriousness and urgency of situation and staff resources available. The RVA informs the SVA about the follow-up investigation through interim and final reports. Time limits for follow-up investigation have not been explicitly determined and the rule of immediate action is set in the instructions.

The audit team noted that:

- the actions taken in several (more than ten) cases following non-compliant sample results and the flow of information between and within the relevant levels of the SVA were checked in the regions visited and the following points were noted:

- follow-up investigations were carried out promptly and were properly documented following the procedures in place;

- investigations included on-the-spot inspections, documentary checks and additional samples. Where the source of the problem was suspected to originate elsewhere such as through contaminated feed, or animals coming from another farm, additional investigations were carried out on these sites;

- the follow-up files seen by the audit team showed that investigations are carried out in different regions and involve relevant competent authorities. In several cases, where contaminated feed had been identified as giving rise to non-compliant results in the NRCP, it could be seen that CISTA had taken steps to ensure the feed manufacturers implemented corrective measures;

- according to the national rules, if a non-compliant sample result is confirmed, the farm is subjected to more stringent checks for a further period of 6 or 12 months for group B or group A substances, respectively. It was possible to verify that this had been done in certain cases, including a fish farm where malachite green had been detected.

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

There is a broad range of sanctions applicable for different types of non-compliance with the requirements relating to veterinary medicinal products which are set down in national legal provisions. In most cases, the regional or district veterinary inspector may impose administrative fines or a range of 'extraordinary veterinary measures' which may include the seizing or destruction of animals or their products or the imposition of fines. In serious cases, criminal proceedings may be taken which can lead to imprisonment.

The audit team noted that:

- documents provided by the SVA showed that a range of administrative or 'extraordinary veterinary measures' were imposed where non-compliant sample results were obtained (see Section 5.4.1.) which also may be considered as sanctions;

- according to the ISCVBM, during 2008 and 2009 administrative measures were imposed for a range of non-compliances including dispensing veterinary medicines without a prescription, breaches of the terms of the marketing authorisation, sale of veterinary medicinal products not intended for retail sale and shortcomings in the use of veterinary medicines. In 2009, fines were imposed totalling 322,500 CZK (approximately €13,500).

Conclusions on Enforcement Measures

Procedures are in place which ensure that appropriate and prompt action is taken when non-compliances with requirements within the scope of this audit are detected, as required by Article 54 of Regulation (EC) No 883/2004. There is a range of sanctions available which may be imposed when such non-compliances are found which are potentially dissuasive, proportionate and effective as required by Article 55 of Regulation (EC) No 882/2004.

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

According to the SVA, a number of approaches are followed to ensure the effectiveness of official controls which include: information systems to monitor implementation of the NRCP and 'planned' on farm controls on the use of veterinary medicinal products and; on-the-spot supervision of

inspectors. Additional measures include regular discussion meetings with inspectors and appraisals of work performance.

The ISCVBM ensures the effectiveness of official controls mainly by checking the reports from inspections and through regular meetings with the inspectors.

The audit team noted that:

- in the regions visited, it was possible to confirm that the information systems provide an effective means of monitoring the implementation of the NRCP and 'planned' controls of veterinary medicinal products;

- according to officials met in one region visited, the relevant regional inspectors carry out regular on-the-spot checks to observe the implementation of controls by the district inspectors. Documents were provided showing that corrective measures, including the provision of training, were taken where weaknesses were identified;

- although it is possible to monitor the implementation of certain 'unplanned' controls on the use of veterinary medicines on farms, where a standard check-list is used and the results have been entered into the IS SVA, this is not possible for the random checks on veterinary medicines use included in animal welfare controls. In this case, the controls are recorded as documentary checks, which could include requirements other than those concerning veterinary medicines and a summary of the controls performed is not included in the IS SVA.

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

According to the SVA an office for internal audits has been established and regular audits carried out of the regional and district veterinary administrations.

The audit team noted that:

- according to the SVA, audits which included in their scope official controls of residues and the use of veterinary medicinal products are carried out in regions on a rotating basis. The implementation of the NRCP was included in an audit of all regions carried out in 2008. The next round of audits on this topic is expected to be carried out in 2013;

- in one region visited, documents were provided showing that audits of the departments for veterinary hygiene and for animal health had been audited in 2008 and 2010, respectively. The main focus of these audits was to establish whether procedures in place had been followed and relevant documents or check-lists completed as required. In one case, recommendations had been made to merge check-lists used for controls of veterinary practitioners on farms. The audits had not identified the lack of procedures for planning and implementation of certain controls on veterinary medicinal products (e.g. "unplanned controls". See Section 5.3.2).

Conclusions on Verification Procedures

The SVA has arrangements in place to monitor and audit the implementation of the NRCP and other controls relevant to the scope of this audit and procedures to verify their effectiveness and correct any deficiencies identified as required by the relevant articles of Regulation (EC) No 882/2004.

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 multi-annual national control plan (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 systems in place for official controls of topics within the scope of this audit are generally described in the MANCP, although no reference has been made to the role of the district veterinary inspectors in implementing the NRCP or the official controls on the use of veterinary medicinal products.

Conclusions on Multi-Annual National Control Plan

In general the requirements of Articles 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

Council Directive 96/23/EC (Article 5) requires Member States to submit to the Commission an annual national residues control plan for its approval. Articles 5-7 set the requirements for the plan. Decision 97/747/EC lays down sampling levels and frequencies. Regulation (EU) No 37/2010 lists Maximum Residue Limits (MRLs) for residues of pharmacologically active substances in food, while Regulation (EC) No 396/2005 sets Maximum Residue Levels for pesticides in food/feed. Regulation (EC) No 1881/2006 lays down Maximum Levels (MLs) for contaminants in food. Minimum Required Performance Limits (MRPLs) are defined in Article 4 of Commission Decision 2002/657/EC.

Findings

According to the Veterinary Act No. 166/1999 the veterinary administration bodies at central and regional level have full competence for the monitoring of residues and contaminants in food producing animals and products thereof. The implementing Decrees of the Ministry of Agriculture

No. 291/2003 (concerning monitoring) and No. 298/2003 (concerning NRLs) transpose all aspects of Council Directive 96/23/EC, Council Directive 96/22/EC, Commission Decision 97/747/EC and Commission Decision 98/179/EC.

The Food Safety Division of the Public Health, Veterinary Hygiene and Ecology Department (PHD) within the SVA is responsible for the preparation of the NRCP. They start with the planning process for the next year's NRCP usually in September in co-operation with the Department for Information and Communication Technologies (DICT) of the SVA, heads of relevant NRLs and regional NRCP coordinators from RVAs. DICT is providing technical support e.g. by extracting and processing of data from different databases. Two to three working meetings are held during autumn between the relevant parties in order to determine the scope of testing for each commodity. The NRCP is agreed by all parties by the end of December and entered into the IS SVA. By the end of January at the latest, RVA coordinators have to allocate samples to District Veterinary Inspectorates (DVIs) and to train DVI inspectors responsible for sampling. The NRCP is approved by the Director General of the SVA (Chief Veterinary Officer) in January or February which makes it officially binding.

The audit team noted that:

- all relevant parties are included in the planning process of the NRCP. Minutes of the working meetings dealing with planning were available to the audit team;
- according to the SVA, other factors in addition to production data are taken into account for the NRCP planning e.g. trend analysis of occurrence of residues, previous non-compliant results and new information about possible or emerging residue problems. These factors may also be addressed by extraordinary control programmes (see Section 6.1.3.2). Examples of both approaches were presented, e.g. additional testing for amoxicillin in sows is planned in 2010 NRCP to investigate possible residue problems with this medicine in older animals. On the other hand, the number of tests for malachite green/leucomalachite green (MG/LMG) remained steady over the last few years although this is the major residue problem in the country. To address this problem, it is expected that RVAs ensure that previously positive farms are sampled during the next year;
- the NRCP prepared for national use is more comprehensive than the one sent to Commission services and goes beyond EU requirements, for example by also including sampling of processed animal products, baby foods and testing of substances such as tin in fishery products;
- data on consumption of veterinary medicines have been collected by the ISCVBM. The system has been fully in place since 2003. These data, expressed as groups of active substances are available to the SVA and the top selling groups are included in the NRCP. However, the scope of testing for Group B1 substances is somewhat narrow and does not always include commonly used antibiotics. For example, frequent use of lincomycin and spectinomycin was noted during the audit, however neither of these two substances are tested under the NRCP. Also rafoxanide and mebendazole which are authorised and – according to ISCVBM – commonly used in the Czech Republic, are not tested for under the NRCP;
- whilst for antibiotics (e.g. penicillins and cephalosporin) a narrow scope of substances was listed in the plan, additional information was provided to the audit team showing that a more comprehensive range of substances is actually tested for. The explanation given was that not all substances which could be confirmed in the laboratories are necessarily listed in the plan as this would make the list too long, therefore only some of them are provided within the scope of a particular screening method.

Conclusions on planning of the national residue control plan

The national residues control plan is generally comprehensive in scope, is designed in line with EU requirements, takes account of relevant data and goes beyond EU requirements in some aspects. However, its effectiveness is weakened to a certain extent by a somewhat narrow scope of testing for certain groups of substances.

6.1.2 Implementation of the national residue control plan

Legal Requirements

Directive 96/23/EC (Articles 3, 4, 12) deals with the implementation of the national residue control plan, while Article 4(2)(b) and (c) lays down co-ordinating obligations for central competent authorities, next to those contained in Regulation (EC) No 882/2004. The latter also contains obligations on the organisation of controls, and on corrective action (see section 5.5.). Decision 97/747/EC lays down sampling levels/frequencies, while Decision 98/179/EC lays down rules for official sampling under the national residue control plan. EU sampling methods are laid down in: Directive 2002/63/EC (pesticides); Regulation (EC) No 1883/2006 (dioxins and dioxin-like PCBs); Regulation (EC) No 333/2007 (certain chemical elements) and Regulation (EC) No 401/2006 (mycotoxins).

Findings

Two officials are responsible for co-ordination of the NRCP at central level. There is one NRCP coordinator at each RVA who allocates the samples to be taken to DVIs within a particular region. Each DVI also has a coordinator which further allocates samples to different working stations (e.g. Veterinary Hygiene Stations at slaughterhouses) within a district. Allocation of samples to DVIs and working stations is done through IS SVA. Authorised inspectors from DVIs and working stations are responsible for sampling in accordance with the plans. Instructions for sampling and general targeting criteria are included in the NRCP. Staff authorised for sampling are included in relevant lists and receive an annual update on the criteria to be used for sampling. All sampling has to be registered in IS SVA and documented. Supervision of NRCP implementation is carried out at DVI, RVA and SVA levels by using the IS SVA. SVA organises meetings with RVA coordinators at least twice per year in order to discuss issues related to residues monitoring and RVAs should take appropriate actions to address these issues.

The audit team noted that:

- in two RVAs visited they had usually received the NRCP at the beginning of January each year both through the IS SVA and in paper form (a version for national use, including instructions). Allocation of samples to DVIs and further to working stations had usually been completed in January;
- minutes of meetings where annual updates had been provided to staff authorised for residue sampling were available to the audit team. In general, staff interviewed on-the-spot showed good knowledge of criteria for the selection of sampling sites and animals for residue sampling;
- in general, allocation of samples did not include time distribution of sampling and this is left to samplers which are instructed to take samples on an on-going basis through the year. Time distribution of sample collection is planned for Group A substances;
- sampling for the current year usually starts at the end of January. According to national instructions the majority of samples have to be collected by 15 November each year, except

for seasonal commodities i.e. carps (mainly consumed at Christmas) and some wild game. It was observed in the laboratory visited that samples for Group B1 substances have been sampled in a substantially lower proportion during November, December and January compared to the rest of the year. The sampling for Group B1 substances closely correlated to the overall distribution of samples received in this laboratory through the year;

- ISCVBM is the only laboratory responsible for testing of Group A substances under the NRCP. They receive samples within five defined time periods (rounds) during the year in order to economise the use of resources. RVAs receive plans from ISCVBM with detailed information on samples to be taken in their regions within pre-determined deadlines (usually one week every two to three months is selected for sample reception). It was observed by the audit team that samples were collected during the course of up to approximately three weeks before being sent collectively to the ISCVBM from a particular working station;
- despite the favourable average turnaround time for analysis calculated at the ISCVBM, since the laboratory receives large amounts of samples (more than 500) in a short period of time (one week) within each round, this sometimes leads to a delayed start of analysis of samples. An example of an interval of more than two months between sample taking and receipt of laboratory results was found by the audit team;
- IS SVA enables the SVA, RVA and DVI coordinators to closely monitor the implementation of the NRCP, including *inter alia* the information on date of sampling, sampling site and identification of the animal. Several meetings between SVA and RVA coordinators and also at district levels visited were organised during 2009 to discuss the implementation of the plan. In one of the RVAs visited the NRCP coordinator monitored the performance of each inspector responsible for sampling;
- in general, the 2009 NRCP was implemented according to the plan and evidence was seen that implementation of the 2010 NRCP to date was broadly carried out as planned;
- when an RVA is not able to take a particular sample according to the plan, it should notify this to the SVA which then reallocates that sample to another RVA through IS SVA. Such communication and sample reallocations were properly documented and could be verified on-the-spot;
- sampling is generally carried out without prior warning. According to SVA, there are rare exceptions from this rule, e.g. when the farmers are not permanently present at farms.

Conclusions on implementation of the national residue control plan

In general, the national residues control plan is implemented as planned and in line with EU requirements. There are tools for supervising the implementation of the NRCP and supervision of implementation is effective.

6.1.3 Other residues control programmes

Legal Requirements

Directive 96/23/EC (Art. 11) allows Member States to conduct other testing, particularly to detect illegal treatment. Directive 96/23/EC (Article 9) foresees own-checks by food business operators, to which competent authorities must have access and examine in the context of official controls (Articles 8, 10 of Regulation (EC) No 882/2004).

6.1.3.1 CISTA annual monitoring and control programme

Findings

CISTA is responsible for official controls of feedingstuffs. It also runs an annual monitoring and control programme which includes *inter alia* controls on undesirable substances (in line with Directive 2002/32/EC), feed additives comprising *inter alia* coccidiostats and phased-out antibiotics. According to CISTA, approximately 350-400 samples have been tested annually under this monitoring for the presence of coccidiostats which could be present in feed due to cross-contamination. From 2010 the monitoring includes also residues of veterinary medicinal products (22 samples will be analysed this year by ISCVBM). Results of controls carried out by CISTA are published on their website.

The audit team noted that:

- since February 2010 there is an agreement in place between SVA and CISTA on mutual co-operation, according to which each party has to *inter alia* inform the other one in case of positive results for coccidiostats found under the NRCP or under the CISTA annual monitoring. Evidence of such exchange of information was observed at regional level.

6.1.3.2 SVA / RVA additional and extraordinary control programmes

Findings

In addition to residue testing under the NRCP, SVA and RVAs can decide to carry out additional and extraordinary residues control programmes in order to address potential and actual problems identified. These programmes are carried out by Veterinary Hygiene Departments.

The audit team noted that:

- extraordinary control programmes are usually coordinated centrally in order to address specific problems. One such programme has been carried out on the basis of frequent non-compliant results for MG/LMG under NRCP testing of aquaculture fish. It was noted that fish from domestic production has been sampled on the market under this extraordinary programme. According to SVA and RVAs visited, other extraordinary programmes included e.g. testing for aflatoxin M1 in milk, beta-lactam antibiotics in honey and testing for inhibitors in raw milk intended for direct sale to consumers.

6.1.3.3 Establishment own-checks

Findings

According to Veterinary Act No 166/1999 food business operators are obliged to perform laboratory analyses under their Hazard Analysis Critical Control Point system system (HACCP) in order to ensure safety of food. The scope and frequency of these checks are based on hazard analysis, carried out by food business operators, and may include residues testing if considered necessary. For example, each consignment of milk delivered to dairy plants is tested for inhibitory substances. Results of these analyses are checked during official controls of establishments. In addition, the SVA informed the audit team that food business operators are obliged to report non-compliant results of their own checks to the competent authority.

Conclusions on other residues control programmes

Other residues control programmes further aid in ensuring the safety of foodstuffs of animal origin.

6.2 Laboratories

Legal Requirements

Requirements for the designation, accreditation, capacity and capability of laboratories are laid down in Regulation (EC) No 882/2004 (Article 12(1) and Directive 96/23/EC (Article 14), Regulation (EC) No 882/2004 (Article 12(2) and (3)) and Decision 98/179/EC (Annex), and Article 4(2)(c) of Regulation (EC) No 882/2004, respectively. Decision 2002/657/EC (Articles 3-6), Regulation (EC) No 1883/2006, Regulation (EC) No 333/2007 and Regulation (EC) No 401/2006 establish requirements for the validation of analytical methods.

6.2.1 General description

Findings

The laboratory network participating in the NRCP includes four designated NRLs covering all of the substance groups listed in Council Directive 96/23/EC. The four NRLs are the State Veterinary Institutes (SVIs) in Prague, Jihlava and Olomouc and the Institute for State Control of Veterinary Biologicals and Medicaments (ISCVBM) in Brno, and all act as Routine Laboratories (RLs), too.

The national legal basis for the designation of laboratories for residue testing under the NRCP is laid down in Decrees of the Ministry of Agriculture (MoA) No. 291/2003 and No. 298/2003. The laboratories were appointed by the MoA in 2006. The SVA with respect to the specific analytical capability and capacity fixes the distribution of the NRCP samples to the four laboratories on an annual basis. The results of the NRCP analyses are sent as soon as available to both the RVAs and the SVA.

All laboratories involved in the NRCP are accredited to ISO 17025. The sole national accreditation body, the Czech Accreditation Institute (CAI) has published a list of all of the analytical methods included in each of the laboratories' accreditation scopes.

The audit team noted that:

- Commission Decision 2002/657/EC has been transposed into the national legislation (SD CR 04/2004). SD10 “Model for preparing a testing method SOP in the sector laboratory control” contains information on how to perform specific validation experiments for both screening and confirmatory analyses. However, there was little information concerning the performance acceptance criteria specified in Commission Decision 2002/657/EC for analytical methods, *e.g.* the Identification Point system, ion tolerances and retention time requirements.

6.2.2 On-the-spot visits in the laboratories

The audit team visited two of the national reference laboratories – the ISCVBM in Brno and the SVI in Jihlava.

The audit team noted that:

- both laboratories carried out their NRL functions as required by Article 14 of Directive 96/23/EC. Most of the analytical methods used in the NRCP are developed by the respective NRLs (based on Community Reference Laboratory (CRL) methods) and disseminated

together with training to the RLs (as appropriate);

- not all methods listed in the NRCP are necessarily included within the scope of accreditation of the respective laboratories. However, all of the methods used in the NRCP had been validated in accordance with Commission Decision 2002/657/EC with the exception of the screening method for the antibiotic tulathromycin. In both laboratories visited the majority of the residue methods were included in the scope of accreditation;
- both laboratories were operating in a manner consistent with ISO 17025 accreditation and had been audited annually by the CAI with generally favourable results. The laboratories were adequately equipped with modern, well-maintained analytical instrumentation suitable for the identification, quantification and confirmation of chemical residues in foods including LC-MS/MS, GC-MS and HPLC with DAD, FL and UV detectors and ELISA plate readers;
- the number of staff in each laboratory was commensurate with the volume of work to be performed. Training files were available and up-to-date and staff from both laboratories have participated in training at both the national and European level. All the staff interviewed were knowledgeable on the relevant analytical issues, legislation concerning residues, method validation and quality control criteria;
- internal audit programmes were in place in both laboratories. Where shortcomings had been identified, corrective actions had been carried out, documented and verified to the quality control manager;
- participation in CRL and commercial provider organised Proficiency Testing (PT) schemes relating to the laboratories specific area of analytical expertise was demonstrated. Most of the results obtained indicated satisfactory to good performance;
- target times for the submission of samples to the laboratories, and from sample receipt to reporting of a result were not formally established by the SVA. There was a requirement that samples should be sent/tested as soon as possible;
- in accordance with SVA instructions, the temperature and the general condition of samples arriving the laboratories are recorded in the Laboratory Management Information System (LIMS). The samples are divided into an A sample (used for screening) and a B sample (for confirmatory analysis). The split was performed prior to sample homogenisation. There are no national guidelines on how to perform the sample division or detailing acceptance criteria for samples;
- samples arriving at the laboratories are individually packaged in plastic bags or glass bottles (as appropriate for the sample type) and labelled with the sample code, identifiers and signature of the responsible inspector. The method of securing the exterior sample packaging was not “tamper-proof” thus, the chain of custody could not be guaranteed. Different methods for sample package sealing are used by different inspectors. A method of sample sealing was demonstrated to the audit team. A member of the audit team was able to remove the seal, open and re-seal the package without leaving any visible evidence of tampering;
- the sample receipt facilities at both laboratories apply adhesive identification labels to the sample packaging prior to storage and subsequent analysis. There is potential for these labels to become detached from the sample especially under freezer storage conditions with the consequent possibility of sample mix up. During an examination of the sample storage location (SVI Jihlava) a sample was removed from the freezer and the adhesive label was detached;

- analytical samples are retained under the appropriate storage conditions for a period of one month for compliant samples and three months for confirmed non-compliant samples. These timescales were considered too short especially in the case of a non-compliant sample and the possibility of a second laboratory verification check being requested.

6.2.2.1 Institute for State Control of Veterinary Biologicals and Medicaments (ISCVBM), Brno

Findings

The monitoring division within the ISCVBM is designated NRL for Group A1-A6 and B2d and carries out all testing for these substance groups in the country and does not co-ordinate the activities of any RLs. There are three departments based on analytical techniques used: ELISA (screening analysis), LC-MS/MS and GC-MS (confirmatory analysis).

The audit team noted that:

- CCα/ CCβ values (as appropriate) had been calculated for methods including all analyte / matrix combinations included in the 2010 NRCP. However method validation files did not include all of the required experiments (repeatability, reproducibility, specificity, selectivity, applicability, stability etc.);
- the Quality Manager was aware of the recent CRL guidelines (January 2010) concerning the validation of screening methods and a representative from the laboratory had attended the consultation meetings. However the guidelines have not as yet been implemented;
- internal quality control measures within analytical batches were used, including, inter alia, matrix-matched calibration curves, positive and negative control samples, single "blind" check samples, stable isotope-labelled internal standards and incurred samples (as available). The performance data generated however were not being monitored in the form of control charts;
- appropriate analytical standard reference materials including the relevant metabolites were available and stored under appropriate conditions;
- the analytical methods examined by the audit team (chloramphenicol ELISA screening, chloramphenicol GC-MS confirmation, multi-residue β-agonists LC-MS/MS) were appropriately validated and fit for purpose.

6.2.2.2 State Veterinary Institute (SVI), Jihlava

Findings

The SVI Jihlava coordinates the NRCP work of two RLs, the SVIs in Prague and Olomouc and is the largest residue laboratory in the network.

The audit team noted that:

- in its role as an NRL, the laboratory organised and conducted an inter-laboratory test for the detection of antibiotics in lyophilised milk in 2009. In total there were nine participants including the RLs. The NRL collated the performance data and provided a report to the participants indicating their performance and the LC-MS/MS assigned residue concentrations for the samples. The records were well kept and readily available. As a result of the inter-laboratory performance the NRL had issued guidance/ recommendations to the

RLs concerning which methods must be used for broad-spectrum screening of inhibitory substances;

- there is an NRL-audit programme in place for the two RLs involved in the 2010 NRCP. In 2008 and 2009 the NRL had conducted two audits at the SVI Hradec Králové. The findings of these audits were documented including the results of the corrective actions undertaken by the RL;
- the NRL had organised training for the RLs in the use and performance of rapid tests and issued a guidance document concerning the validation of screening methods based on CRL Fougerès guidelines. Records of the meetings and copies of the documents were provided;
- on-the-spot checks of equipment records, training records and authorisation of results showed good compliance with the in-house procedures;
- whilst the most important (top 10 used) Group B1 substances were adequately covered within the scope of the analytical methods, methods were not available for lincomycin and spectinomycin. Both of these pharmacologically active substances are included in authorised veterinary medicinal products which were used in two of the farms visited by the audit team;
- the validation pack for the four-plate microbial inhibition test for milk was examined. The six classes of inhibitory substances were included in the validation; the experiments were performed using two compounds from each class including a "weak" responding substance. The CCβ values determined for all substances is around 1 to 1.5 times the respective Maximum Residue Limits (MRLs). Whilst CCβ for a screening test at the MRL is considered acceptable, the risk of obtaining a false compliant result is increased when the detection capability approaches the permitted limit. For those analytes where CCβ of the screening test has exceeded the MRL, the method is not fit for purpose;
- the validation pack for malachite green in fish (LC-MS/MS) was also examined and found to be compliant with Commission Decision 2002/657/EC;
- there was one shortcoming identified relating to the use of the parent form of tulathromycin instead of the marker residue as defined in Commission Regulation (EU) No. 470/2010. The use of the inappropriate marker residues could result in an underestimation in the concentration of analyte present;
- traceability of standard reference materials was assured. Each standard reference material is given a unique reference number and all information relating to that standard including its certificate of analysis could be tracked as demonstrated for two randomly selected compounds (leucomalachite green and tulathromycin);
- control charts are used to monitor analytical performance. In one example selected at random, (the HPLC-DAD method for sulfachloropyradiazine), the result obtained for the positive control sample included in each analytical batch had been recorded since 2007 and the control limits of the method had not been exceeded.

Conclusions on laboratories

The performance of both laboratories visited by audit team was consistent with that expected of laboratories accredited to ISO 17025. The regular participation in external proficiency tests along with the internal quality control checks and dissemination of NRL developed methods to the wider laboratory network contribute to a consistent laboratory performance. In general, the competent authorities can have confidence in the laboratory results, thus ensuring guarantees on the residue status of food of animal origin in the Czech Republic. Nevertheless some minor shortcomings such as the use of an inappropriate marker residue for one analyte and inadequate sample

packaging/identification have the potential to weaken the effectiveness of the national residue control plan.

6.3 Veterinary medicinal products and medicated feedingstuffs

6.3.1 Distribution and use of veterinary medicinal products

Legal Requirements

Directive 2001/82/EC sets conditions for distribution and use of veterinary medicinal products (Articles 65-71). Article 67(aa) of Directive 2001/82/EC requires that veterinary medicinal products are only dispensed under veterinary prescription unless exempted (Directive 2006/130/EC, Article 2).

Authorised veterinary medicinal products may only contain substances listed in Regulation (EU) No 37/2010 (Annex, Table 1). Directive 96/22/EC prohibits the authorisation of hormones and beta-agonists for use as growth promoters, with certain exemptions for zootechnical and/or therapeutic purposes (Articles 4, 6-9)

Directive 90/167/EEC sets rules for distribution and use of medicated feedingstuffs (Articles 2, 8-9). Regulation (EC) No 183/2005 (Articles 9-11, 13) states that they can only be produced in establishments authorised for the production of feedingstuffs containing additives, and the production must satisfy certain conditions.

Findings

The Act on Pharmaceuticals No. 378/2007 deals with various aspects of authorisation, manufacture, distribution and control of veterinary medicinal products. Registered veterinary practitioners can acquire medicines from wholesalers and pharmacies, or directly from manufacturers or importers. Medicines may be dispensed to farmers for administration to animals. Farmers can obtain veterinary medicines through registered veterinary practitioners or directly from distributors and manufacturers, based on a veterinary prescription.

The audit team noted that:

- all veterinary medicines authorised for food producing animals which may give rise to residues are available only upon prescription;
- a list of authorised veterinary medicinal products is published on the website of the ISCVBM (http://www.uskvbl.cz) and is regularly updated. In addition, a printed form of *vademecum* is published approximately every three years;
- some veterinary medicinal products have been authorised for animal species which are not listed in Regulation (EU) No 37/2010 e.g. xylazine and gentamicin for sheep and goats and rafoxanide and mebendazole for several species of (wild) game. For some of these products the withdrawal periods are equal or longer than that which would be required under the "cascade" provisions of Directive 2001/82/EC. According to ISCVBM, SVA has also issued guidelines on using one of these medicines in wild game only within specified period of the year in order to have animals "free" from residues before the start of hunting season;
- a special license system is in place. Exemptions from marketing authorisations for 17 veterinary medicinal products (ten of them are vaccines) for food producing animals have been granted to private veterinary practitioners by the SVA.

Conclusions on distribution and use of veterinary medicinal products

In general, conditions governing the distribution and use of veterinary medicinal products comply

with the EU requirements. However, some veterinary medicinal products have not been authorised in line with the EU rules. From a residue perspective, this is mitigated to a certain extent by the adoption in several cases of withdrawal periods in excess of those which would be applicable if the pharmacologically active substances in question were used under the cascade provisions of Directive 2001/82/EC.

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

Legal Requirements

Directive 2001/82/EC (Articles 65, 66, 68, 69) specifies competent authorities' control obligations throughout the veterinary medicinal products distribution chain. Directive 90/167 lays down rules for competent authority controls of medicated feedingstuffs (Articles 4, 9, 13).

Directive 2001/82/EC, Directive 96/23/EC (Article 10), and Regulation (EC) No 852/2004 (Annex 1) establish veterinary medicinal product record keeping requirements of stock-owners. Regulation (EC) No 853/2004 sets out the requirements for food chain information accompanying animals submitted for slaughter (Annex II).

Findings

ISCVBM and SVA (through RVAs) are involved in official controls of veterinary medicinal products, including medicated feedingstuffs. ISCVBM is responsible for controls of manufacturers, wholesalers, pharmacies, veterinary practitioners and farmers. Minimum frequencies of controls of manufacturers and wholesalers are laid down in national legislation. RVAs carry out controls of veterinary practitioners and farmers. According to national legislation the competencies of ISCVBM and RVAs with regard to controls on the use of veterinary medicines by veterinary practitioners and on farms are in principle the same. In practice, ISCVBM carry out these controls mainly as follow-up investigations after potential problems have been identified e.g. non-compliant NRCP results, farmers' complaints about the work of veterinary practitioners etc. These controls can be carried out jointly with the RVAs and in such cases ISCVBM provides expert support to RVA inspectors. Decisions whether ISCVBM will be engaged in official controls on the use of veterinary medicines by veterinary practitioners and on farms are taken on a case-by-case basis and depend on the seriousness of the situation and staff resources available. RVA controls on the use veterinary medicines are meant to be more frequent and systematic than ISCVBM controls.

The audit team noted that:

- an annual plan of ISCVBM inspection activities is prepared every year, including the estimated (expected) number of controls to be carried out on the use of veterinary medicines by veterinary practitioners and on farms. In total, 230 ISCVBM inspections were planned in 2009 on different segments of veterinary medicinal products distribution chain and 270 were actually carried out;
- several records of ISCVBM inspections of veterinary practitioners and on farms were examined by the audit team. Controls were mainly related to non-compliant NRCP results and some of them were carried out jointly with RVAs;
- instructions (SOPs) for carrying out ISCVBM controls are included in their Manual of procedures. No instructions for carrying out official controls on the use of veterinary medicines by veterinary practitioners and on farms have been issued by the SVA and the audit team was informed that instructions are currently under elaboration by the Animal Health and Welfare Department which is responsible for these controls;

- central planning of controls to be carried out by RVAs on the use of veterinary medicines on farms is done through IS SVA. The IS SVA automatically selects farms to be inspected on the basis of pre-determined risk criteria such as the number and type of animals on the holding and previous non-compliances. A check-list is available for these controls and results of controls are recorded in the IS SVA;
- in 2009, a total of 186 RVA controls (85 were "planned") on the use of veterinary medicinal products were carried out on cattle, sheep/goat, pig, horse and poultry farms. No such controls were either planned or carried out on other types of farms including aquaculture, despite major residues problems having been related to the use of malachite green in trout;
- according to the SVA, most controls on veterinary medicinal products are "unplanned" or carried out randomly in the framework of animal welfare controls or included in the annual checks of 20% of veterinary practitioners involved in animal disease control programmes;
- decisions to carry out "unplanned" controls or to include veterinary medicinal products controls in animal welfare or animal disease control programme checks are made by inspectors at RVAs/DVIs. In the regions visited, no clear or consistent description of the criteria taken into account for such decisions could be provided, while SVA stated that "unplanned" controls may be triggered by indications of possible problems on farms, e.g. following suspicious results of checks at slaughterhouses, complaints from farmers etc. Standardised check-lists for these types of controls are in place except for controls included in animal welfare inspections;
- in the regions visited, it was possible to obtain an overview of "unplanned" controls carried out during 2009, as these are based on the same check-list and reporting procedures as for "planned" controls. The results of other types of controls were recorded on check-lists or on inspection reports but an overview of the numbers of such controls carried out or the items checked could not be provided;
- apart from centrally "planned" controls, other types of controls on the use of veterinary medicines on farms were not coordinated between different levels and departments of SVA and RVAs, respectively, who had been carrying them out;
- food chain information is compulsory for all food producing animals arriving at slaughterhouses except for wild game. Examples of food chain information for bovines and pigs were available in the slaughterhouse visited. A non-compulsory form was published on the SVA website. Farmers may use other formats provided they include all relevant information as required by Regulation (EC) No 853/2004.

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

Controls on the use of veterinary medicinal products by the veterinary practitioners and on farms are generally carried out and a centrally coordinated, risk-based system for "planned" controls is being implemented. However, controls do not cover all types of farms even when there is compelling evidence to do so. For controls on veterinary medicinal products outside the centrally planned system, the criteria for their initiation are not clear. In addition, there is a lack of instructions and weak co-ordination between and within different SVA levels involved in various types of controls on the use of veterinary medicinal products. Collectively these shortcomings reduce the effectiveness of the control system for veterinary medicinal products.

6.3.3 Identification of equidae and medicines records requirements

Legal Requirements

Regulation (EC) No 1950/2006 lists “essential” substances which may be used to treat *equidae* intended for human consumption (for which there is a mandatory six-month withdrawal period), even if such substances are not listed in Regulation (EU) No 37/2010. *Equidae* treated with a substance neither listed in this Regulation nor in Regulation (EC) No 1950/2006, are permanently excluded from the food chain. The owner must document any of the treatments described above in the "equine passport" with which *equidae* must be identified (Regulation (EC) No 504/2008). Thus, the passport serves the purpose of a) identifying the animal and b) providing some of the “food chain information” as required by Regulation 853/2004, and which has to be checked by the food business operator at the slaughterhouse. All food chain information and the identity document must also be checked by the official veterinarian under Regulation (EC) No 854/2004.

Findings

According to the CBI, identification and passport system has been fully implemented for all *equidae* since 2005 and is currently in line with the Regulation (EC) 504/2008. There are 13 national bodies authorised for identification and microchiping of equine animals and for issuing equine passports. The SVA/RVAs have access to the central database on equine animals, held by the MoA. Since 2005 there is an agreement in place between SVA and CBI according to which controls on identification and passports are carried out by CBI during the lifetime of animals i.e. on holdings, in connection with competitions, shows etc. The SVA performs these controls at slaughterhouses as part of the food chain information checks, and before exports of *equidae*. Veterinary practitioners are obliged to fill in Section IX of the passport when treating an equine animal. According to the SVA, issuing of a duplicate passport results in automatic exclusion of the animal from the food chain (slaughter).

The audit team noted that:

- the audit team was informed that the current population of *equidae* in the Czech Republic is approximately 72 000 and all have been registered. Approximately 350 horses were slaughtered in the Czech Republic in 2009, mainly in small-scale establishments;
- CBI carried out controls on identification and registration of *equidae* on 173 holdings in 2008 (2495 animals) and 127 holdings in 2009 (1540 animals). Data on numbers of non-compliances identified during these controls were provided to the audit team. Most frequent deficiencies included inadequate reporting of changes in animal status to the central database (e.g. change of ownership, death of the animal) and lack of a passport. Several follow-up files of these controls were provided, including reports and documents on measures and legal actions taken;
- in the slaughterhouse visited it was not possible to verify the implementation of equine passport controls as that establishment did not slaughter horses. The official veterinarian demonstrated how the on-line de-registration of a slaughtered equine animal should be done in practice. After slaughter, the equine passport has to be destroyed (made void) and returned to the issuing body.

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

The identification and passport system for *equidae* is in place in accordance with EU rules and official controls during the lifetime of equine animals are carried out and are effective.

7 Overall Conclusion

The national residues control plan is designed in line with EU requirements. An effective flow of sampling information between all levels of the competent authority and the laboratories provides for adequate supervision. Effective follow-up actions are carried out after non-compliant residue results. The effectiveness of residue controls could be further strengthened by including certain commonly used substances in the scope of testing. All laboratories involved in residues analyses are accredited to ISO 17025 and in general, the competent authority can have confidence in the laboratory results. Overall, conditions governing the distribution and the use of veterinary medicinal products comply with the EU requirements. However, some shortcomings with regard to marketing authorisation and controls on the use of veterinary medicinal products undermine the overall effectiveness of the residues control system. Requirements of Regulation (EC) No 882/2004 relevant to this specific audit are complied with, except in relation to shortcomings in official controls on the use of veterinary medicinal products.

8 Closing Meeting

A closing meeting was held on 3 May 2010 with representatives of the competent authorities. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities did not express disagreement with the main findings and preliminary conclusions.

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.	To ensure that scope of testing carried out under the NRCP includes all relevant substances in line with the range of veterinary medicinal products on the market taking into account the requirements of Article 7 of Council Directive 96/23/EC.
2.	To ensure that sampling for residues is carried out in accordance with the requirements laid down in point 2.6 in the Annex to Commission Decision 98/179/EC i.e. that samples are handled and labelled in such a way as to guarantee their legal validity in line with the requirements of Article 11(7) of Regulation (EC) No 882/2004.
3.	To ensure that in residue laboratories samples are not identifiable to the farm of origin in order to guarantee impartiality in the implementation of official controls in accordance with Article 4(4) of Regulation (EC) No 882/2004.
4.	To ensure that veterinary medicinal products on the market are authorised in accordance with the requirements of Article 6 of Directive 2001/82/EC.
5.	To ensure that all official controls on the use of veterinary medicinal products are carried out on a risk-basis, consistently, in accordance with documented procedures and that efficient and effective co-ordination and co-operation between all relevant

N°.	Recommendation
	levels and units within the competent authority takes place in line with the requirements of Articles 3(1), 4(4) and 4(5) and 8(1) 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_cz_2010-8442.pdf

Annex 1 - Legal References

Legal Reference	Official Journal	Title
General Audit		
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		
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

Legal Reference	Official Journal	Title
		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		
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

Legal Reference	Official Journal	Title
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
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		

Legal Reference	Official Journal	Title
Dir. 90/167/EEC	OJ L 92, 7.4.1990, p. 42-48	Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community
Reg. 1831/2003	OJ L 268, 18.10.2003, p. 29-43	Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition
Reg. 183/2005	OJ L 35, 8.2.2005, p. 1-22	Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene
Sampling methods and methods of analysis for contaminants in foodstuffs		
Reg. 333/2007	OJ L 88, 29.3.2007, p. 29-38	Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs
Reg. 401/2006	OJ L 70, 9.3.2006, p. 12-34	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs
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.	Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives

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