EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2012-6524 - MR FINAL

# FINAL REPORT OF AN AUDIT

# CARRIED OUT IN

# BULGARIA

# FROM 26 TO 30 NOVEMBER 2012

# IN ORDER TO EVALUATE THE MONITORING OF RESIDUES AND CONTAMINANTS IN LIVE ANIMALS AND ANIMAL PRODUCTS

***Executive Summary***

*This report describes the outcome of a Food and Veterinary Office (FVO) audit in Bulgaria, carried out from 26 to 30 November 2012, as part of the published programme of FVO audits on the monitoring of residues in live animals and animal products in European Union (EU) Member States and in third countries.*

*The objective of the audit was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products. The evaluation was based on the standards set out in Council Directive 96/23/EC, and other relevant EU legislation in this field. The audit assessed the performance of the competent authorities and other officially authorised entities involved in residues controls and the legal and administrative measures put in place to give effect to the relevant EU requirements. Attention was also paid to examining the implementation of corrective actions promised in response to relevant recommendations made in the report of a previous FVO residues audit to Bulgaria (DG (SANCO)/8436/2010) in March 2010.*

*It is concluded that whilst the responsibilities of, and co-operation between competent authorities involved in the planning of the residue monitoring plan are clearly defined, the design of the plan and its consequent effectiveness is weakened as some relevant risk criteria, such as data on the use of veterinary medicinal products, are not properly taken into account in deciding the substances to be tested for.*

*Regarding the implementation of the plan, improvements in the maintenance of medicines records and provision of food chain information underpin guarantees on the proper use of veterinary medicinal products and thus the chemical (residue) safety of food of animal origin. The establishment of an internal audit system also provides assurances that the control systems are functioning as intended for the areas covered by these audits. Sampling under the residue monitoring plan is carried out in line with planned arrangements and staff are properly trained to undertake this task. However, sampling is not evenly distributed throughout the entire year which is not in line with EU requirements. More significantly, the effectiveness of the plan is weakened by its publication specifying the substances to be tested for and, in particular by the failure to carry out all of the planned analyses due to shortcomings in laboratory capability and/or analytical capacity. In this latter respect, although the national reference laboratory is accredited and has validated methods for most of the substances to be tested for under the plan, ongoing deficiencies in its performance - caused by several distinct but inter-related resourcing problems – substantially weaken the effectiveness of the residue control system.*

*Concerning verification of the effectiveness of official controls, whilst procedures have been put in place to address this legal requirement, the fact that no clear criteria have been established against which the competent authorities can evaluate effectiveness, is an issue. Finally, despite a well functioning electronic system for equine passports, Bulgaria continues to lag behind in its legal obligations to identify all equidae on its national territory and thus is not in compliance with the requirements of Regulation (EC) No 504/2008.*

*The report makes a number of recommendations to the Bulgarian 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

| | |
|---|---|
| BAS | Bulgarian Accrediting Service |
| BFSA | Bulgarian Food Safety Authority |
| CC-alpha / CC-beta | Decision Limit / Detection Capability |
| CLVSEE | Central Laboratory for Veterinary Sanitary Expertise and Ecology |
| DG(SANCO) | Health and Consumers Directorate-General |
| EC | European Community |
| ELISA | Enzyme-linked immuno-sorbent assay |
| EU | European Union |
| EU-RL | European Union Reference Laboratory |
| 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 | High Performance Liquid Chromatography |
| ISO | International Organisation for Standardisation |
| LAD | Laboratory Activities Directorate |
| LC-MS/MS | Liquid Chromatography-(Tandem) Mass Spectrometry |
| MANCP | Single Integrated Multi-Annual National Control Plan |
| ML | Maximum Level |
| MRL | Maximum Residue Limit |
| MRPL | Minimum Required Performance Limit |
| NSAIDs | Non-Steroidal Anti-Inflammatory Drugs |
| NRL | National Reference Laboratory |
| QA | Quality assurance |
| RASFF | Rapid Alert System for Food and Feed |
| RFSD | Regional Food Safety Directorates |
| RMP | Residue Monitoring Plan |
| SOP | Standard Operating Procedure |
| VMPCD | Veterinary Medicinal Products Control Directorate |

## 1 Introduction

The audit took place in Bulgaria from 26 to 30 November 2012. The audit team comprised two auditors from the Food and Veterinary Office (FVO) and one expert from an European Union (EU) Member State. 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 26 November 2012 with the central competent authority responsible for implementing residue monitoring in live animals and animal products. At this meeting, the objectives of, and itinerary for, the audit were confirmed and the control systems were described by the authorities.

## 2 Objectives

The objective of the audit was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products and the implementation of corrective actions promised in response to relevant recommendations made in the report of a previous FVO residues audit to Bulgaria (DG (SANCO)/8436/2010/MR Final) in March 2010. The audit was based on Council Directive 96/23/EC and other relevant EU legislation in this field. The audit focused on the roles of the competent authorities at central and regional levels, the legal and administrative measures in place to give effect to the relevant EU requirements, residue controls and the performance of residue laboratories. Attention was also paid to examining enforcement measures and verification of effectiveness of official controls. The table below lists sites visited and meetings held in order to achieve these objectives.

| **Meetings/Visits** | | **n** | **Comments** |
|---|---|---|---|
| **Competent Authorities** | **Central** | 2 | Opening and closing meetings with the Bulgarian Food Safety Authority (BFSA) |
| | **Regional** | 2 | Meetings at the BFSA Regional Food Safety Directorates (RFSDs) in Plovdiv and Lovech |
| Laboratories | | 1 | Governmental laboratory |
| Farms | | 1 | Dairy farm |
| Establishments | | 1 | Slaughterhouse, slaughtering horses, cattle, sheep/goats and pigs |

## 3 Legal Basis

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

- Article 21 of Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products, and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC;
- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;

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

# 4 BACKGROUND

## 4.1 SUMMARY OF PREVIOUS FVO AUDIT RESULTS

The residues sector was inspected by the FVO in 2010 (DG(SANCO)2010-8436 MR Final). The report of this audit (henceforth referred to as the 2010 FVO audit) has been published on the website of the European Commission's Health and Consumers Directorate–General here: http://ec.europa.eu/food/fvo/ir_search_en.cfm. The report concluded that deficiencies in planning of the residue monitoring plan and failure to carry out analyses due to inadequate laboratory capability and capacity compromised the effectiveness of the residue control system. In addition, it was concluded, that the central competent authority could not ensure that horses sent for slaughter were eligible for food production due to the failure to implement EU equine passport requirements and to carry out any residue testing for horses.

# 5 FINDINGS AND CONCLUSIONS

## 5.1 RESIDUE MONITORING

### *5.1.1 Competent authorities involved*

The BFSA within the Ministry of Agriculture and Food is the national competent authority responsible for the residue monitoring plan (RMP = National Monitoring Program for Control on Residues (NMPCR)). Under supervision of the BFSA, the Regional Food Safety Directorates (RFSDs) are responsible for the implementation of the RMP within the regions. An organisational chart showing the structure and relationships of the competent authorities is provided in point 2.6 of the Country Profile for Bulgaria (DG(SANCO)2011/6086) published here:

http://ec.europa.eu/food/fvo/country_profiles_en.cfm.

### *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**

BFSA Executive Director's Order No RD 11-1537/13.12.2011 determines the responsibilities of the different central and regional competent authorities and the laboratory involved in the planning of the RMP and provides for co-operation and co-ordination between these authorities as required in Article 4 of Regulation (EC) No 882/2004. The planning process is described in the Country Profile (see point 5.1.1. of this report).

The audit team evaluated whether the recommendations of the 2010 FVO audit related to the planning of testing of horses and honey had been taken into consideration in the planning process for 2012 and noted that:

- the geographical distribution of horse slaughter facilities and farms as well as honey production had been taken into account for planning of the respective RMPs. In this regard, **recommendation no 2** of the 2010 FVO report has been addressed;
- the Veterinary Medicinal Products Control Directorate (VMPCD) provides a list of annual sales data for veterinary medicinal products. Despite the availability of this information, the use pattern of veterinary medicinal products for horses and bees was not adequately reflected in the selection of substances to be tested for under the RMP. For example, while the anthelmintic closantel is tested for in horse liver, flubendazole and fenbendazole are not tested for, although sold in much higher amounts (x 3 and x 60). Amitraz, which has an MRL established for honey is not (and has never been) included in the RMP for honey, although, since 2006, sales have increased (588 litres in 2006, 1288 litres in 2010). **Recommendation no 2** of the 2010 FVO report has therefore not been addressed with regard to taking into account all of the relevant data and be based on risk.

**Conclusions on planning of the residue monitoring plan**

Whilst the responsibilities of, and co-operation between competent authorities involved in the planning of the RMP are clearly defined, the effectiveness of the plan is partly weakened as some relevant risk criteria - data on the use of veterinary medicinal products - are not properly taken into account in deciding the substances to be tested for.

### *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 whilst Article 8 states that the competent authority shall have procedures in place to verify the effectiveness of official controls and to ensure that corrective action is taken when needed. Article 4(6) requires competent authorities to audit control activities, ensuring that such audits are carried out in a transparent manner, are subject to independent scrutiny and that appropriate measures are taken in light of their results. Article 8(3) places the obligation on competent authorities to *inter alia* ensure that corrective action is taken when needed.

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. Article 4.2(d) of this Regulation requires that competent authorities have appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls efficiently and effectively.

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

The veterinary medicines record keeping requirements of stockowners are laid down in Article 69 of Directive 2001/82/EC, Article 10 of Council Directive 96/23/EC and Annex I, Part A III, point 8(b) to Regulation (EC) No 852/2004.

The requirements for food chain information accompanying animals submitted for slaughter for human consumption are laid down in Annex II, Section III, point 3(c) to Regulation (EC) No 853/2004. In accordance with Articles 4(4), 5 and Annex I, Section I, chapter IIA, point 1 of Regulation (EC) No 854/2004, food chain information must be checked by the official veterinarian in the slaughterhouse and he/she must verify that animals accepted for slaughter by the food business operator have been properly identified in accordance with Annex I, Section II, Chapter III, point 1 to Regulation (EC) No 854/2004. Equidae must be identified by an identification document (equine passport) as established in Commission Regulation (EC) No 504/2008, and Section IX of the equine passport is considered as part of the food chain information for equidae as in this section the horse may be permanently or temporarily excluded from the food chain.

**Findings**

Order No RD 11-1537/13.12.2011 defines the responsibilities of all directorates/authorities within BFSA involved in the implementation of the RMP and determines the "Laboratory Activities" Directorate (LAD) to co-ordinate as a central competent authority within the BFSA, as required by Article 4(2)(b) and (c) of Directive 96/23/EC.

The 2012 RMP was approved by the Minister on 29 March 2012, and on 2 April 2012, LAD informed the 28 RFSDs that the new RMP (in the general version drafted by LAD) had been published on the BFSA web-page. Within the deadline 30 April 2012, the RFSDs sent their detailed regional plans back to LAD and then monthly reports on the ongoing implementation of the regional plans (template LAD – 1, approved by BFSA Executive Director's Order No 11-226/08.04.2011).

The published RMP contains (in an Annex) detailed instructions for sampling which comply with the requirements for sampling of Directive 96/23/EC and Decision 98/179/EC.

The audit team noted that:

- with regard to the 2012 RMP, on 7 December 2011, BFSA signed an one-year contract with a private laboratory in order to outsource testing of substances for 2012, for which the national laboratory did not have validated methods. These included Group A2 (thyrostats in meat and urine), Group A6 (nitrofurans in honey), group B2b (anticoccidials in meat and eggs), group B2c (pyrethroids in honey and meat) and group B2e (non-steroidal anti-inflammatory drugs – NSAIDs – in meat and milk). On 9th May 2012 the BFSA revoked this contract for one branch of the private laboratory, as this branch had not maintained its accreditation related to the outsourced testing and the respective information had been provided only after signing the contract. An Order for a new tender to contract a laboratory

was issued on 7 November 2012. Therefore, in 2012, there will be no testing of honey for nitrofurans (A6) and pyrethroids (B2c) and no testing of meat and eggs for anticoccidials (B2b) other than nicarbazin. In addition, the national laboratory informed the audit team, that no samples had been sent to the contracted laboratory to be analysed for thyrostats, as the national laboratory has been accredited for its own validated method in April 2012. However, testing for thyrostats only commenced in autumn 2012, and therefore not all planned samples will be tested for this substance group. As a consequence, **recommendation no 5** of the 2010 FVO report has not been fully addressed;

- as the RMP is publicly accessible via the BFSA web-page, food business operators can see the substances planned to be tested for. Thus the element of surprise as required in Annex III to Directive 96/23/EC is not fully ensured and **recommendation no 4** of the 2010 FVO report has not been fully addressed in this regard;
- considering that the 2011 RMP started 1 March 2011 and was finalised 31 March 2012, the RFSDs were advised by BFSA that samples should be taken during the first three months of 2012 based on the previous year's RMP. However, few samples were planned for January and February 2011, and the majority of sampling took place from May to October 2011. In 2012, only six of the 28 regional plans foresaw taking samples in January, February or March. The sample submissions to the national laboratory revealed an uneven distribution of sampling in 2012 ranging from as few as 11 samples in January to 289 in September. Sampling is thus not carried out in variable intervals spread over the whole year as required under point 2.1 of the Annex to Decision 98/179/EC and therefore, **recommendation no 2** of the 2010 FVO report has not been fully addressed with regard to the distribution of sampling throughout the full year;
- in general, samples were taken in line with the plans developed by RFSDs. Based on the monthly reports of the RFSDs, LAD reallocated samples between regions if necessary (e.g. if a horse slaughterhouse in one region had closed, samples were reallocated to another region);
- in one RFSD visited, due to a clerical error, sampling submission forms for milk samples in 2011 did not include B2d substances as indicated in the centrally approved plan. The national laboratory did not report this omission to the respective RFSD nor to LAD;
- routine sampling under the RMP is unannounced and targeted in line with the national instructions. The RFSDs are requested to deliver samples within five days to the national laboratory. For the sample records selected at random by the audit team, this target had been achieved. Samples are officially sealed before their transport to the laboratory and therefore, **recommendation no 4** of the 2010 FVO report has been addressed with regard to sealing of official samples;
- although RMP samples are generally taken as planned, various laboratory and resource issues (such as a lack of consumables, faulty equipment or the unavailability of an analytical method - see also section 5.2) have led to samples being discarded unanalysed after three months of storage. At the time of the audit, the national laboratory had not yet analysed some samples for PCBs, organochlorine and organophosphorus pesticides, due to non-functioning laboratory equipment. **Recommendations no 4** and **5** of the 2010 FVO report have therefore not been fully addressed in this regard.

With regard to **medicinal treatment records** as required by Article 10 of Directive 96/23/EC and food chain information as required in Annex II to Regulation (EC) No 853/2004 the audit team noted that:

- on the dairy farm visited, the responsible veterinarians maintained the treatment records

(firstly treatment logbook of the veterinarian of the farm and, secondly a treatment record book to be signed off for each treatment by the owner of the farm) as required by national rules. These records provided the relevant information as laid down in Article 10 of Directive 96/23/EC. Therefore **recommendation no 8** of the 2010 FVO report has been addressed;

- in the slaughterhouse visited, all animals (cattle and horses) examined by the audit team were accompanied by the nationally required veterinary health certificate and declaration of the farmer on individual treatments of the animals. The declaration provides for the food chain information as laid down in Annex II to Regulation (EC) No 853/2004 and also allows the official veterinarian in the slaughterhouse to identify individual animals which may have been treated with veterinary medicinal products and thus target them for residues testing in line with the requirements of Point 2.3.3.1 of the Annex to Decision 98/179/EC. The official veterinarian stated that he checks these documents (requirement of Annex I to Regulation (EC) No 854/2004) and that so far he had not received a document, in which a treatment was indicated. **Recommendation no 8** of the 2010 FVO report has therefore been addressed.

With regard to **training** of staff responsible for the implementation of the RMP as required in Article 6 of Regulation (EC) No 882/2004, the audit team noted that:

- on 7 June 2012, 37 staff had received training on "improving official controls on residues of veterinary medicinal products: rules for sampling". The official veterinarians of the 28 RFSDs, responsible for implementation of the RMP in the regions, participated in this training. The participants had to pass a multiple choice test (ten questions) at the end of the training, and relevant documentation (tests, participant list) for the training was available at the BFSA. Afterwards, the centrally-trained staff had to deliver on-the-spot training for other local staff;
- in both RFSDs visited, the required on-the-spot training had been implemented and documented. In Plovdiv two cascade trainings had taken place on the 12th (63 staff) and 22nd June 2012 (44 staff) and in addition, on the 27th June 2012, training for 36 staff was provided on follow-up measures to be taken in case of non-compliant results.

With regard to **verification of the effectiveness** of official controls as required in Article 8 (3) of Regulation (EC) No 882/2004, the audit team noted that:

- the VMPCD develops an annual inspection programme for official controls on the use of veterinary medicinal products together with templates for check lists and records of these controls. The RFSDs provide quarterly records to BFSA about these controls, their results and measures/infringement procedures undertaken, which are analysed by the VMPCD to see if they comply with the aims and requirements of the annual plan. The RFSDs' reports focus on detected non-compliances and do not contain comparable and structured information on other data which would allow a verification of the effectiveness of official controls or a meaningful comparison to be made between the different RFSDs. To-date in 2012, the VMPCD has undertaken five joint inspections with RFSDs in case of alerts, which also served to evaluate the effectiveness of official controls carried out by these RFSDs;
- in March 2011, the Co-ordination and Control Directorate within BFSA was established. It carries out integrated controls (covering all areas of official controls within the responsibility of the BFSA) with the aim to verify the effectiveness of these controls. Based on an annual action plan, certain RFSDs are visited. The Directorate checks control reports and verifies whether findings have been made properly, non-compliances have been detected, recorded and followed-up. The audit team could not establish whether criteria against which the effectiveness of the official controls could be measured, had been drawn

up.

With regard to **internal (external) audits** as required in Article 4 (6) of Regulation (EC) No 882/2004, the audit team noted that:

- the Quality Management Directorate within BFSA is responsible for internal audits and its respective responsibilities are described in Article 25 of the Council of Ministers' Decree No 35, dated 14 February 2011. The current five-year audit programme (2012-2016) includes an internal audit on official controls on the use of veterinary medicinal products. This is planned for November 2013 and will include four audits of the respective official controls carried out by four RFSDs. These audits will be conducted and recorded based on standardised procedures approved by Order of the BFSA Executive Director No. RD-11-354, dated 4 May 2011;
- in 2011 (25 to 27 May), an audit on the VMPCD assessed if the overall performance of this Directorate was compliant with the BFSA Organisation Rules. The audit report contains a number of recommendations, *inter alia* relating to updating Standard Operating Procedures (SOPs), implementing risk criteria for the annual inspection programme, including information on effectiveness of official controls in respective reports/notes and developing an annual training programme. The VMPCD undertook corrective actions in response to the recommendations of the audit report. For example the Instruction on performing inspections in animal holdings to control the use of veterinary medicinal products and medicated feed has been changed and now indicates that these inspections are to be carried out without notification, as required by Article 3 (2) of Regulation (EC) No 882/2004. **Recommendation no 7** of the 2010 FVO report with regard to internal audits, has therefore been addressed.

With regard to the **implementation of the equine passport** as established in Regulation (EC) No 504/2008, and the use of Section IX of the equine passport as part of the food chain information for *equidae*, the audit team noted that:

- the Animal Health and Welfare Directorate within BFSA is the competent authority responsible for issuing identification documents to all *equidae*. In addition, four national horse breeding organisations are authorised to issue equine passports;
- relevant information related to equine passports (as required in Regulation (EC) No 504/2008) is kept in a national electronic information system -VetIS. This database allows information to be entered including, for example, whether a horse has been either temporarily or definitively signed out of the food chain (as provided for in Part II of Section IX of the horse passport). All veterinarians responsible for farms (about 1100) have been given access to VetIS. The official veterinarians of the slaughterhouse visited, demonstrated to the audit team, how they record in this system, if a horse has been slaughtered;
- BFSA and the four breeding associations had agreed on the deadline 31 July 2012 for issuing equine passports for all pure-bred animals. However, this deadline has not been achieved and mainly one breeding organisation has not finalised its task;
- there are approximately 139,000 horses in Bulgaria. Until November 2012, BFSA and the breeding organisations had issued 15,362 equine passports. **Recommendation no 10** of the 2010 FVO report has therefore not been adequately addressed in this regard. BFSA explained, that despite this incomplete implementation of horse passports, there is no major risk that horses would be moved to slaughterhouses, as according to national requirements, for such movements a veterinary health certificate has to be issued. This certificate would not be issued without the horse being properly identified with the unique horse identification number. For the 28 horses, slaughtered in 2012 at the slaughterhouse visited, the horses had

been identified in VetIS and indicated as slaughtered. **Recommendation no 11** of the 2010 FVO report has therefore been addressed in this regard;

- BSFA stated that in 2011, 592 administrative measures and 111 infringement procedures had been imposed related to unidentified *equidae* detected by official veterinarians during their controls of competitions or exhibitions or by the police during controls of animal movements. In one of the RFSDs visited, an example was provided to the audit team where three horses had been moved in an unlicensed vehicle without the nationally required veterinary health certificate and without an equine passport. The driver of the vehicle was fined and the horses sent back. Identification and issuing of passports for the horses was not possible as their ownership could not be established.

**Conclusions on implementation of the residue monitoring plan**

Improvements in the maintenance of medicines records and provision of food chain information underpin guarantees on the proper use of veterinary medicinal products and thus the chemical (residue) safety of food of animal origin. The establishment of an internal audit system also provides assurances that the control systems are functioning as intended for the areas covered by these audits. Sampling under the RMP is carried out in line with planned arrangements and staff are properly trained to undertake this task. However, sampling is not evenly distributed throughout the entire year which is not in line with EU requirements. More significantly, the effectiveness of the plan is weakened by its publication specifying the substances to be tested for and, in particular by the failure to carry out all of the planned analyses due to shortcomings in laboratory capability and/or analytical capacity.

Whilst procedures have been put in place to verify the effectiveness of official controls, the fact that no clear criteria have been established against which the competent authorities can evaluate effectiveness, is an issue. Finally, despite a well functioning electronic system for equine passports, Bulgaria continues to lag behind in its legal obligations to identify all *equidae* on its national territory and thus is not in compliance with the requirements of Regulation (EC) No 504/2008.

### *5.1.4 Other residues monitoring programmes*

**Legal Requirements**

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

**Findings**

For raw milk and honey, other residue monitoring programmes are in place. The audit team noted that:

- internal monitoring plans of honey-processing plants are based on Article 33 of Ordinance No. 9 of 22.05.2005, concerning procedures applicable to approval of plants for manufacturing of honey and bee-wax;
- internal monitoring plans for control of residues of pharmacologically active substances present in raw milk are legally based on Article 6 of Ordinance No. 4 of 19.02.2008

concerning the specific requirements applicable to manufacturing, of raw cow milk;

- national legislation requires, that samples are analysed in accredited laboratories and that non-compliant results are reported to the competent authorities.

#### *5.1.4.1 Establishment own-checks*

**Findings**

In general, establishments have own-check programmes in place, included in their HACCP plans. Exporting establishments often include demands of trading partners into these programmes. The slaughterhouse visited had no establishment own-checks implemented, and therefore the audit team could not further evaluate this topic.

**Conclusions on other residues monitoring programmes**

Other residue monitoring programmes in place can provide reassurances on the residues status of the products processed and placed on the market by those establishments.

### *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 and 55 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 and that sanctions provided for must be effective, proportionate and dissuasive.

**Findings**

Ordinance No. 119 of 21.12.2006, which transposes Council Directive 96/23/EC, contains the relevant national requirements with regard to follow-up of and actions to be taken in case of non-compliant results, depending whether the non-compliant results relate to Group A or Group B substances. Documented procedures (Instructions LD-2 and LD-3) describe the follow-up actions to be taken for all non-compliant results, whether obtained under the RMP, in the 'other' residue monitoring programmes or reported under the RASFF. The audit team noted that:

- the specified actions are in compliance with the requirements of the respective Articles of Directive 96/23/EC and staff had received relevant training to perform their tasks;
- since the 2010 FVO audit there has only been one non-compliant result reported under the RMP (2011, slaughterhouse sample with chlortetracycline detected in a duck muscle). Prompt follow-up actions had been taken and, on the day the result was reported the RFSD had established an enquiry team, inspected the slaughterhouse, taken follow-up samples and issued an order to impound the affected product batch. Three days later the farm was inspected and follow-up feed samples were taken. When questioned, the farmer admitted he had used a premix product containing chlortetracycline without a veterinary prescription and a fine was levied. Further follow-up samples were taken from the impounded product batch and the batch was finally sent for rendering;
- the audit team saw evidence that the farmer had been charged for the cost of sampling and testing as required by Article 19 of Directive 96/23/EC. In 2012, the farm was also targeted

for subsequent testing under the RMP (suspect sampling);

- non-compliant residue results from 'other' monitoring programmes are notified to the BFSA and RFSDs. In 2011, a non-compliant result (tetracyclines in duck muscle) was reported from a sample taken under a slaughterhouse's own-check programme. The RFSD responsible for the slaughterhouse issued an order to trace the affected product and started a follow-up investigation. The ducks had originated from another region. There was effective communication and co-ordination as required by Article 4 (3) of Regulation (EC) No 882/2004 between the two involved RFSDs. Detailed follow-up files documented the investigations undertaken on-farm and at the slaughterhouse, the results of follow-up samples taken and confirmation that the affected product had been sent for rendering;
- one non-compliant result for residues was reported in October 2011 under the RASFF - sulphathiazole in honey. The file was examined and was comprehensive in scope, well documented and demonstrated that timely follow-up actions had been undertaken.

**Conclusions on follow-up investigations/actions**

The legal and administrative framework in place for the follow-up of non-compliant results and its implementation are in line with the relevant provisions of Directive 96/23/EC and Regulation (EC) No 882/2004. Follow-up investigations and associated enforcement measures of the non-compliant results evaluated were carried out in a timely, comprehensive and effective manner.

### 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).

**Findings**

In Bulgaria, one governmental laboratory - the Central Laboratory for Veterinary Sanitary Expertise and Ecology (CLVSEE) - is responsible for testing official samples under the RMP. It is also designated as a National Reference Laboratory (NRL) for the tasks described in Article 14 of Directive 96/23/EC. The laboratory receives its budget from the BFSA.

As the laboratory does not have validated methods for all substances to be tested under the RMP within its scope of accreditation, since December 2011, BFSA has outsourced testing of these substances to a private laboratory (see point 5.1.3 of this report). The CLVSEE was visited by the audit team and it was noted that:

- Order No. RD 09-773 of MAF (dated 15.09.2011) designates the CLVSEE as NRL for all substance groups except Group B2f (carbadox/olaquindox);

- the laboratory contributes to the planning of the RMP by supplying information on compounds, CC-alphas and methods;
- in its function as NRL, in 2010 and 2012, the CLVSEE has organised proficiency tests for other/private laboratories with regard to residues of antimicrobials in raw milk. In 2010, in addition to these tests, the CLVSEE organised an in-house training for all the participants of the proficiency test programme;
- the national accreditation body (Bulgarian Accrediting Service - BAS) has accredited the CLVSEE to be compliant with the requirements of ISO 17025. The accreditation (certificate Ref. No. 61-LI issued on 07.03.2008) was renewed on 2 April 2012 and is now valid until 30 April 2016. The scope of the accreditation is published by BAS and can be found here: http://nab-bas.bg. In this accreditation document, 33 different methods are listed to be accredited to test for either a specific substance (e.g. chloramphenicol) or for a group of substances (e.g. beta-agonists). While each listed method is accredited for all animal tissues (raw material, products of animal origin and biological liquids) the CLVSEE does not use its methods for all possible tissues and often analytical methods vary depending on the different tissues in which the substances are tested for;
- during its re-accreditation visit in February 2012, BAS had recorded a number of shortcomings related *inter alia* to internal calibration, observation records and follow-up actions. The laboratory had implemented new procedures for calibration (thermometer and weighing scales), observation records and follow-up action. BAS also recorded, that two LC-MS/MS instruments were out of order, which was still the case at the time of the present audit. The laboratory transferred the respective testing to other LC-MS/MS instruments and controls before use of the other equipment had been undertaken and were documented;
- although there is a well documented procedure for the repair of broken equipment, the procedure is lengthy and additionally is often hampered by financial constraints. At the time of the audit, two GCs, one HPLC and one LC-MS/MS were not operational. As there are no service contracts for repairs of equipment, the laboratory sent a request via the BFSA to its Deputy Minister to receive the additional financial resources needed for the repair. Due to the breakdown of this equipment it has not been possible to analyse for PCBs, organochlorine and organophosphorus pesticides (see also 5.1.3 of this report);
- for some of the testing included in the RMP, the laboratory does not have validated confirmatory methods under its scope of accreditation. The laboratory stated, that in case of putative non-compliant screening results, the confirmatory testing would have to be outsourced to another suitable laboratory. However, at present, no laboratory is contracted for this procedure;
- at the end of 2011 tenders had been prepared for consumable items, analytical standards and small laboratory supplies, but at the time of the audit, not all these tenders were used to establish contracts for supply. As only few samples were received in the first quarter of 2012, supplies were sufficient for analysing in the first months of 2012, but not for all samples received in August and September, due for example, to the lack of ELISA kits for screening of Group A6 substances and a lack of solid phase extraction cartridges;
- staff are trained based on annual training plans and records of this are available. Participation of staff in training courses organised by the European Union Reference Laboratories (EU-RLs) is difficult, as individual staff have to prepay the costs of these courses;
- the laboratory participated in a range of proficiency tests organised by the EU-RLs, ten in 2010, eight in 2011 and ten so far in 2012. In 2010, the proficiency test results for the heavy

metals Pb and Cd were questionable and unsatisfactory, respectively. The responsible scientists concluded that malfunctioning microwave equipment could be the reason for the under-performance, the equipment was not changed. At the end of 2010 a scientist from an EU-RL provided in-house training, which improved the analytical results. For PCBs the proficiency test results for 2010, 2011 and 2012 were not satisfactory. In 2011 a proficiency test for quinolones in fish resulted in five false positive analytical results. The follow-up investigation identified that cleaning of the glassware was insufficient. However, the cleaning procedure for glassware was not amended. In 2010, 2011 and 2012, the laboratory could not participate in commercially available proficiency tests other than those organised by the EU-RLs;

- BFSA has established a targeted turn-around time of 30 days for the contracted laboratory and 14 days for RMP samples to be analysed following arrival in the CLVSEE. The CLVSEE frequently did not meet this turn-around time, due *inter alia* to the lack of a testing method, shortage of laboratory consumables or malfunctioning equipment. Occasionally samples were not analysed at all. Although compliance with the target turn-around time was monitored in the CLVSEE for the handling of individual samples, overall statistics were not available on the proportion of samples processed within the target turn-around time;
- incoming samples are entered into an electronic database and assigned to a unique identification number which ensures anonymity and traceability. Whilst a procedure (SOP 407-1) for sample reception is in place, as described in 2010 FVO report, this procedure does not include quality criteria for acceptance of samples, such as temperature and the state of packaging or sealing of the samples. Meat samples were not homogenised after registration, instead, pieces needed for the different analyses were cut-off and the remaining parts of the samples were stored in unsealed plastic bags in the freezer. The freezer was locked and temperature controlled;

The audit team evaluated some of the SOPs in place:

- SOP 504-1, dated 20 February 2012, describes different validation procedures for in-house screening and confirmation methods according to EU legislation;
- Quality form QF 505-4 describes the procedure for calibrating thermometers and temperature control of refrigerators and freezers, but does not contain the required corrective actions when temperature limits were exceeded;
- SOP 509-1 for quality assurance of analytical methods describes *inter alia* sample sequence, spikes and blank controls, but criteria for the acceptance of an analytical run are not mentioned;
- SOP 505-2 for control charts describes the actions to be taken when quality control samples are analysed and plotted in quality control charts. In practice, corrective actions after exceeding of limits had been taken but were not recorded.

The audit team also evaluated some of the analytical methods in place and their implementation:

- the validated and accredited ELISA screening method for chloramphenicol (Group A6) - SOP 504-33 - consists of a work instruction flowchart provided by the supplier of the ELISA kit to which the laboratory added instructions on the spiking concentration per matrix and instructions on the calibration of the equipment used;
- the newly developed, validated and accredited LC-MS/MS method for beta-agonists (Group A5), can analyse more then ten different beta-agonists. Chromatograms in matrix and spiked samples looked acceptable. However, so far in 2012, this method has not been used and the 2012 RMP includes only the two beta-agonists clenbuterol and salbutamol which are

analysed using GC-MS.

**Conclusions on laboratories**

Although the responsible governmental laboratory is accredited and has validated methods for most of the substances to be tested for under the RMP, ongoing deficiencies in its performance - caused by several distinct but inter-related resourcing problems – substantially weaken the effectiveness of the residue control system.

## 5.3 FOLLOW-UP OF RELEVANT RECOMMENDATIONS MADE IN PREVIOUS FVO REPORT ON RESIDUES (DG SANCO 2010-8436 MR FINAL)

| N | Recommendation | Findings |
|---|---|---|
| 2 | To ensure that the national residue control plan complies with requirements laid down in Articles 3 and 5 of Directive 96/23/EC particularly to in relation to addressing the deficiencies observed in relation to the geographical distribution of sampling and coverage throughout the full year. Planning should take into account all relevant data and be based on risk as required by Article 3 (1) of Regulation (EC) No 882/2004. | Corrective actions have been undertaken with regard to better geographical distribution of the samples (see point 5.1.2 of this report). Sampling over the year is not equally distributed (see point 5.1.3) and not all relevant data are taken into account as risk factors for planning the RMP (see point 5.1.2 and recommendations no 1 and 2 of this report). |
| 3 | To ensure that food business operators are not informed in advance of the scope of testing under the national residue control plan (i.e. by not publishing the scope of testing, regions and months of sampling in advance) in order to ensure that the element of surprise in checks is constantly maintained, in accordance with the requirements of Annex III to Directive 96/23/EC. | Corrective action was partially undertaken, as regional plans, which include the months of sampling are not longer published. However, the published RMP still indicates substances tested (or not tested) for (see point 5.1.3 and recommendation no 3 of this report). |
| 4 | To ensure that sampling for residues is carried out in accordance with all of the requirements laid down in the Annex to Decision 98/179/EC, and that testing is implemented in accordance with planned arrange-ments, if necessary taking appropriate corrective action to ensure this outcome as required by Article 8 (3) b of Regulation (EC) No 882/2004. | This recommendation has been partially addressed with regard to distribution of sampling and sealing of official samples. However, failure to carry out analyses as planned have resulted in the fact that legally required substance groups such as A2 and A5 have not been tested for in 2010, 2011 and partly in 2012 (see point 5.1.3 and recommendation no 4 of this report). |
| 5 | To ensure the provision of adequate laboratory capacity for residue analysis as required by Article 4 (2) c of Regulation (EC) No 882/2004. | As the contract - signed with a private laboratory in order to outsource certain testing in 2012 - was not implemented as planned, adequate laboratory capacity was not provided (see point 5.1.2 and recommendation no 4 of this |

| | | |
|---|---|---|
| | | report). In addition, the laboratory did not fulfil its analytical tasks due to a lack of consumables and broken equipment (see point 5.2.2 and recommendation no 6 of this report) |
| 6 | To ensure that appropriate quality control measures are put in place in the laboratory in line with Article 5 of Decision 2002/657/EC. | Various SOPs have been either newly drafted or updated and are implemented, therefore this recommendation has been addressed (see point 5.2.2 of this report). |
| 7 | To put in place an audit system as required by Article 4 (6) of Regulation (EC) No 882/2004, which covers all official controls falling under the scope of the above Regulation, including in particular those controls related to the use of veterinary medicinal products in food producing animals and the presence of residues and contaminants in food. | A five year internal audit plan (2012 – 2016) has been put in place for official controls under the responsibility of the BFSA. With regard to residue controls, four audits at four RFSDs are planned which will cover controls on the use of veterinary medicinal products (see point 5.1.3 of this report). |
| 8 | To ensure that the requirements for on-farm medicines records, as laid down in Article 10 of Council Directive 96/23/EC, are complied with. | On-farm medicines records, as laid down in Article 10 of Council Directive 96/23/EC, are implemented (see point 5.1.3 of this report). |
| 9 | To consider amending the format of food chain information in order to allow official veterinarians in slaughterhouses to identify individual animals which may have been treated with veterinary medicinal products and thus be targeted for residues testing in line with the requirements of Point 2.3.3.1. of the Annex to Commission Decision 98/179/EC. | The nationally implemented templates for food chain information provide for data on treatments of individual animals and therefore would enable the official veterinarian to carry out targeted sampling (see point 5.1.3 of this report). |
| 10 | To ensure that a system for equine identification is put in place without delay in accordance with the provisions of Commission Regulation (EC) No 504/2008. | A sufficiently detailed electronic system has been designed, which allows all required data to be recorded. However, as identification is only implemented for about 11 % of the existing horses, the requirements of Regulation (EC) No 504/2008 are not met and this recommendation is not fully addressed (see point 5.1.3 and recommendation no 5 of this report). |
| 11 | To ensure that horses without individual identification or an equine passport or appropriate food chain information do not enter the food chain in accordance with Commission Regulation (EC) No 504/2008. | This recommendation has been addressed (see point 5.1.3 of this report). |

## 6 Overall Conclusions

Whilst the responsibilities of, and co-operation between competent authorities involved in the planning of the residue monitoring plan are clearly defined, the design of the plan and its consequent effectiveness is weakened as some relevant risk criteria, such as data on the use of veterinary medicinal products, are not properly taken into account in deciding the substances to be tested for.

Regarding the implementation of the plan, improvements in the maintenance of medicines records and provision of food chain information underpin guarantees on the proper use of veterinary medicinal products and thus the chemical (residue) safety of food of animal origin. The establishment of an internal audit system also provides assurances that the control systems are functioning as intended for the areas covered by these audits. Sampling under the residue monitoring plan is carried out in line with planned arrangements and staff are properly trained to undertake this task. However, sampling is not evenly distributed throughout the entire year which is not in line with EU requirements. More significantly, the effectiveness of the plan is weakened by its publication specifying the substances to be tested for and, in particular by the failure to carry out all of the planned analyses due to shortcomings in laboratory capability and/or analytical capacity. In this latter respect, although the national reference laboratory is accredited and has validated methods for most of the substances to be tested for under the plan, ongoing deficiencies in its performance - caused by several distinct but inter-related resourcing problems – substantially weaken the effectiveness of the residue control system.

Concerning verification of the effectiveness of official controls, whilst procedures have been put in place to address this legal requirement, the fact that no clear criteria have been established against which the competent authorities can evaluate effectiveness, is an issue. Finally, despite a well functioning electronic system for equine passports, Bulgaria continues to lag behind in its legal obligations to identify all *equidae* on its national territory and thus is not in compliance with the requirements of Regulation (EC) No 504/2008.

## 7 Closing Meeting

A closing meeting was held on 30 November 2012 with representatives of the central competent authority. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities did not express disagreement and stated that they considered the findings and conclusions to have been made in an objective manner.

Following the final meeting a new Order was shown to the audit team, with which the RFSDs have been instructed, to carry out sampling in the first quarter of 2013 based on the planning in the second quarter on 2012, in order to ensure a more equal distribution of sampling over the year.

## 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. | To ensure that the residue monitoring plan complies with requirements laid down in Articles 3 and 5 of Council Directive 96/23/EC and takes into account relevant data such as use of veterinary medicinal products in order to be based on risk as required by Article 3 (1) of Regulation (EC) No 882/2004. |
| 2. | To ensure that sampling is implemented in variable intervals spread over the whole year in line with the requirements of the Annex to Commission Decision 98/179/EC. |
| 3. | To ensure that the published residue monitoring plan does not specify the substances to be tested, so that the element of surprise in the checks performed is maintained in line with Annex III to Council Directive 96/23/EC. |
| 4. | To ensure effective implementation and supervision of implementation of the residue monitoring plan and to guarantee that for identified problems, corrective actions are taken as required by Article 8 (3) (b) of Regulation (EC) No 882/2004. |
| 5. | To ensure that a system for equine identification is put in place without delay in accordance with the provisions of Regulation (EC) No 504/2008. |
| 6. | To ensure the provision of adequate laboratory capacity for the proper performance of residue analysis as required by Article 4 (2) (c) of Regulation (EC) No 882/2004. |

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6524

**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 |
| *Maximum Residue Limits for veterinary medicinal products in food of animal origin* | | |
| Reg. 37/2010 | OJ L 15, 20.1.2010, p. 1-72 | Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin |
| *Maximum Residue Levels for pesticide residues in food of animal origin* | | |
| Reg. 396/2005 | OJ L 70, 16.3.2005, p. 1-16 | Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC |
| *Maximum Levels for contaminants in food* | | |
| Reg. 1881/2006 | OJ L 364, 20.12.2006, p. 5-24 | Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs |
| *Authorisation of veterinary medicinal products* | | |
| Dir. 2001/82/EC | OJ L 311, 28.11.2001, p. 1-66 | Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products |

| Legal Reference | Official Journal | Title |
|---|---|---|
| *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 |