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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

AUSTRIA

FROM 14 TO 20 JUNE 2011

IN ORDER TO EVALUATE THE MONITORING OF RESIDUES AND CONTAMINANTS IN LIVE ANIMALS AND ANIMAL PRODUCTS, INCLUDING CONTROLS ON VETERINARY MEDICINAL PRODUCTS

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

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in Austria, carried out from 14 to 20 June 2011, as part of the published programme of FVO audits on the monitoring of residues in live animals and animal products in European Union (EU) Member States and in third countries.

The objective of the audit was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, 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 EU legislation in this field, including legislation on the control and distribution of veterinary medicinal products. The audit 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.

In general, the systems of residues controls and controls on the use of veterinary medicinal products in Austria are effective and in compliance with EU rules. Official personnel are adequately trained for their tasks. The minor deficiencies observed regarding the supervision of sampling and the follow-up of antibiotic screening positive results as well as certain shortcomings in the scope of antibiotic testing and the validation of certain analytical methods are not considered to have an adverse impact on the overall effectiveness of the control systems.

The report makes a number of recommendations to the Austrian 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

AGES	Austrian Agency for Health and Food Safety (*Österreichische Agentur für Gesundheit und Ernährungssicherheit*)
AGES-DSR	AGES Department for Data, Statistics and Risk Assessment
BMG	Federal Ministry of Health (*Bundesministerium für Gesundheit*)
CC-alpha / CC-beta	Decision Limit / Detection Capability
CC-TAHO	Competence Centre for Veterinary Drugs and Hormones (*Kompetenzzentrum Tierarzneimittel und Hormone*)
DG(SANCO)	Health and Consumers Directorate-General
EC	European Community
ELISA	Enzyme-linked immuno-sorbent assay
EU	European Union
FVO	Food and Veterinary Office
GC-MS/MS	Gas Chromatography-(Tandem) Mass Spectrometry
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC
HPLC-DAD	High Performance Liquid Chromatography with Diode Array Detector
ISO	International Organisation for Standardisation
LC-MS/MS	Liquid Chromatography-(Tandem) Mass Spectrometry
ML	Maximum Level
MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
NRL	National Reference Laboratory
RMP	Residues Monitoring Plan
SOP	Standard Operating Procedure
URL	(European) Union Reference Laboratory

1 Introduction

The audit took place in Austria from 14 to 20 June 2011. The audit team comprised three auditors from the Food and Veterinary Office (FVO). The audit was undertaken as part of the FVO's planned audit programme, evaluating control systems and operational standards in the residues sector.

Representatives from the central competent authority accompanied the audit team during the whole audit. An opening meeting was held on 14 June 2011 with the central competent authority responsible for implementing residue monitoring in live animals and animal products and representatives of the central competent authority responsible for the authorisation of veterinary medicinal products. At this meeting, the objectives of, and itinerary for, the audit were confirmed and the control systems were described by the authorities.

2 Objectives

The objective of the audit was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, 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 audit was based on 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 audit focussed on the roles of the competent authorities at central and regional levels, the legal and administrative measures in place to give effect to the relevant EU requirements, controls with regard to residues and veterinary medicinal products and their operation, and the performance of residue laboratories. Attention was paid to examining the implementation of corrective actions promised in response to recommendations made in the report of a previous FVO residues audit to Austria (DG (SANCO)/7507/2005) in June 2005. 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 Federal Ministry of Health
	Regional	2	Meetings with two regional competent authorities (the Provincial Department for Veterinary Affairs and Food Controls of Lower Austria and the Provincial Veterinary Service of Salzburg)
Laboratories		2	The Austrian Agency for Health and Food Safety Competence Centre for Veterinary Drugs and Hormones and the Food Control Laboratory of Vienna
Farms		1	One pig farm with on-farm mixing of medicated feedingstuffs
Establishments		1	One bovine slaughterhouse

3 Legal Basis

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

– Article 21 of Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products, and repealing Directives

85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC;

– Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;

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

4 Background

4.1 Summary of previous FVO Audit results

The residues sector was inspected by the FVO in 2005 (DG (SANCO)/7507/2005 MR Final). The report has been published on the website of the Directorate-General for Health and Consumers here: http://ec.europa.eu/food/fvo/ir_search_en.cfm The report concluded that, although there were certain deficiencies with regard to controls on the production of medicated feedingstuffs and validation of analytical methods, the official controls on residues and veterinary medicinal products were generally satisfactory.

5 Findings And Conclusions

5.1 Residue monitoring

5.1.1 Competent authorities involved

The Federal Ministry of Health (*Bundesministerium für Gesundheit,* BMG) is the central competent authority for the residue monitoring plan (RMP). Within the BMG, Department II/B/12 has the overall responsibility for the Austrian RMP as well as the responsibility for planning and implementation of the RMP for live animals, fresh meat and aquaculture (RMP-animals). Department II/B/13 is responsible for planning and implementation of the RMP for milk, eggs and honey (RMP-food) and Department II/B/10 is responsible for residue controls in Border Inspection Posts.

5.1.2 Planning of the residue monitoring plan

Legal Requirements

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

Article 3 of Regulation (EC) No 882/2004 deals with the general obligations with

regard to the organisation of official controls. Articles 3 to 7 of Council Directive 96/23/EC deal with the requirements for residue monitoring plans. Commission Decision 97/747/EC lays down levels and frequencies of sampling for residues. Table 1 of the Annex to Commission Regulation (EU) No 37/2010 lays down Maximum Residue Limits (MRLs) for residues of pharmacologically active substances in food. Regulation (EC) No 396/2005 lays down maximum residue levels of pesticides in or on food and feed of plant and animal origin. Commission Regulation (EC) No 1881/2006 lays down Maximum Levels (MLs) for certain contaminants in food. Minimum Required Performance Limits (MRPLs) are defined in Article 4 of Commission Decision 2002/657/EC.

Findings

The annual sampling plans (RMP-animals and RMP-food) are prepared by Departments II/B/12 and II/B/13 of the BMG and issued to the Provincial Governments as Decrees comprising inter alia the annual sampling plans, sampling instructions, instructions for follow-up and relevant templates. On behalf of each Provincial Veterinary Service AGES-DSR makes the risk-based selection of farms and slaughterhouses for RMP-animals and draws up monthly sampling plans for each province. Some Provincial Veterinary Services may request that residue sampling on farm is combined with cross-compliance checks or they may request weekly sampling plans for slaughterhouse sampling. The selection of when and where to sample eggs, milk and honey under the RMP-food is normally made by the Provincial Food Inspectorates but they may choose to request assistance from AGES-DSR. The audit team noted that:

- the 2011 RMP meets the requirements of EU legislation and previous comments from the Commission and from the EU Reference Laboratories (URL) have been taken into account in its elaboration;
- the planning process involves the main national reference laboratory and takes into account risk criteria outlined in the multi-annual national control plan, which also describes the planning meetings between the authorities;
- the risk criteria for selections of farms for residue controls had been defined based on discussions between the BMG, the Austrian Agency for Health and Food Safety (*Österreichische Agentur für Gesundheit und Ernährungssicherheit,* AGES) and representatives from the Provincial Veterinary Services;
- for the preparation of the risk-based sampling plan each Provincial Veterinary Service provides AGES' Department for Data, Statistics and Risk Assessment (AGES-DSR) with information on all farms and slaughterhouses, non-compliant results from the previous year and information on which farms are members of the Animal Health Service, which entitles farmers to carry out certain treatments prescribed by the contracted veterinarian (see point 5.3.1.);
- to ensure implementation throughout the calendar year the RMP-animals is sent to the Provincial Veterinary Offices by the BMG in two parts. An interim plan covers the months December-February and once all non-compliant results from the previous year are available the main RMP-animals for March-November is finalised. Both parts detail the total sample numbers, species and analytes broken down for each province;
- the RMP-food covers the whole sampling year and ensures that sampling starts in January, based on the previous year's plan, even if the new plan has not yet arrived to the samplers;
- a number of the antibacterial substances authorised for food producing animals in

Austria cannot be detected at the relevant MRLs by the screening method used for the RMP, as evidenced by recent validation data published by the Union Reference Laboratory[1] and in data generated by the Austrian National Reference Laboratory (NRL) for substance Group B1. Examples are: dihydrostreptomycin, enrofloxacin, florfenicol, gentamicin, lincomycin and oxytetracycline. [2]

Conclusions on planning of the residue monitoring plan

The planning of the residue monitoring plan is timely and risk-based and the plan meets the requirements in EU legislation. However, its effectiveness is somewhat hampered by the limited scope of substances which can be detected at MRL level by the screening method for antibacterial substances.

5.1.3 Implementation of the residue monitoring plan

Legal Requirements

Articles 3, 4 and 12 of Council Directive 96/23/EC deal with aspects pertaining to the implementation of the residue monitoring plan. Article 4(2)(b) and (c) of Council Directive 96/23/EC lays down the requirements for central competent authorities in co-ordinating the activities of all bodies involved in residues controls. General principles governing the co-ordination of activities and ensuring the co-operation between the various competent authorities are laid down in Articles 4.3, 4.4 and 4.5 of Regulation (EC) No 882/2004. Article 3 of Regulation (EC) No 882/2004 deals with the general obligations with regard to the organisation of official controls and Article 8(3) of this Regulation places the obligation on competent authorities to *inter alia*, ensure that corrective action is taken when needed.

Commission Decision 97/747/EC lays down levels and frequencies of sampling for residues and Commission Decision 98/179/EC lays down the rules for official sampling under the residue monitoring plan. EU methods of sampling for the official control of a wide range of residues in products of animal origin are laid down in several pieces of EU legislation: Commission Directive 2002/63/EC (pesticides); Commission Regulation (EC) No 1883/2006 (dioxins and dioxin-like PCBs); Commission Regulation (EC) No 333/2007 (certain chemical elements); Commission Regulation (EC) No 401/2006 (mycotoxins).

Findings

The RMP-animals is implemented by the Province Veterinary Services, mainly by official staff of its District Veterinary Services. The RMP-food is implemented by the Provincial Food Inspectorates and all sampling is carried out by food inspectors. The audit team noted that:

1 Gaudin *et al.*(2010) 'Validation of a Five Plate Test, the STAR protocol, for the screening of antibiotic residues in muscle from different animal species according to European Decision 2002/657/EC', Food additives and contaminants Part A, First published on: 29 April 2010 (iFirst))

2 In its response to the draft report, the Austrian competent authority remarked that the screening method used is that developed by the EU Reference Laboratory (EU RL) and that improvements to this method are primarily the responsibility of the EU RL. Nevertheless, recognising the shortcomings in the current screening procedure, the competent authority has undertaken to implement LC-MS/MS screening for macrolides in 2012 (as is already the case for sulphonamides) and develop the use of such analytical methodology for further antibiotic groups.

- in some provinces the Provincial Food Inspectorates and the Provincial Veterinary Offices have been merged while in others they are separate Departments under the Provincial Government;
- comprehensive training programmes, comprising *inter alia* controls on residues and veterinary medicinal products, are compulsory for all official veterinarians;
- the provincial offices distribute the sampling plans to the sampling officers at district level and monitor the sampling. All samples for the RMP are taken by official staff;
- the provincial offices order sampling equipment from AGES and distribute it to the samplers. Sampling forms are standardised and one copy of the sampling form is given to the farmer or food business operator;
- there is a national transport system for residue samples, which are normally delivered to the laboratories within 24 hours of sampling;
- the RMP had generally been implemented as planned. In the provinces visited sampling for the 2011 RMP had started in January and samples had been submitted promptly to the laboratories for analysis. However, for the slaughterhouse visited recent examples of clustered sampling were seen. The District Official Veterinarian had repeatedly sampled several animals from the same producer on the same date. This is not in line with the requirements described in point 2.3.3.1 of the Annex to Commission Decision 98/179/EC as specified in the instructions issued with RMP-animals. This non-conformity had not been noted by the supervising Provincial Veterinary Officer; [3]
- in the slaughterhouse visited sampling had included both Austrian animals and animals submitted for slaughter from other Member States, should such animals be present on the day of sampling;
- suspect samples were taken by the District Official Veterinarian who would be called to the slaughterhouse for sampling by the authorised veterinarians responsible for ante-mortem or post-mortem inspections when suspect animals were identified;
- the Provincial Veterinary Services and the Provincial Food Inspectorates are required to send half yearly status reports to the BMG indicating samples taken, non-compliances and follow-up investigations and such reports were available in the provincial offices visited. Additionally AGES DSR submits a quarterly status report to the BMG indicating the samples taken;
- sampling had been supervised and checked against the monthly sampling plans in the Provincial Veterinary Services visited;
- evidence was seen that the sampling was supervised from central level and a reminder had been sent to the provincial authority when samples under the RMP-food had not been taken in accordance with the plan.

Conclusions on implementation of the residue monitoring plan

The implementation of the residue monitoring plan is well organised and timely. Notwithstanding minor implementation deficiencies with regard to the sometimes clustered sampling, sampling instructions and guidelines covering the relevant EU requirements are available, and compulsory comprehensive training is provided for

3 In its response to the draft report, the Austrian competent authority stated that it had been asked officially by the Federal Ministry of Health to follow strictly the requirements of Decree No. 6 version 4 where it is laid down that it is not allowed to take several samples from animals of the same producer on the same day. In the WG Residues on 7 July 2011 the representatives of the provinces had been required to follow this provision strictly. Additionally, the BMG will verify, if the requirements are being observed by checking randomly the sampling in the database VIS.

official staff.

5.1.4 Other residue monitoring programmes

Legal Requirements

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

Findings

In accordance with Commission Recommendation 2010/161/EU on the monitoring of perfluoroalkylated substances in food (OJ L68, 18.3.2010, pp. 22-23), official samples were collected in 2010 from food of animal origin produced at higher altitude to monitor the presence of perflouroalkylated substances. These samples had also been used for the monitoring of dioxins and polychlorinated biphenyls (PCBs). Results were not yet available.

In 2010, twenty official samples of wild game in Lower Austria were tested for anthelmintics (benzimidazoles) and coccidiostats. All these samples were compliant.

Routine screening for antibiotic residues in raw milk is compulsory and the tests are carried out under the own-check programmes in the dairies. The audit team noted that:

- all positive findings under the dairies' own-check programmes must be reported to the relevant District Veterinary Services.

Conclusions on other residues monitoring programmes

The additional residue monitoring programmes and the compulsory reporting of positive results from dairies' own-checks for antibiotic residues provides the competent authorities with useful additional information about the residue status of food of animal origin.

5.1.5 Follow-up of non-compliant results

Legal Requirements

The measures to be taken by the competent authorities in response to the finding of non-compliant residues results are described in Articles 13, 16, 17, 18, 19, 23, 24, 27 and 28 of Council Directive 96/23/EC. In addition Article 54 of Regulation (EC) No 882/2004 lays down the principles to be followed in the application of national enforcement measures and actions to be taken in cases of non-compliance.

Findings

All findings of residues above the limit of detection are reported from the laboratories to the sampler at district level, to the BMG and to the Provincial Veterinary Services. The Provincial Veterinary Services are responsible for initiating the follow-up on farm for all commodities. When a non-compliant result is obtained under the RMP-food the Provincial Food Inspectorate informs the Provincial Veterinary Service of the farm of origin. The audit team noted that:

- all on-farm investigations were carried out by official staff from the Provincial or District Veterinary Services using standardised forms/check lists;
- follow-up visits on farm, checking *inter alia* treatment records, compliance with withdrawal periods and storage of veterinary medicinal products, were carried out whenever a residue of a veterinary medicinal product is detected in the laboratories, irrespective of whether the residue concentration detected is below or above EU limits;
- when non-compliant results had been detected in slaughterhouse samples from animals originating from other EU Member States the BMG had promptly informed the central competent authority in the Member State concerned.

5.1.5.1 Non-compliant results in the 2010 residue monitoring plan

Findings

There were no non-compliant results for group A substances under the 2010 RMP. Under the targeted sampling eleven aquaculture samples were non-compliant for leuco-malachite green and three for leuco-crystal violet, anticoccidials were found in one poultry sample and one egg sample, a non-steroidal anti-inflammatory drug was found in one bovine sample and antimicrobial substances were detected in one pig and six bovine samples. The audit team noted that:

- the non-compliant findings (those exceeding EU limits) and the outcomes of corresponding follow-up investigations had been clearly described in the documentation submitted to the Commission services with the 2011 RMP;
- follow-up investigations had been carried out promptly and reports of the follow-up investigations, on the standardised forms, were available in the Provincial Veterinary Services visited;
- for antibacterial substances (Group B1), the follow-up investigation had normally taken place based on the screening test result, i.e. before the confirmatory analysis had been carried out. Consequently the official veterinarian did not know at the time of the farm visit if an MRL had been exceeded or which antibacterial substance(s) the sample contained[4];
- the suspected source of the non-compliance had been identified in many of the investigations, with the exception of the investigations of residues of dyes in aquaculture production;
- legal or administrative proceedings had been initiated in most cases, remaining fish in certain aquaculture farms had been destroyed and a number of the farms had been placed under intensified supervision/checks for six months (MRL violations) or 12 months (dyes).

4 In its response to the draft report, the Austrian competent authority stated that in the meeting of the WG Residues (7 July 2011) it was agreed with the representatives of the provinces to continue this procedure, because it had paid off to check the farm when the screening test result is available and to have the possibility to act immediately. Additionally, the official veterinarian will control the farm again when the confirmatory test result is available.

5.1.5.2 Non-compliant results in the 'other' residue monitoring programmes

When positive results from the dairies' own-check programmes are reported to the relevant District Veterinary Service follow-up investigations are carried out as for non-compliances under the RMP. The audit team noted that:

- in a recent example of a screening-positive sample from a dairy the Provincial Veterinary Services had promptly initiated an on-farm follow-up investigation by the District Official Veterinarian. The source of the residue had been identified and administrative proceedings had been started. The Provincial Food Inspectorate had also been informed and official samples of milk had been taken from the farm.

Conclusions on follow-up investigations/actions

Follow-up investigations are comprehensive, carried out promptly and mostly effective. Dissuasive sanctions are frequently applied. However, as the follow-up investigations for antibacterial substances are carried out following positive screening test results, before confirmatory analyses have been carried out, the investigations are hampered by a lack of information on whether an MRL-violation has been detected and if so, for which substance(s).

5.2 LABORATORIES

Legal Requirements

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

5.2.1 General description

Findings

All ten laboratories providing analytical services under the RMP are approved by the BMG under articles 65, 72 and 73 of the Food Safety and Consumer Protection Act. Eight of these laboratories are included within the AGES. All ten laboratories are accredited to ISO 17025 by the Austrian Accreditation body, *Bundesministerium fur Wirtschaft, Familie und Jugend* (Federal Ministry of Economic Affairs, Family and Youth).

Six of the ten laboratories are designated as National Reference Laboratories (NRLs),

four of which are in AGES and are referred to as analytical competence centres (CC). The NRLs are as follows:

- AGES Competence Centre Veterinary medicinal products and Hormones (*Tierarzneimittel und Hormone,* CC-TAHO): Substance groups A1-A6, B1, B2a, B2b, B2d, B2e and B2f (corticosteroids);
- AGES Competence Centre Residue analysis (*Rückstandsanalytik)*: Substance groups B2c, B2f (amitraz), B3a, B3b and B3f (neonicotinoids);
- AGES Competence Centre Radiation protection and Radiochemistry (*Strahlenschutz und Biochemie)*: Substance group B3c;
- AGES Competence Centre Cluster Chemistry (*Cluster Chemie)*: Substance group B3d (mycotoxins);
- Federal Environment Agency (*Umweltbundesamt)*: Substance group B3a (dioxins and PCBs);
- Food Control Laboratory of Vienna (*Lebensmitteluntersuchungsanstalt der Stadt Wien*): Substance group B3e.

5.2.2 On the spot visits in laboratories

The audit team visited two laboratories analysing samples for the RMP, CC-TAHO and the Food Control Laboratory of Vienna.

5.2.2.1 AGES Competence Centre Veterinary medicinal products and Hormones (CC-TAHO)

Findings

The laboratory functions both as an NRL and also as a routine control laboratory, analysing the majority of samples (~ 8,500) for the RMP. It carries out confirmatory analyses on screening non-compliant samples (for antibiotic residues) submitted from other laboratories in the network.
CC-TAHO is located in state of the art premises and is well equipped with a range of modern instrumentation including several high performance liquid chromatography machines with diode array (HPLC-DAD), ultraviolet and fluorescence detectors, gas chromatography tandem mass spectrometers (GC-MS/MS) and liquid chromatography tandem mass spectrometers (LC-MS/MS). Commercially sourced immunochemical methods are employed for screening of a range of substances including chloramphenicol, natural steroids, resorcylic acid lactones and a number of antibiotics. In relation to the role of CC-TAHO as an NRL the audit team noted that:

- the laboratory carries out all of the functions required by Article 14 of Council Directive 96/23/EC. It assists the central competent authority in the planning of the RMP, and organises comparative tests for the other laboratories in the network;
- examples of comparative tests in 2010 included a ring test for chloramphenicol analysis by enzyme-linked immuno-sorbent assay (ELISA) and screening of antibiotics by five-plate test. Comprehensive reports of both ring tests were presented to the audit team. Unsatisfactory performance of some of the laboratories in the ring test for chloramphenicol ELISA analyses had led to all such testing being centralised in CC-TAHO and one other satisfactorily performing laboratory for the 2011 RMP;

- the laboratory has developed new methods (e.g. thyrostats in urine by LC-MS/MS) which had been incorporated into the 2011 RMP. New confirmatory methods for *inter alia* testosterone and oestradiol were in the process of being developed;
- although designated as an NRL for *inter alia* Group A3 and A6, the laboratory did not have confirmatory methods in place for some substances within these groups (e.g. oestradiol in plasma, gestagens in fat, chlorpromazine and corticosteroids). However, a formal contract with the URL was in place for it to provide chemical confirmation in the event of a putative non-compliant screening result. In 2010 CC-TAHO did not need to avail of this service.

In relation to the role of CC-TAHO as a routine laboratory the audit team noted that:

- sample handing and processing procedures in place could guarantee full traceability of the sample and integrity of the analyte. A laboratory information management system was in place and data were easily retrievable;
- in the event of a screening positive antibiotic result in a control laboratory in the network, CC-TAHO was informed electronically of the imminent arrival of the sample and the screening result;
- in a selection of 2010 cases examined by the audit team, chemical confirmation of antibiotics in screening positive samples had been performed within the agreed turnaround times (28 days) set by the competent authority;
- the last accreditation audit had been carried out in September 2010. No non-compliances in the residues area were noted. There is a schedule in place for internal audits. The deficiencies noted (mainly documentary) in the most recent internal audit (June 2010) had been corrected;
- all analytical methods used have been validated according to Commission Decision 2002/657/EC;
- the standard operating procedure (SOP) for validation of analytical methods was in draft form – having been updated to take account of the URL guidelines for analysis of screening methods published on the European Commission's web site;
- the ELISA kit supplier for the chloramphenicol screening assay had changed in 2011. A revalidation of the new kits had been performed and documented, demonstrating that the new kit was fit for purpose (i.e. capable of detecting the compound at the MRPL);
- the laboratory has participated in a large number of externally organised proficiency tests for residues of veterinary drugs (48 in 2009 and 31 in 2010) with satisfactory performance in the majority of cases. However, in 2010 unsatisfactory *z*-scores (over-estimation of the quantity present) had been received for analysis of tetracyclines in three proficiency tests. Corrective action reports were in place and the appropriate measures had been taken to prevent a recurrence;
- a number of methods were examined by the audit team including chloramphenicol in animal tissues, milk, honey and blood by ELISA, and sulphonamides in animal tissues by HPLC-DAD:
    - the chloramphenicol ELISA method employed a buffer standard curve with one well per sample. Positive (fortified samples at the MRPL) and negative (blank) quality control samples as well as a standard in buffer solution were run in every assay. The quality control charts for the assay demonstrated that it had been out of statistical control on a number of occasions, when the

results for the positive quality control samples had fallen outside the acceptable range defined in the SOP. These events had been documented on the raw data file (protocol) for the affected runs and all of the samples had been re-analysed. In one case, the second ELISA run had also failed and the samples were tested by GC-MS. All were compliant. Whilst the procedures followed in the above cases were 'good laboratory practice' it was noted that such events are not catered for in the method SOP [5](i.e. when samples should be repeated, how many times etc);

- the sulphonamide method in routine use covered several compounds. Recoveries of samples fortified at the MRL were very variable (approximately 10 – 50% at 100 µg/kg). A sulphonamide not authorised for use in food producing animals (sulphisomidine) was used as an internal standard but was not used for recovery correction. A five point calibration curve in buffer was run once annually and the results of samples were read off this pre-prepared curve and were then corrected for the recovery of the spiked blank sample in the assay in which they were run. As calibration could vary from day to day, this practice may lead to under or over estimation of the true quantity of the analyte present in the sample[6];
- the SOP for the sulphonamide method indicates that non-compliant samples should be repeated on two further occasions and the reported result is the mean of these determinations. This approach had been used in the non-compliant samples examined;
- the quality control chart for the sulphonamide method demonstrated that it had been out of statistical control on a number of occasions for some of the compounds (e.g. very low recoveries for sulphamethoxazole and sulphadimidine). On one such occasion examined, the samples had not been repeated. The SOP did not indicate what action to take in such instances[7];
- the sulphonamide method had been validated to Commission Decision 2002/657/EC. CC-alpha and CC-beta had been calculated on the basis of a single day's repeatability data (not three days as stipulated in section 3.1.2.2. of Chapter 3.1. of the Annex to Commission Decision 2002/657/EC). Furthermore the six replicates used had been spiked at two concentrations – half MRL and MRL – not three as stipulated in the above Decision) and in the case of porcine and chicken muscle, three replicates (and not six) had been analysed.

5.2.2.2 Food Control Laboratory of Vienna

Findings

Under the RMP, this laboratory is solely carrying out analyses for Group B3e (dyes)

5 In its response to the draft report, the Austrian competent authority stated that the SOP has been modified in such a way that screening 'positive' samples will be repeated twofold or analysed forthwith using a valid method according to Commission Decision 2002/657/EC (e.g. GC-MS or LC-MS). If the results of the twofold analyses are again non-compliant, in any case, the sample has to be tested with a specified confirmation method.

6 In its response to the draft report, the Austrian competent authority stated that in addition to this spiked control sample a mixed standard will be analysed as well in order to verify the actual five point calibration curve. If the result of this standard lies inside the limit of the permitted deviation (quality chart card), it can be assumed that the actual five point calibration curve is still valid.

7 In its response to the draft report, the Austrian competent authority stated that in future, all analytical sequences where the control samples lie outside the limit of tolerance of the quality control chart, have to be repeated. This procedure will be implemented in the next version of the SOP.

in aquaculture products. The laboratory is mainly involved in other food control activities, e.g. testing of pesticides in food of plant origin. The audit team noted that:

- the laboratory is equipped with state of the art LC-MS/MS equipment;
- the most recent accreditation audit had been carried out in May 2010. The LC-MS/MS analytical method for dyes had been included in the scope of the audit and a recommendation had been made to maintain a quality control chart for the method;
- the method for dyes covers six compounds (malachite green, crystal violet and brilliant green and their leuco forms) and the SOP has been adapted from the URL published method (analyte stability of the leuco-forms in the sample has been improved by the addition of an anti-oxidant in the sample preparation phase);
- the method had been comprehensively validated according to Commission Decision 2002/657/EC) and shown to be fit for purpose. Estimates of CC-alpha and CC-beta for each of the above substances range between 0.1 and 0.6 µg/kg for CC-alpha and 0.2 and 1.2 µg/kg for CC-beta;
- the laboratory had performed successfully in four proficiency tests for dyes in aquaculture products organised by international proficiency test providers from 2009 to date;
- examination of raw data and control charts for the last year showed that the method was in full statistical control.

Conclusions on laboratories

The fact that all laboratories are accredited to ISO 17025, all methods in place have been validated (where appropriate) in accordance with EU rules, and in general laboratories have performed satisfactorily in a comprehensive selection of proficiency tests means that, notwithstanding some minor shortcomings in the validation of analytical methods seen in one of the two laboratories visited, the competent authority can have confidence in the reliability of laboratory performance and the results generated under the residue monitoring programme.

5.3 VETERINARY MEDICINAL PRODUCTS AND MEDICATED FEEDINGSTUFFS

5.3.1 Authorisation, distribution and use of veterinary medicinal products

Legal Requirements

Conditions governing the marketing authorisation of veterinary medicinal products are laid down in Articles 5-15, 21-30, 58-62 and 83 of Directive 2001/82/EC and for certain products authorised on an EU-wide basis, Articles 30-40 of Regulation (EC) No 726/2004. Veterinary medicinal products which are authorised for use in food producing animals may only contain pharmacologically active substances which are listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010. The use of one specific category of veterinary medicinal product – medicated premixes – is governed by Council Directive 90/167/EEC. Council Directive 96/22/EC prohibits the authorisation of hormones and beta-agonists for use as growth promoters in food producing animals.

Conditions governing the distribution and use of veterinary medicinal products are laid down in Articles 65-71 of Directive 2001/82/EC. Article 67(aa) of Directive 2001/82/EC requires that veterinary medicinal products for food producing animals are only dispensed to the public under a veterinary prescription unless exempted under the conditions laid down in Article 2 of Commission Directive 2006/130/EC.
In respect of medicated feedingstuffs conditions governing the distribution and use are laid down in Articles 2, 8 and 9 of Council Directive 90/167/EEC. Production of medicated feedingstuffs can only take place in establishments which have been authorised for the production of feedingstuffs containing additives in accordance with Articles 9, 10, 11 and 13 of Regulation (EC) No 183/2005 and the production process must satisfy the conditions laid down in Annexes I and II to that Regulation.
With regard to the use of certain hormones and beta-agonists for zootechnical and/or therapeutic purposes, the conditions governing such use are laid down in Articles 4, 5, 6, 8 and 9 of Council Directive 96/22/EC.

Findings

Veterinary (and human) medicinal products are authorised by the Federal Office for Safety in Health Care under the BMG. The competent authority stated that there are no products for food producing animals used under special license.
In each province there is an Animal Health Service, which is an association governed by state rules. In general, veterinary medicinal products for food producing animals may only be administered by a veterinarian. However, if affiliated to the Animal Health Service a farmer or designated persons on the farm may be authorised to administer veterinary medicinal products under the supervision of a contracted veterinarian. One pre-requisite is that the person(s) concerned completes a mandatory training (minimum eight 50-minute lessons) organised by the Animal Health Service. The BMG estimates that 60% of the bovine population, 90% of the pig population, 70% of the poultry population and 40% of the sheep and goat population are covered by Animal Health Service contracts. The audit team noted that:

- all veterinary medicinal products containing pharmacologically active substances are prescription-only medicines and a prescription template has been included in national legislation;
- a small number of veterinary medicinal products have been authorised for horses not intended for food production[8] and one product containing pentobarbital sodium (not listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010) has been authorised for euthanasia of small and large animals;
- in addition to any visits to diagnose and treat animals a contracted veterinary practitioner must carry out regular visits (1-4 times per year, depending on the number of animals on the farm) *inter alia* to monitor and control the use of veterinary medicinal products on all contracted farms. These visits were documented on standardised forms, a copy of which was provided to the farmers;
- the Animal Health Services carry out internal audits and BMG will organise external audits on veterinary practitioners and farmers to check that the system functions in line with national legislation;

8 In its response to the draft report the Austrian competent authority stated that on 20 June 2011, the Federal Office for Safety in Health Care was asked to initiate relevant procedures with regard to the authorisation of two veterinary medicinal products which are not authorised in line with legal requirements.

- before a farmer/keeper may treat animals under the responsibility of the contracted veterinarian this person must complete a course in general handling of veterinary medicinal products;
- on the back of each prescription there was a table for registration of when and to which animals the prescribed medicine had been administered by the farmer/keeper. This only applies in farms affiliated to the Animal Health Service where farmers/keepers have been authorised to administer prescribed medicines to the animals;
- two veterinary medicinal products containing policresulen, which according to Commission Regulation (EU) No 37/2010 may only be authorised for topical use in certain food producing animals, were authorised for intrauterine use in horses, cattle and pigs.

Conclusions on authorisation, distribution and use of veterinary medicinal products

Farmers' access to veterinary medicinal products is restricted and controlled, which reduces the risk of illegal or unauthorised use of such products which may give rise to residues exceeding EU limits in commodities or in animals submitted for slaughter.

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

Legal Requirements

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

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

5.3.2.1 Controls at retail level , on veterinary practitioners and on farm

Findings

Controls on the distribution and use of veterinary medicinal products in pharmacies, veterinary practices and farms (including the on-farm mixing of medicated feedingstuffs) are carried out by the District Veterinary Services. Veterinary practitioners and veterinary home dispensaries are inspected at least once every five years. AGES-DSF prepares a risk-based annual plan for each province for controls on veterinary medicinal product use on 2% of the farms. Each Provincial Veterinary

Service can specify what proportion of the controls is to be combined with cross-compliance checks.
The audit team noted that:

- approximately 10% of the on-farm mixing facilities for medicated feedingstuffs and 2.4% of farms had been inspected by provincial authorities in 2010, which was in accordance with the 2010 inspection plan. Non-compliances had been detected for 2% of the on-farm mixers and on 7% of the inspected farms;
- the controls on farm are carried out by District Veterinary Officers using standardised protocols;
- in addition to the planned inspections under the annual programme prepared by AGES-DSF, on-farm checks on treatment records, storage and use of veterinary medicinal products are carried out whenever a residue of a veterinary medicinal product had been detected under the RMP or in a dairy own-check programme. Records showed that a number of these checks had identified deficiencies, particularly with regard to record keeping also when the result from the laboratory had been compliant with EU limits (see point 5.1.5);
- the Animal Health Service contracted veterinarians are obliged to set deadlines for corrective actions and to carry out follow-up visits for major non-conformities noted during regular inspections;
- non-conformities observed during the controls and audits carried out by the Animal Health Service had been reported to the District Veterinary Services;
- veterinary medicinal products in stock on the pig farm visited by the audit team were labelled in line with legal requirements and all products could be linked to veterinary prescriptions. Treatments carried out by the farmer had been listed on back of each prescription. All prescriptions had been retained on the farm;
- all preparation of medicated feedingstuffs on the pig farm had been recorded in line with national rules;
- inspection reports from official controls carried out by the District Veterinary Service and from controls carried out during regular visits by the contracted veterinarian were available on the pig farm.

5.3.2.2 Controls on the production of medicated feedingstuffs

Findings

There is currently one commercial feed mill authorised for the production of medicated feedingstuffs (for fish) under the Medicated Feed Manufacturers Regulation. The Federal Office for Safety in Health Care is responsible for controls on production of medicated feedingstuffs in commercial feed mills.

On-farm mixing of medicated feedingstuffs is regulated under the Veterinary Medicinal Products Control Act. The District Administrative Authorities are responsible for controls on the on-farm production of medicated feedingstuffs.

Only farmers/designated persons who are members of the Animal Health Service and have been authorised to administer veterinary medicinal products may be authorised to produce medicated feedingstuffs on-farm provided that they have completed an additional course on mixing of medicated feedingstuffs. The production must take place under the supervision of the contracted Animal Health Service veterinarian, who prescribes the required medicated premixes. Before on-farm mixing can take

place the mixing facilities must be approved and registered by the District Administrative Authority.. The audit team noted that:

- only medicated premixes may be prescribed for the production of medicated feedingstuffs;
- on the farm visited, preparation of medicated feedingstuffs had been documented in line with national legislation;
- training records for the farmer's participation in the two mandatory courses required for manufacturing of medicated feedingstuffs were available on the farm visited;
- the specifications provided by the manufacturer of the mixer was considered by the competent authority to provide sufficient proof to ensure the homogeneity of the medicated feedingstuffs.

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

Official controls on the distribution and use of veterinary medicinal products are effective and increase confidence that food of animal origin does not contain residues of pharmacologically active substances at concentrations in excess of EU MRLs.

5.3.3 Identification of equidae and food chain information

Legal Requirements

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

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

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

For those equidae which are eligible for human consumption, treatment with any of the essential pharmacologically active substances listed in Commission Regulation (EC) No 1950/2006 must be recorded in Part 3 of Section IX of the equine passport

and a period of six months from the date of last treatment to time of slaughter must be observed.

In accordance with Articles 4(4), 5 and Annex I, Section I, chapter IIA, point 1 of Regulation (EC) No 854/2004, food chain information must be checked by the official veterinarian in the slaughterhouse and he/she must verify that animals accepted for slaughter by the food business operator have been properly identified in accordance with Annex I, Section II, Chapter III, point 1 to Regulation (EC) No 854/2004.

Section IX of the equine passport is considered as part of the food chain information for equidae as in this section the horse may be permanently or temporarily excluded for the food chain.

Findings

The BMG estimates that 90% of the ca 104,000 equines have been identified by the 34 passport issuing bodies recognised by the competent authority. The BMG stated that official controls on the equine passport system will be included in the multi-annual control plan from 2012.The BMG stated that few horses (ca 900 per year) are slaughtered in Austria but that Austrian horses are slaughtered in other Member States, e.g. Italy. Passports from such horses had been returned from Italy to the national contact point in Austria.

Austria has granted a derogation under Article 12 of Regulation (EU) No 504/2008 allowing that certain breeding horses are identified in the passport by branding (with or without an individual number), description diagram, life number and DNA-testing, i.e. without a microchip. This derogation applies to approximately 18% of Austrian horses. The audit team noted that:

- the BMG does not currently have access to the registers kept by the issuing bodies. However, work is ongoing to link these systems with a central database in the BMG, which currently includes approximately 30% of the identified horses;
- since 2008, numerous information campaigns and workshops have been organised by the BMG and by Provincial governments for passport issuing bodies, equine practitioners, official veterinarians, students, horse breeders, and other stakeholders;
- in January 2011 the BMG issued a letter to all provincial governments, detailing all relevant requirements regarding the identification of *equidae* and the rules for documentation of treatments on farm and in the equine passports for horses intended for slaughter for human consumption as well as for those excluded from the food chain;
- food chain information has been implemented for all species. Standardised forms have been issued for bovines, sheep and goat, poultry and pigs. The slaughterhouse visited required its own format of food chain information in German and the national language from suppliers of animals from other Member States;
- food chain information is compulsory also for equines, but the food business operator determines how the information should be provided by the owner/keeper;

- under national legislation the authorised veterinarians carrying out ante-mortem inspections in slaughterhouses are obliged to check all food chain information documents.

Conclusions on requirements for the identification of equidae and food chain information

Whilst the equine passport system has been implemented, official controls of this system will not be initiated until 2012. Food chain information has been implemented for all species, is in line with EU rules and provides guarantees on the residues status of food of animal origin.

6 Overall Conclusions

In general, the systems of residues controls and controls on the use of veterinary medicinal products in Austria are effective and in compliance with EU rules. Official personnel are adequately trained for their tasks. The minor deficiencies observed regarding the supervision of sampling and the follow-up of antibiotic screening positive results as well as certain shortcomings in the scope of antibiotic testing and the validation of certain analytical methods are not considered to have an adverse impact on the overall effectiveness of the control systems.

7 Closing Meeting

A closing meeting was held on 20 June 2011 with representatives of the central competent authority. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authority did not express disagreement with the findings and took immediate action in writing requesting the responsible competent authority to correct the authorisation of the veterinary medicinal products containing policresulen (see point 5.3.1.).

8 Recommendations

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

N°.	Recommendation
1.	Ensure that the method(s) used for screening of antimicrobial substances can detect residues of commonly used antimicrobial substances at the MRLs laid down in Table 1 of the Annex to Commission Regulation (EU) No 37/2010.
2.	Ensure that clustered sampling (taking of samples from several animals from the same holding) is avoided in accordance with point 2.3.3.1. in the Annex to Commission

N°.	Recommendation
	Decision 98/179/EC and national rules.
3.	Ensure that information about the detected antibiotic and the concentration confirmed is taken into account in the execution of follow-up investigations in line with the requirements of Article 18(1) of Council Directive 96/23/EC.
4.	Ensure that analytical methods for residues of veterinary medicinal products are validated in accordance with the requirements of Article 3(c) of Commission Decision 2002/657/EC and in particular take account of the requirements stipulated in sections 3.1.1.5. and 3.1.2.2. of Chapter 3.1. of the Annex to that Decision.

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

http://ec.europa.eu/food/fvo/ap/ap_at_2011-8910.pdf

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Audits by the Commission Services		
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Food Law		
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Monitoring and sampling of residues in food of animal origin		
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
Dec. 97/747/EC	OJ L 303, 6.11.1997, p. 12-15	97/747/EC: Commission Decision of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products

Legal Reference	Official Journal	Title
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
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		

Legal Reference	Official Journal	Title
	1-16	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		
Dir. 90/167/EEC	OJ L 92, 7.4.1990, p. 42-48	Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community
Reg. 1831/2003	OJ L 268, 18.10.2003, p. 29-43	Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition

Legal Reference	Official Journal	Title
Reg. 183/2005	OJ L 35, 8.2.2005, p. 1-22	Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene
Sampling methods and methods of analysis for contaminants in foodstuffs		
Reg. 333/2007	OJ L 88, 29.3.2007, p. 29-38	Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs
Reg. 401/2006	OJ L 70, 9.3.2006, p. 12-34	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs
Reg. 1883/2006	OJ L 364, 20.12.2006, p. 32-43	Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs
Sampling methods for pesticides in foodstuffs		
Dir. 2002/63/EC	OJ L 187, 16.7.2002, p. 30-43	Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC
Horse identification (passport)		
Reg. 504/2008	OJ L 149, 7.6.2008, p. 3-32	Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae
Medicines essential for the treatment of equidae		

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