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FINAL REPORT OF A MISSION CARRIED OUT IN BULGARIA FROM 24 NOVEMBER TO 28 NOVEMBER 2008 IN ORDER TO EVALUATE THE CONTROL OF RESIDUES AND CONTAMINANTS IN LIVE ANIMALS AND ANIMAL PRODUCTS, INCLUDING CONTROLS ON VETERINARY MEDICINAL PRODUCTS

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) mission in Bulgaria, carried out between 24 and 28 November 2008, as part of the published programme of FVO inspections on residue controls in Member States.

The objective of the mission 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 Community legislation in this field, including legislation on the control and distribution of veterinary medicinal products. The mission assessed the performance of the competent authorities involved in residues and veterinary medicinal product controls and the legal and administrative measures put in place to give effect to the relevant Community requirements.

Overall, and in comparison with the 2006 residues mission, progress has been made in the implementation of controls on residues and on veterinary medicinal products. There is a framework for residues controls in place which is largely in line with Community requirements. However, the effectiveness of the residue control system is compromised by deficiencies related to the analytical capability of the national residue laboratory. No provisions are in place to outsource samples which cannot be analysed in the national laboratory so the 2007 and 2008 residue plans have not been implemented in line with Council Directive 96/23/EC. In addition, the regional distribution of residue sampling hampers the consistency of official controls in that the chance of detecting violations varies considerably between regions. As regards the authorisation and control of veterinary medicinal products Bulgaria is largely in line with Community legislation but the equine passport system, comprising inter alia the information whether the animal has been excluded from the food chain, has not been implemented in Bulgaria.

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.

TABLE OF CONTENTS

ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Abbreviation	Explanation
AOZ and AMOZ, AHD and SEM	Marker residues of the nitrofuran drugs furazolidone, furaltadone, nitrofurantoin and nitrofurazone respectively
CLVCE	Central Laboratory for Veterinary Control and Ecology
DG(SANCO)	Health and Consumer Protection Directorate General
EC	European Community
EEC	European Economic Community
ELISA	Enzyme-linked immunosorbent assay
EU	European Union
FVO	Food and Veterinary Office
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC: A1 Stilbenes A2 Thyrostats A3 Steroids A4 Zeranol A5 Beta-agonists A6 Substances listed in Annex IV to Council Regulation (EEC) No 2377/90 B1 Inhibitors (antimicrobials) B2a Anthelmintics B2b Coccidiostats B2c Carbamates and pyrethroids B2d Sedatives B2e Non-steroidal antiinflammatory drugs, NSAIDs B2f Others (e.g. corticosteroids) B3a Organochlorines including PCBs B3b Organophosphorus compounds B3c Chemical elements B3d Mycotoxins B3e Dyes B3f Others

Abbreviation	Explanation
ICVMP	Institute of Control of Veterinary Medicinal Products
ISO	International Organisation for Standardisation
LC-MS/MS	Liquid Chromatography-(Tandem) Mass Spectrometry
MRL	Maximum Residue Limit
NFGS	National Feed and Grain Service
NRCP	National Residue Control Plan
NVS	National Veterinary Service
RVS	Regional veterinary Service
SLCT	Science, Laboratory Control and Training Directorate

1 INTRODUCTION

The mission took place in Bulgaria from 24 to 28 November 2008. The mission team comprised 3 inspectors from the Food and Veterinary Office (FVO) and one national expert. The mission was undertaken as part of the FVO's planned mission programme, evaluating control systems and operational standards in this sector.

Representatives from the central competent authority accompanied the inspection team during the whole mission. An opening meeting was held on 24 November with the central competent authority 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 mission were confirmed by the inspection team and the control systems were described by the authorities.

2 OBJECTIVES OF THE MISSION

The objective of the mission 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 mission was based on Council Directive 96/23/EC and other relevant Community legislation in this field, including legislation on the control and distribution of veterinary medicinal products. The mission 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 mission to Bulgaria (DG (SANCO)/8017/2006) in October 2006. The table below lists sites visited and meetings held in order to achieve that objective.

Meetings/Visits		n	Comments
Competent Authorities	**Central**	3	Opening and closing meetings and one interim meeting with the central competent authorities
	Regional	1	Meetings with the Regional Veterinary Service in Pazardjik
Laboratories		1	Central Laboratory for Veterinary Control and Ecology
Farms		1	One major pig farm with on-farm mixing of medicated feed
Establishments		1	One slaughterhouse for bovines, pigs and small ruminants
Other sites		2	One wholesaler and one retailer of veterinary medicinal products

3 LEGAL BASIS FOR THE MISSION

The mission was carried out under the general provisions of Community 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;

– Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in Member States.

A full list of the legal instruments referred to in this report is provided in Annex 1 and refer, where applicable, to the last amended version.

4 BACKGROUND

4.1 SUMMARY OF PREVIOUS FVO MISSION RESULTS (DG (SANCO)/8017/2006)

The previous FVO residues mission to Bulgaria (DG (SANCO)/8017/2006) took place in October 2006. At the time, a framework for residues controls in line with EU requirements was in place. The coordinating body established in 2005 was functional and an NRCP coordinator had been appointed. However, there were still deficiencies in the supervision and follow-up of non-compliant results of the NRCP which weakened the overall efficiency of the control system. The performance of the residue control system was also affected by deficiencies related to the analytical capability of the one national reference and control laboratory. Several mandatory substance groups could not be analysed in the laboratory. However, new "state of the art" equipment had been purchased and the laboratory was in the process of rectifying these deficiencies. Furthermore, contacts had been made with laboratories in other Member States with the aim of out-sourcing analyses for the substance groups which could not be analysed in-house, until validation and introduction of new methods had taken place in the national laboratory. As regards the authorisation and control of veterinary medicinal products, Bulgaria was largely in line with Community legislation.

5 MAIN FINDINGS

5.1 RESIDUE CONTROL PROGRAMMES

5.1.1 National Residue Control Plan

5.1.1.1 Bodies involved

The National Veterinary Service (NVS) under the Ministry of Agriculture and Food is the central competent authority in accordance with Article 4 of Council Directive 96/23/EC.

5.1.1.2 Planning of the national residue control plan

The Directorate for Science, Laboratory Control and Training (SLCT**)** drafts the plan in co-operation with the Central Laboratory for Veterinary Control and Ecology (CLVCE) in the beginning of the year after receiving production data and the number of establishments from the Regional Veterinary Services (RVS). The SLCT allocates the number of samples and a timetable for sampling to each RVS and sends the draft plan to the regions for detailed planning. The regional plans are resubmitted to the SLCT at the beginning of the sampling year. The SLCT then finalises the National Residue Control Plan (NRCP) and submits it to the Minister of Agriculture and Food for final approval in March. The sampling is implemented at regional level from January, based on the plan for the previous year, pending final approval of the NRCP at central level.

The mission team noted for the NRCP 2008 that:

- all relevant bodies are involved in the planning of the NRCP;
- the criteria that are taken into account during the planning process are the production data, number of establishments, results of the previous year, and laboratory capability;
- the regional breakdown showed that 27 of the 28 regions were involved in the sampling for the 2008 NRCP. However 20 regions each sampled only 1-4 of the 12 commodities. For example, pigs were sampled at slaughter in 10 regions and bovines were sampled at slaughter in 4 regions although slaughterhouses for pigs exist in 25/28 regions and for bovines in 19/28 regions;
- in the region visited, the same four commodities had been sampled 2007 and 2008. Since 2007 this region had two slaughterhouses slaughtering ruminants and pigs, however no ruminants or pigs had been sampled for the NRCP in this region since Bulgaria became a Member State;
- horses are only sampled for group A substances in live animals. The competent authority stated that the one slaughterhouse approved for slaughter of equidae intermittently slaughters horses only from Romania and the meat is sent to Romania, therefore no sampling had been conducted in this slaughterhouse under the NRCP;
- most of the following deficiencies in the 2008 NRCP were pointed out by the Commission during the evaluation of the plan:
    - - A2 (thyrostats): although included in the 2008 NRCP, as in 2006 neither screening nor confirmation methods are available;
      - B2b (coccidiostats): as in 2006 no methods are available for bovine, pigs or sheep/goat;
      - B2d (sedatives): as in 2006, no methods are available for bovines or sheep/goats;
      - B2e (non-steroidal anti-inflammatory drugs, NSAIDs): as in 2006, no methods are available;
      - B3c (carbamates and pyrethroids): there is no method for honey,

- the screening methods (ELISA) for nitrofurans (A6) detect only one (AOZ in milk) or two (AOZ, AMOZ in the other commodities) marker residues instead of the four which should be included (AOZ, AMOZ, AHD, SEM);
- the scopes of analytes are limited *inter alia* for substance groups A5, A6 (honey), B1(honey), B2a, B2b, B2f (honey);

- for antimicrobials (B1) all substances covered are not specified in the NRCP although the screening method had been comprehensively validated and the information about the scope was available in the laboratory;
- for antimicrobials confirmatory methods are available only for tetracyclins (in bovine, ovines/caprines, poultry, rabbits and pheasant) and sulphonamides (in these commodities and in milk and honey). These deficiencies were pointed out by the Commission also with regard to the 2007 NRCP;
- as in 2006, the limit of detection for the screening method for aflatoxin M1 in milk is 10 times higher than the Community ML;
- certain substances are listed in the 2008 NRCP with maximum residue limits (MRLs) although no MRLs exist in Council Regulation (EEC) No 2377/90 for those substance/matrix combinations. Examples are sulphonamides, penicillins, streptomycin, enrofloxacin and nicarbazin in eggs, streptomycin in poultry and aquaculture and closantel in pigs.

5.1.1.3 Implementation of the national residue control plan

On the basis of the regional distribution of the NRCP, each RVS breaks down the number of samples allocated to it and distributes sampling plans to the appointed official veterinarians in the municipalities who carry out sampling. These official veterinarians decide which farms and establishments are sampled.

The mission team noted that:

- although outsourcing of samples pending development and validation of methods in the CLVCE was foreseen in the action plan provided by the competent authority in response to the recommendations in the 2006 report (DG SANCO 8017/2006), such funding requested for the budget years 2006, 2007 and 2008, had not been granted to the laboratory from the central competent authority. Samples for a number of the missing substance groups had been collected during 2006, 2007 and 2008 and were stored in the laboratory pending their possible analysis in foreign laboratories;
- sampling for the 2008 NRCP had started in January and sampling was routinely carried out without prior warning;
- a two-day training had been given in October 2008 as regards the NRCP sampling, packaging and transport of samples and the recently amended follow-up procedures. All RVS had been obliged to participate and participation lists were available;
- the implementation of the 2007 NRCP was not in line with the requirements of Council Directive 96/23/EC since:

- no samples were analysed for A2 (thyrostats), B2b (coccidiostats) in bovines, ovines/caprines or swine, B2c (pyretroids) or for B2d (sedatives) in bovines or ovines/caprines, B2e (NSAIDs);
- B2d (sedatives) had been analysed in pigs only, however only in 50% of the collected samples and only for one substance since the method was not available until the second semester 2007;

- the implementation of the 2008 NRCP was not in line with the requirements of Council Directive 96/23/EC since:
  - equidae had not been sampled for A2 or any group B substances although equidae had been slaughtered for human consumption in 2008;
  - no samples had been analysed for A2 (thyrostats) in any species, B2b (coccidiostats) in bovines, ovines/caprines or swine, B2d (sedatives) in bovines or ovines/caprines or B2e (NSAIDs) in any species;
- as noted in the report of the 2006 residue mission, samples are not always delivered to the laboratory until weeks after sampling. Target turnaround times for analyses have not been agreed between the laboratory and the competent authority;
- each RVS is responsible for obtaining and providing sampling and packaging material to the samplers. There are no specific guidelines or requirements from the central level or from the laboratory as long as the sample does not leak. In the two regions visited the procedures for sealing the sample were different. In addition, in one follow-up investigation of chloramphenicol in bovines it had been noted that the sampler had cleaned and re-used an old bottle, said to have previously contained chloramphenicol, for the sample taken on farm. Thus the integrity of the samples (i.e. prevention of cross-contamination and degradation) could not be ensured as required by point 2.6 of the Annex to Commission Decision 98/179/EC.

5.1.1.4 Supervision of the national residue control plan

The responsibility for the supervision of the implementation of NRCP lies with the SLCT. The RVSs inform the SLCT on a monthly basis of the implementation of the plan and they also send quarterly summary reports to the SLCT. The NRCP coordinator collates these data and prepares 6 and 12 month reports for the NVS.

The mission team noted that:

- comprehensive details about the number of samples received and analysed during 2008 to date was available from the CLVCE;
- the clear allocation of samples to be taken monthly by each region and the comprehensive reporting system allow rapid action in case of under-sampling. The SLCT stated that samples had been re-allocated to other regions during 2008 in order to meet the overall target;
- for the slaughterhouse visited the RVS had ordered sampling of lambs for May 2008, while the bulk of lambs were slaughtered already in April. This had been noted by the RVS during the autumn and sampling of lambs had been re-scheduled

to November.

5.1.2 Other residue control programmes

Other than the national residue control plan, there are no official residue control programmes in Bulgaria.

5.1.3 Establishment own-checks

Self-monitoring programmes including controls for certain residues are in operation e.g. in dairies, honey producers and in most slaughterhouses. The results from these analyses are available to the competent authorities upon request. In addition, a number of the analyses of honey, milk, poultry, eggs, aquaculture products, and meat for private companies are conducted in the CLVCE.

5.1.4 Follow-up of non-compliant results

The SLCT is responsible for co-ordination of the follow-up actions and each RVS is responsible for the follow-up of non-compliant results in the region. The CLVCE reports non-compliant results to the SLCT and the RVS in question.

The mission team noted that:

- complete follow-up files were kept at the SLCT;
- the instruction on follow-up has been amended recently. However, as in 2006 the instruction does not clarify the purpose of the follow-up and does not give detailed enough guidelines for the veterinary officer on what to include in the on-farm investigation (e.g. sampling of feed or water, investigation of feed sources, which types of animals to sample) depending on the type of substance. Nor are there uniform report templates for the investigations. Further instructions may exist in RVSs but the SLCT cannot ensure that follow-up investigations are equally effective in all regions, which is a key requirement of Article 4.4 of Regulation (EC) No 882/2004;
- the non-compliant findings of antimicrobials in honey have represented 4.4-7.4% of the samples analysed for group B1 during 2006-2008 and have not been reduced in spite of a ban on the use of antibiotics and sulphonamides for honey bees in place since 2003;
- several follow-up files from 2007 and 2008 were studied (two cases of antimicrobials in honey, one case of malachite green in trout and one case of AOZ in poultry): The results were communicated without delay to the RVS and to the officials involved. Prompt follow-up measures including on-farm investigations, movement restrictions and intensified monitoring had been carried out in all cases, and the RVSs in question had reported the outcome of the investigations to the SLCT. However, the source of the residue was in most cases not identified and the extent of the on-farm investigations could not be evaluated on the basis of the reports.

5.2 LABORATORIES

5.2.1 The Central Laboratory of Veterinary Control and Ecology

The Central Laboratory of Veterinary Control and Ecology (CLVCE) is the only residue control laboratory involved in testing for the NRCP. The CLVCE is an autonomous unit within the NVS, and receives a budget for the NRCP activities from the NVS. In addition to the NRCP testing (ca 70% of the analytical work), the CLVCE also performs analyses for export and import certification, for the auto control system of food producers and in research projects together with the university.

Since 2003 the CLVCE is appointed as the National Reference Laboratory (NRL) for all substance groups listed in Annex I to Council Directive 96/23/EC. As an NRL, the CLVCE is involved in the planning and supervision of the NRCP and has contacts with the Community Reference Laboratories and residue laboratories in other Member States.

The CLVCE is accredited according to ISO 17025 by the Bulgarian Accreditation Service, which is a member of the European co-operation for Accreditation.

The mission team noted that:

- the director of the CLVCE had repeatedly notified the NVS in writing of the adverse impact on method validation and the implementation of the NRCP, linked to receipt of 33%, 70% and 21% of the budget applied for in 2006, 2007 and 2008, respectively;
- the accreditation is valid until 31.03.2012 and specifies the SOP number of all residue methods included in the scope. Some of these methods are validated using the traditional approach but not yet fully validated in accordance with Commission Decision 2002/657/EC and therefore not used for the NRCP;
- one minor non-compliance had been found during the last audit by the Bulgarian Accreditation Service in November 2007 and corrective action had been taken;
- when samples are registered the software in the laboratory automatically sets a target turnaround time for screening analyses of less than one week. However, in many cases this turnaround time had not been adhered to;
- samples are traceable and anonymous when analysed. However, there is no instruction in place defining quality criteria for acceptance or rejection of samples arriving to the laboratory to ensure the integrity of the sample as required by point 2.6 of the Annex to Commission Decision 98/179/EC;
- a break down of the one LC-MS/MS and lack of a service contract for this equipment has led to major analytical delays, e.g. samples taken on farm in the end of October as part of a follow up investigation of a finding of chloramphenicol had not yet been analysed one month later. The farm is under restrictions pending the result;
- progress has been made in method development and validation and the validation files studied were comprehensive and in line with the requirements of Commission

Decision 2002/657/EC;

- methods are under development for screening/confirmation of thyrostats (A2), screening/confirmation of all four nitrofuran marker residues (A6), and confirmation of relevant antibacterial substances in all matrices;
- for substance group A2, the file for validation according to Commission Decision 2002/657/EC showed that the validation was almost completed. In addition, the CLVCE stated that for substance groups A3, A5 and A6 the validations of methods with extended scopes would be finished by the end of 2008 so that these methods would be used from the beginning of 2009. For substance groups B2c, B2d and B2e the methods would not be available until later during 2009;
- the CLVCE had participated in proficiency tests organised by the CRLs in the field of veterinary drug residues when the available methods had been fully validated and most of the obtained results had been satisfactory. The laboratory had not participated in any commercially available proficiency tests for residues of veterinary medicinal products in food.

5.3 VETERINARY MEDICINAL PRODUCTS AND MEDICATED FEEDINGSTUFFS

5.3.1 Authorisation of veterinary medicinal products

The NVS, through the Department of Veterinary Medicines and Feed Safety Control, is the national authority responsible for the marketing authorisation of veterinary medicinal products. The Institute of Control of Veterinary Medicinal Products (ICVMP) under the NVS evaluates the dossiers and reports to the advisory body, Commission of veterinary medicinal products. The NVS authorises the veterinary medicinal products on the basis of the Commission's proposal. The ICVMP keeps the dossiers for the marketing authorisations. The authorisations have five years validity from the date of issue.

The mission team noted that:

- the list of authorised veterinary medicinal products were publicly available on the NVS website. The website is amended regularly, approximately every two months;
- all veterinary medicinal products having withdrawal periods or which may influence the production of food producing animals are 'prescription only' medicines. Commission Directive 2006/130/EC has not yet been transposed into Bulgarian legislation but the authorities explained that only some products without withdrawal times e.g. vitamins will be available without prescription;
- no active substances listed in Annex IV to Regulation 2377/90 were present on the list of authorised veterinary medicinal products for food producing animals;
- some veterinary medicinal products containing active substances not listed in Annexes I, II and III to Regulation 2377/90 were authorised for use in animals intended for food production e.g. acepromazine;

- immediately after the 2006 residues mission marketing authorisations for several veterinary medicinal products were revoked or amended e.g. as regards target species. However, in the current list of veterinary medicinal products there were a number of products containing pharmacologically active substances for target species not listed in Annexes I, II or III to Regulation (EC) No 2377/90 for this substance. Examples of such active substances are:
    - dexamethasone also for sheep (MRL for bovine, porcine, equidae, caprine);
    - metamisol also for small ruminants (MRL for bovine, porcine, equidae);
    - apramycin for several species (MRL for bovine);
    - albendazol, fenbendazol, deltamethrin, flumethrin and permethrin also for horses;
- several active substances e.g. ivermectin and rafoxanide were authorised for bovines without restriction "not for use in animals from which milk is produced for human consumption";
- preparations containing flavophospholipol (prohibited in Bulgaria from 30 September 2006 as a feed additive for growth promotion) were still included on the list of authorised veterinary medicinal products. This was noted also during the 2006 mission;
- use of antimicrobials for honey bees has been forbidden with a Ministerial Ordinance in 2003. A memorandum, including *inter alia* training of beekeepers, was signed by all relevant stakeholders.

5.3.2 Distribution and use of veterinary medicinal products

The NVS authorises wholesalers and veterinary pharmacies. Distributors are licensed only after a pre-authorisation inspection by the NVS or RVS. The national legislation requires the presence of a responsible veterinarian during opening hours. Wholesalers distribute veterinary medicinal products to veterinary pharmacies, veterinarians and large farms.

The mission team noted that:

- the minimum content of veterinary prescriptions is specified in the national legislation;
- medicated premixes can be prescribed for use directly on farms which have no authorised feed mill. This is neither in line with national legislation nor foreseen in Council Directive 90/167/EEC.

5.3.3 Controls on the distribution and use of veterinary medicinal products

The RVSs are responsible for the controls on distribution and use of veterinary medicinal products. Each RVS is obliged to nominate an official for the controls related to distribution and use of veterinary medicinal products, including feed mills manufacturing medicated feed. In addition, each municipality has an official responsible for these

controls in its area.

The mission team noted that:

- the NVS issues annually a national inspection plan for veterinary medicinal products. This plan is distributed to all regions. The current plan stipulated *inter alia* an inspection frequency of two inspections per year for all farms as well as for distributors of veterinary medicinal products. In addition, it contained checklists for inspections at wholesalers, veterinary pharmacies and private veterinary practitioners. There were no checklists for inspections of farms or feed mills manufacturing medicated feedingstuffs;
- risk criteria for inspections (e.g. past performance of the operators) had been identified in the annual inspection plan and were used only to increase the inspection frequency when necessary;
- the target inspection frequencies for the on farm visit had not been met. The RVS visited applied lower inspection frequencies based on animal welfare requirements and annually visited ca 10% of cattle herds, 5% of small ruminant herds, 100% of pig and poultry herds;
- the RVSs are obliged to report on controls on veterinary medicinal products to the NVS on a quarterly basis. Evidence of this was seen;
- an audit team comprising of officials from the NVS and two other RVSs had carried out an audit in 2008 in the RVS visited. The control of the veterinary medicinal products had been included in the scope of the audit. An audit report was available, corrective actions had been requested and actions had been taken. However, the audit procedure was not completely in line with the audit guide lines laid down in Commission Decision 2006/677/EC.

5.3.3.1 Controls at wholesale and retail level

The mission team noted that:

- in the wholesaler and veterinary pharmacy visited, regular inspections had been carried out in accordance with the annual inspection plan, reports were available and centrally issued checklists had been used;
- batch numbers of purchased and sold veterinary medicinal products were recorded in the wholesaler and veterinary pharmacy visited in accordance with the requirements of Art 66 of Directive 2001/82/EC;
- prescriptions were kept by the veterinary pharmacy visited. However, several prescriptions did not contain relevant information required by the national legislation e.g. species, dosage and duration of the treatment. These deficiencies had not been detected during the inspections.

5.3.3.2 Controls in feed mills (medicated pre-mixes and medicated feedingstuffs)

The National Feed and Grain Service (NFGS), under the Ministry of Agriculture and Food, approves all feed mills. Although there is no separate license for manufacturing

medicated feedingstuffs, this manufacturing is subject to the RVS approval. Inspections of all feed mills are performed independently by the inspectors of the NFGS and the RVS but the responsibility of controls on medicated feedingstuffs lies with the RVS. The production of medicated feedingstuffs is allowed only on veterinary prescription and an inspection and an expert opinion by the RVS is required before production may take place. In addition, the competent authority stated that future national legislation will require a separate licence for manufacturing of medicated feed both in commercial feed mills and in on-farm mixers.

The mission team noted that:

- there was an agreement between the NFGS and NVS as regards *inter alia* communication of non-compliant findings;
- the RVSs were not obliged to inform the NVS of feed mills producing medicated feed and consequently the central level was not aware of the number and location of these feed mills;
- there are no centrally issued guidelines or checklists for inspectors as regards the control of medicated feed. Feed mills are obliged to have a system to prevent cross contamination from the medicated feed to non-medicated feed but there are no guidelines available for the business operators;
- it was seen at the on-farm feed mill visited that the RVS had carried out inspection visits as well as having evaluated relevant documents before authorising the manufacturing of the medicated feedingstuffs. The feed mill had procedures in place to ensure homogeneity and prevent cross contamination but the effectiveness of these measures had not been verified by laboratory tests as required by Article 4 of Council Directive 90/167/EEC. In addition, the competent authority stated that there are no laboratories in Bulgaria to carry out these tests.

5.3.3.3 Controls on veterinary practitioners and farms

The mission team noted that:

- all farms are obliged to keep treatment records. However, only treatments administered by the veterinarian are entered in the records. This was a finding already during the 2006 residues mission and the competent authority had promised that this would be rectified when the legislation is next amended. However, this has not yet happened;
- complete treatment records were seen at the pig farm visited as the farm employed a private practitioner who was responsible for all treatments;
- there was evidence that regular inspections of the pig farm visited and the veterinary practitioner had been carried out;
- the RVS visited stated that use of veterinary medicines is always checked in connection with animal welfare checks although the animal welfare checklists do not cover use of veterinary medicines in all animal species;
- all farmers are obliged to send food chain information of all species when sending

animals into slaughter;

- in the pig farm visited a veterinary medicinal product authorised only for poultry was found. The private practitioner responsible for treatments in this farm was not aware that the default withdrawal period described in Article 11 of Directive 2001/82/EC should be applied when administering this drug to pigs under the "cascade".

5.3.3.4 Equine passport system

Two organisations, "Bulgarian Equestrian Federation" and the "National Horse-breeding Association" are designated by the competent authority as issuing bodies for identification documents for sports horses and breeding horses.

The mission team noted that:

- identification documents for equidae, including section IX (medical treatments), as required under Commission Decision 93/623/EEC as amended by Commission Decision 2000/68/EC, have not been implemented;
- the Competent authority stated that the issuing bodies for sport and breeding horses are to include Section IX in all passports issued after 1 January 2009. Passports for other equidae are to be issued by the Regional Veterinary Services but there are currently no procedures in place for issuing identification documents for such animals (including farm horses and donkeys);
- a new model equine passport for sport and breeding horses has been drafted based on Commission Regulation (EC) No 504/2008, which comes into force in the Community on 1 July 2009, repealing Commission Decisions 93/623/EEC and 2000/68/EC. This draft comprised medical treatment information but it made no reference to the Sections as defined in Community legislation and the layout was also different for Section IX compared to the model document in the Community legislation;
- there have been no training activities and there are no documented procedures regarding the use and control of identification documents for equidae;
- there are several veterinary medicinal products on the market for which the indications are restricted to "horses not intended for human consumption". However, there is no system in place to permanently exclude from the food chain those equidae treated with these products or other substances which are neither listed in Annexes I-III to Regulation (EEC) No 2377/90 nor in Commission Regulation (EC) No 1950/2006;
- Regulation (EC) No 1950/2006, establishing a list of substances essential for the treatment of equidae, has not been applied in Bulgaria;
- equidae can be transported within Bulgaria without equine passports and are accepted for slaughter provided that they are accompanied by a transport certificate and a declaration (food chain information) signed by the owner and a veterinary certificate stating *inter alia* that withdrawal times have been respected if the animal has received treatments and that the horse has not been treated with prohibited

substances;

- horses transported to other Member States (mainly Italy) for slaughter do not have equine passports containing Section IX as required under Commission Decision 93/623/EEC as amended by Commission Decision 2000/68/EC. In the region visited, approximately 50 such horses per month were issued with the standard documents (see previous bullet point) and transported to other Member States, mostly for slaughter. According to the RVS most of these horses were accepted for slaughter in Italy.

6 CONCLUSIONS

6.1 NATIONAL RESIDUE CONTROL PLAN

1. A framework for residue controls is in place and it is mostly in line with Community requirements. However, several mandatory substance groups are not tested due to lack of methods and no provisions have been made to submit these samples to foreign laboratories. In addition, the scope of substances included is narrow for some substance groups and no sampling is foreseen in slaughtered equidae. As a result of these shortcomings, misuse or illegal use of a number of important pharmacologically active substances cannot be detected and residue controls are not implemented in line with the requirements of Council Directive 96/23/EC.
2. The distribution of sampling between regions, with certain commodities sampled only in a few regions and few changes in the regional distribution between years, leads to a very uneven chance of detecting violation depending on the geographical location of farms, slaughterhouses and other sampling sites. Consequently the competent authority cannot guarantee the consistency of official controls as required under Article 4.4 of Regulation (EC) No. 882/2004.
3. Delays in submitting samples to the laboratory, delays in analysis and lack of defined criteria for sample packaging and acceptance in the laboratory means that the competent authority cannot ensure the integrity of the samples as required by point 2.6 of the Annex to Commission Decision 98/179/EC.
4. Lack of detailed guidelines as regards follow-up investigations on farm mean that the competent authority cannot guarantee that these investigations are effective in identifying the source of the residue and that they are carried out in a uniform manner in all regions. Consequently the competent authority cannot guarantee the consistency of official controls as required under Article 4.4 of Regulation (EC) No. 882/2004.

6.2 LABORATORIES

1. The analytical capability of the laboratory has improved compared to the situation in

2006. However, due to lack of funding several important methods are not available and a number of available methods have a narrow scope. As a consequence the residue control laboratory is not yet been able to provide all analyses required for the NRCP. These shortcomings make it impossible for the competent authority to detect residues of many of the relevant authorised and unauthorised substances as required under Council Directive 96/23/EC.

2. The validation of analytical methods is in accordance with Commission Decision 2002/657/EC and allows the competent authority to have confidence in the quality of results generated by the laboratory. However, a number of relevant methods will not be validated and ready to use from the beginning of 2009 and, as in 2008, in the absence of outsourcing certain tests to competent laboratories in other Member States, the NRCP 2009 will not fulfil the requirements of Council Directive 96/23/EC.
3. The lack of service contracts for important analytical equipment, has caused delays in repairs and very long turnaround times for analysis of samples. In addition, no target turnaround times have been agreed with the competent authority and the internal targets set by the laboratory are not always met. These factors may lead to unnecessary delays which hamper timely follow up of non-compliant results.
4. There are no defined quality criteria for acceptance / rejection of samples in the laboratory which may lead to the analysis of unsuitable samples and an inability to guarantee the integrity of the samples as required by point 2.6 of the Annex to Commission Decision 98/179/EC.

6.3 VETERINARY MEDICINAL PRODUCTS AND MEDICATED FEEDINGSTUFFS

1. The general process for marketing authorisations is in line with EU requirements. However, the target species for authorised veterinary medicinal products are not fully in line with EU requirements. This increases the risk that residues of pharmacologically active substances, for which there are no maximum residue limits listed for the species in question in Council Regulation (EEC) No 2377/90, are present in food derived from treated animals.
2. There are no guidelines or checklists for controls on veterinary medicinal products on farms or in feed mills manufacturing medicated feed. Consequently, the central competent authority cannot guarantee the consistency of controls throughout the country which is required by Article 4.4 of Regulation (EC) No. 882/2004.
3. The fact that on-farm treatment records are not required for veterinary medicinal products administered by animal holders means that at present, Bulgaria is not complying with Article 10 of Council Directive 96/23/EC and the lack of on-farm treatment records may reduce the effectiveness of controls on the use of veterinary medicinal products in food producing animals as well as hamper the implementation of the food chain information as required under Article 7 and Annex II to

Regulation (EC) No 853/2004.

4. The identification system for equidae (equine passport), as required under Commission Decision 93/632/EEC amended by Commission Decision 2000/68/EC, comprising *inter alia* Section IX (administration of veterinary medicinal products) has not been implemented. Therefore, there is no system in place to register the permanent exclusion of those equidae from the food chain which have been treated with certain veterinary medicinal products not listed in Annexes I-III to Council Regulation (EEC) No 2377/90, several of which are available in Bulgaria. When these horses are presented for slaughter (regularly in Italy) there are no documents to show if the animal may be slaughtered for food production.

6.4 OVERALL CONCLUSION

Overall, and in comparison with the 2006 residues mission, progress has been made in the implementation of controls on residues and on veterinary medicinal products. There is a framework for residues controls in place which is largely in line with Community requirements. However, the effectiveness of the residue control system is compromised by deficiencies related to the analytical capability of the national residue laboratory. No provisions are in place to outsource samples which cannot be analysed in the national laboratory so the 2007 and 2008 residue plans have not been implemented in line with Council Directive 96/23/EC. In addition, the regional distribution of residue sampling hampers the consistency of official controls in that the chance of detecting violations varies considerably between regions. As regards the authorisation and control of veterinary medicinal products Bulgaria is largely in line with Community legislation but the equine passport system, comprising *inter alia* the information whether the animal has been excluded from the food chain, has not been implemented in Bulgaria.

7 CLOSING MEETING

A closing meeting was held on 28 November 2008 with representatives of the central competent authority. At this meeting, the inspection team presented the main findings and preliminary conclusions of the mission. The competent authorities did not express disagreement with the findings and preliminary conclusions.

8 RECOMMENDATIONS

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

No.	Recommendation
1	To ensure that all substance groups required for each commodity are included in the plan and that samples are analysed, in the national laboratory or outsourced to

No.	Recommendation
	competent laboratories in other Member States, during the whole sampling year in accordance with the requirements of Article 5 of Council Directive 96/23/EC.
2	To ensure that the samples are distributed between regions so that the production processes of all species and primary products are monitored, irrespective of geographical location, in line with Article 3 of Council Directive 96/23/EC and to ensure consistency of official controls in line with the requirements of Article 4.4 of Regulation (EC) No 882/2004.
3	To ensure that there are provisions in the NRCP to implement sampling for all substance groups when equidae are slaughtered in Bulgaria in order to fulfil the requirements of Article 5 of Council Directive 96/23/EC.
4	Ensure that comprehensive instructions are available for on-farm investigations to ensure that all follow-up investigations are carried out in line with Articles 16-19 of Council Directive 96/23/EC and with a consistent approach as required under Article 4.4 of Regulation (EC) No 882/2004.
5	Ensure that all samples for the 2009 NRCP are analysed, with appropriate methods, for all relevant substance groups in accordance with the requirements of Article 5 of Council Directive 96/23/EC and Commission Decision 2002/657/EC.
6	Ensure that the scope of substances covered by each method is relevant and risk based considering the availability and use of veterinary medicinal products for food producing animals in Bulgaria in line with the requirements of Article 7 of Council Directive 96/23/EC.
7	Ensure that adequate target turnaround times are agreed with the competent authority and avoid unnecessary delays in analytical work by ensuring that samples which cannot be analysed in the national laboratory, e.g. due to lack of validated methods or break down of equipment, are outsourced to competent laboratories in other Member States. This is to ensure timely follow-up of non-compliant results in accordance with Articles 16-19 of Council Directive 96/23/EC.
8	Ensure that quality criteria for acceptance / rejection of samples are defined and controlled at sample reception to ensure the integrity of the samples as required by point 2.6 of the Annex to Commission Decision 98/179/EC.
9	Ensure that all marketing authorisations for veterinary medicinal products for food producing animals are in line with the requirements of Council Regulation (EEC) No 2377/90.
10	Ensure that all controls on veterinary medicinal products, including those on farms for food producing animals and in feed mills producing medicated feedingstuffs, are carried out in a consistent manner in line with the requirements of Article 4.4 of Regulation (EC) No. 882/2004.
11	Ensure that treatment records on farm include all veterinary medicinal products administered to food producing animals as required under Article 10 of Council Directive 96/23/EC.

No.	Recommendation
12	To urgently implement the identification system for equidae (equine passport), as required under Commission Decision 93/632/EEC amended by Commission Decision 2000/68/EC, comprising inter alia Section IX (administration of veterinary medicinal products). Please note that this legislation will be repealed by Commission Regulation (EC) No 504/2008 from 1 July 2009.

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

http://ec.europa.eu/food/fvo/ap/ap_bulgaria_8013_2008.pdf

ANNEX 1 - LIST OF LEGISLATION REFERENCED IN THE REPORT

Reference	OJ Ref.	Detail
Directive 96/93/EC	OJ L 13, 16.1.1997, p. 28–30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
Audits by the Commission Services		
Regulation (EC) No 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
Decision 98/139/EC	OJ L 38, 12.2.1998, p. 10–13	98/139/EC: Commission Decision of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States
Food Law		
Regulation (EC) No 178/2002	OJ L 31, 1.2.2002, p. 1–24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Regulation (EC) No 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
Regulation (EC) No 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
Decision 2006/677/EC	OJ L 278, 10.10.2006, p. 15–23	2006/677/EC: Commission Decision of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under

Reference	OJ Ref.	Detail
		Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules
Residues Monitoring and Sampling		
Directive 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
Decision 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
Decision 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
Validation of analytical methods for residues and Minimum Required Performance Limits (for certain prohibited substances)		
Decision 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		
Directive 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 medicines in food of animal origin		
Regulation (EC) No 2377/90	OJ L 224, 18.8.1990, p. 1–8	Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin
Maximum Residue Levels for pesticides in food of animal origin		

Reference	OJ Ref.	Detail
Directive 86/363/EEC	OJ L 221, 7.8.1986, p. 43–47	Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin
Maximum Levels of contaminants		
Regulation (EC) No 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		
Directive 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
Directive 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
Medicated feedingstuffs and additives		
Directive 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
Regulation (EC) No 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
Regulation (EC) No 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 analytical methods for contaminants		
Regulation (EC) No 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
Regulation (EC) No 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
Regulation	OJ L 88,	Commission Regulation (EC) No 333/2007 of 28

Reference	OJ Ref.	Detail
(EC) No 333/2007	29.3.2007, p. 29–38	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
Sampling methods for pesticides in foodstuffs		
Directive 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)		
Decision 2000/68/EC	OJ L 23, 28.1.2000, p. 72–75	2000/68/EC: Commission Decision of 22 December 1999 amending Commission Decision 93/623/EEC and establishing the identification of equidae for breeding and production
Regulation (EC) No 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		
Regulation (EC) No 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