FINAL REPORT OF A MISSION
CARRIED OUT IN ROMANIA
FROM 24 TO 27 MAY 2005
CONCERNING THE EVALUATION OF THE CONTROL OF RESIDUES
AND CONTAMINANTS, INCLUDING CONTROLS ON VETERINARY
MEDICINAL PRODUCTS, AS THEY APPLY TO ANIMALS
AND ANIMAL PRODUCTS EXPORTED TO THE EU
EXECUTIVE SUMMARY

This report describes the outcome of a mission carried out by the Food and Veterinary Office (FVO) in Romania, from 24 to 27 May 2004.

The mission was carried out in the general framework of co-operation with the candidate countries, and in agreement with the Competent Authority (CA) of Romania. The objective of the mission was to evaluate the performance of the CA and other officially authorised entities involved in residues and veterinary medicinal product (VMP) control and the legal and administrative measures put in place to give effect to the relevant Community requirements. For the purposes of this report, the control systems were examined to ascertain whether they can ensure that live animals and animal products exported to the EU meet Community requirements vis a vis their residue status. The evaluation was based on the standards set out in Council Directive 96/23/EC, and other applicable Community legislation in this field, including legislation on the control and distribution of VMPs.

The report concludes that, a framework for residues controls following EU requirements is in place. Its current performance is adversely affected by a number of deficiencies related to the analytical capability of the laboratories and the availability of VMPs. Cumulatively, deficiencies in controls on VMP availability and distribution, allied with insufficient laboratory capability weaken CA guarantees on the on the residue status of animals and animal products which are liable to be exported to the EU.

The report makes a number of recommendations to the Romanian CA, aimed at addressing the shortcomings identified in relation to the export of animals and food of animal origin to the EU.
# TABLE OF CONTENTS

1. **INTRODUCTION** .................................................................................................................. 1
2. **OBJECTIVES AND SCOPE OF THE MISSION** ................................................................. 1
3. **LEGAL BASIS FOR THE MISSION** .................................................................................... 1
4. **BACKGROUND** ............................................................................................................... 1
5. **MAIN FINDINGS** ............................................................................................................. 2
   5.1. National Residue Control Plan ................................................................................... 2
   
   5.1.1. Planning ................................................................................................................. 2
   
   5.1.2. Implementation ..................................................................................................... 3
   
   5.1.3. Supervision of implementation .............................................................................. 3
   
   5.1.4. Follow-up of non-compliant results ...................................................................... 3
   
   5.2. Laboratories .............................................................................................................. 4
   
   5.2.1. General description .............................................................................................. 4
   
   5.2.2. National Reference Laboratory ............................................................................ 4
   
   5.3. Veterinary medicinal products and medicated feedingstuffs .................................... 5
   
   5.3.1. Authorisation of VMPs ....................................................................................... 5
   
   5.3.2. Distribution of VMPs .......................................................................................... 6
   
   5.3.3. Controls on VMPs .............................................................................................. 6
6. **CONCLUSIONS** .............................................................................................................. 7
   
   6.1. National Residue Control Plan ................................................................................... 7
   
   6.2. Laboratories .............................................................................................................. 8
   
   6.3. Veterinary medicinal products and medicated feedingstuffs .................................... 8
   
   6.4. Overall conclusion .................................................................................................... 8
7. **CLOSING MEETING** ...................................................................................................... 8
8. **RECOMMENDATIONS** .................................................................................................. 8
9. **ADDENDUM TO MISSION REPORT 7762/2005** .............................................................. 9
# ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

<table>
<thead>
<tr>
<th>CA</th>
<th>Competent Authority</th>
<th>HCH</th>
<th>Hexachlorocyclohexane</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAP</td>
<td>Chloramphenicol</td>
<td>HPLC</td>
<td>High Performance Liquid Chromatography</td>
</tr>
<tr>
<td>CCA</td>
<td>Central Competent Authorities</td>
<td>IBVMP</td>
<td>Institute for Biological and Veterinary Medicinal Products Control</td>
</tr>
<tr>
<td>CRL</td>
<td>Community Reference Laboratory</td>
<td>IHVPH</td>
<td>Institute for Hygiene and Veterinary Public Health</td>
</tr>
<tr>
<td>CSVFSD</td>
<td>County Sanitary Veterinary and Food Safety Directorate</td>
<td>ISO</td>
<td>International Standardisation Organisation</td>
</tr>
<tr>
<td>EC</td>
<td>European Community</td>
<td>LOD</td>
<td>Limit of Detection</td>
</tr>
<tr>
<td>EEC</td>
<td>European Economic Community</td>
<td>ML</td>
<td>Maximum Level</td>
</tr>
<tr>
<td>ELISA</td>
<td>Enzyme-Linked Immunosorbent Assay</td>
<td>MRPL</td>
<td>Minimum Required Performance Level</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
<td>NRCP</td>
<td>National Residue Control Plan</td>
</tr>
<tr>
<td>FVO</td>
<td>Food and Veterinary Office</td>
<td>NRL</td>
<td>National Reference Laboratory</td>
</tr>
<tr>
<td>GC-ECD</td>
<td>Gas Chromatography - Electron Capture Detector</td>
<td>NSVFSA</td>
<td>National Sanitary Veterinary and Food Safety Authority</td>
</tr>
</tbody>
</table>

## 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

### B1
- Inhibitors (antimicrobials)
- **B2a** Anthelmintics
- **B2b** Coccidiostats
- **B2c** Carbamates and pyrethroids
- **B2d** Sedatives
- **B2e** NSAIDs
- **B3d** Mycotoxins
- **B3e** Dyes
- **B2f** Others (e.g. corticosteroids)
- **B3a** Organochlorines including PCBs
- **B3b** Organophosphorus compounds
- **B3c** Chemical elements
- **B3f** Others

## GC-MS

Gas Chromatography - Mass Spectrometry
1. INTRODUCTION

The mission took place in Romania from 24 to 27 May 2005. The mission team comprised two inspectors from the Food and Veterinary Office (FVO). The mission was undertaken as part of the general framework of co-operation with the candidate countries, and in agreement with the Competent Authority (CA) of Romania. Representatives from the central competent authorities (CCA) accompanied the inspection team during the whole mission.

This report deals specifically with the findings of the mission team in relation to the commodities exported to the EU.

2. OBJECTIVES AND SCOPE OF THE MISSION

The objective of the mission was to evaluate the 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 (VMPs) and feed additives, the use of which may give rise to residues in such products. For the purposes of this report, the control systems were examined to ascertain whether they can ensure that live animals and animal products exported to the EU meet Community requirements vis à vis their residue status. The evaluation was based on the standards set out in Council Directive 96/23/EC (1) and other applicable Community legislation in this field, including legislation on the control and distribution of VMPs.

3. LEGAL BASIS FOR THE MISSION

The mission was carried out in the general framework of co-operation with the applicant countries, and in agreement with CCA. A full list of the legal instruments referred to in this report is provided in Annex I.

4. BACKGROUND

A previous residues mission to Romania was undertaken from 9 to 13 October 2000, the report of which (reference DG(SANCO)/1274/2000) has been published on the Health and Consumer Protection Directorate General web site at:


With regard to export to the EU, Romania is the leading exporter of live horses, live cattle, live sheep and live goats and is one of the major exporters of honey. Other commodities exported to the EU include fresh meat for each of the species listed above, poultry meat, dairy and egg products.

In 2003 and 2004, a total of 6 notifications in the Rapid Alert System for Food and Feed (RASFF) in Romanian honey were published (2 chloramphenicol (CAP), 1 sulphathiazole and 3 streptomycin). In 2003, one RASFF alert was published for nitrofurans in poultry.

---

(1) EU legal acts quoted in this report refer, where applicable, to the last amended version.
5. **MAIN FINDINGS**

5.1. **National Residue Control Plan**

5.1.1. **Planning**

The National Sanitary Veterinary and Food Safety Authority (NSVFSA) is the CCA, in accordance with Art. 4 of Council Directive 96/23/EC. NSVFSA operates under the auspices of the Ministry of Agriculture, Forests and Rural Development. Planning of the National Residue Control Plan (NRCP) is initiated by the General Veterinary Directorate of the NSVFSA via letters to the 42 County Sanitary Veterinary and Food Safety Directorates (CSVFSDs) in order to obtain proposals for the county residue control plans. After a verification of the county plans by the National Reference Laboratory (NRL) an approval is granted by the NSVFSA. The mission team noted that:

- the planning process is driven from the county level as each county formulates its own plan independently;
- there is no actual central co-ordinator for the whole planning process;
- the only criteria that are taken into account during the planning process are the production figures and number of establishments. There is no overview of the national usage of VMPs and non-compliant results of the previous years are not considered when the plan is being drawn up (with the exception of contaminants);
- the design of the NRCP generally respects EU requirements. All required commodities are covered. However, several substances are either not included in the plan, or if included, do not take account of the correct marker residue: e.g.
  - the nitroimidazoles (Group A6) metronidazole and ronidazole, including metabolites;
  - nitrofuran metabolites (Group A6);
  - corticosteroids (Group A3);
  - leuco malachite green (Group B3e)
  - phenylbutazone (Group B2e);
  - the antibiotic tylosin (Group B1) and the acaricide bromopropylate in honey;
  - the coccidiostats (Group B2b) nicarbazin and lasalocid in poultry and eggs
- the analytical spectrum (i.e. number of compounds within each substance group that are tested for) is limited for Groups A3, A5, B1 and B2. Furthermore in several cases an inappropriate matrix is used e.g. Groups A1 and B2d;
- there is no on-farm sampling for pigs for the substance groups A1, A2, A3, A4 and A5, although it is required under national law;
- the levels of action in the plan are higher than the limit of detection (LOD) for most Group A substances. Furthermore several analytical methods are either completely inappropriate or have such high LODs that they are incapable of detecting illegal use of most of the unauthorised substances. In addition, action levels do not respect Community MRPLs which have been adopted by the CA;
- the NRCP presented to the Commission does not reflect the actual performance and capability of the performance of the laboratories involved.
5.1.2. **Implementation**

Individual county residue control plans are approved by NSVFSA. Each CSVFSD breaks the plan down by trimester within their county indicating the number of samples to be taken in certain farms and establishments. Appropriate equipment is provided by the CSVFSDs to the sampling staff who also transport the samples directly to the relevant laboratory. The mission team observed that:

- there are general sampling instructions and these are in line with the provisions of Council Directive 96/23/EC, Commission Decisions 97/747/EC and 98/179/EC;
- samples are taken in most cases by official CSVFSD inspectors. In some counties, private veterinary practitioners are contracted for taking samples on farm without any specific measures to avoid a possible conflict of interest;
- on-farm samples are taken only from the major production farms within the county, and not from the so called small ‘backyard’ farms;
- samples are taken randomly and are not targeted as required under national (i.e. transposed Community) legislation.

5.1.3. **Supervision of implementation**

Each trimester, reports on the progress of implementing the NRCP are produced by the CSVFSDs. The reports are checked at the NRL and a summary report is communicated to the NSVFSA. The mission team noted that:

- contrary to the county plans, there is regularly either under- or over-sampling in the counties. Consequently, the equal distribution over time and counties is not assured. The NRL has already informed the General Veterinary Directorate of the NSVFSA, which has recently taken steps to improve the situation;
- there is no actual supervision of county activities by the CCA.

5.1.4. **Follow-up of non-compliant results**

Each CSVFSD is responsible for the follow-up of non-compliant results in their county. Non-compliant results are immediately reported by the laboratories to the CSVFSD and the NSVFSA, while compliant results are communicated regularly to the CSVFSD. The mission team observed that:

- there is no standardised procedure for following up residue violations;
- records of follow-up of non-compliant results are kept at county level; the CCA does not have complete follow-up files nor an overview of all actions taken by the CSVFSDs;
- in recent years antibiotic residues have been detected in honey on several occasions. The CCA stated that in some cases the origin of these residues was the usage of human medicinal products. Regarding the RASFF reports about streptomycin in honey, whilst the CCA initiated follow-up, it has no further information on the outcome of the investigation(s) or the source of residues;
- in a pig farm where illegal treatment with nitrofurans and nitroimidazoles had been detected, all of the legally required follow-up actions were not completed - no additional samples were taken, nor were movement restrictions or destruction of animals ordered.
5.2. Laboratories

5.2.1. General description

The Institute for Hygiene and Veterinary Public Health (IHVPH) in Bucharest, which is the NRL for all substance groups listed in Annex I to Council Directive 96/23/EC, analyses a significant proportion of the total NRCP samples. NRCP samples are also analysed in 7 “zonal” laboratories belonging to the CSVFSDs; six of which cover all commodities and substance groups. IHVPH and the 7 zonal laboratories are each responsible for the analysis of NRCP samples from a specific number of counties. The samples are sent directly from the 42 CSVFSDs to the responsible laboratories. All of the laboratories involved in testing NRCP samples are designated by the NSVFSA.

IHVPH and 2 zonal laboratories are accredited to ISO 17025 by the Romanian national accreditation body RENAR; one additional zonal laboratory will probably receive accreditation in the near future. The NRL has a schedule and an action programme to support these laboratories in their preparation for accreditation and to assess the progress in the development of analytical quality management. The mission team noted that:

- four zonal laboratories responsible for the analysis of NRCP samples are not yet accredited although this is a requirement under national and Community law. There are delays in the schedule for the preparation for the accreditation of the 4 zonal laboratories;
- a very limited number of analytical methods are included in the scope of accreditation, mainly screening methods and methods for environmental contaminants. There is no plan in place for the further accreditation of analytical methods.

5.2.2. National Reference Laboratory

Regarding the NRL activities the mission team noted that:

- many of the NRL activities, foreseen in Community legislation, are performed. The institute is actively involved in the design, planning and supervision of the annual NRCP. Staff regularly visit and have meetings with the zonal laboratories. The NRL delivers analytical methods to the laboratory network, and, each trimester, organises national proficiency tests (PTs) and training seminars which are mandatory for all zonal laboratories;
- in the NRL-organised PTs, spiked materials are employed, however the fortification levels are frequently too high in comparison with Community limits e.g. 6 µg/kg CAP in meat (EU MRPL = 0.3 µg/kg) and 10 µg/kg clenbuterol in urine (CCα recommended by the CRL: 0.03 µg/kg);
- participation of the NRL in internationally organised PTs is very limited and has not been satisfactory. In a PT organised by the CRL in Fougères in 2003, the NRL detected several sulphonamides in muscle samples containing no residues and misidentified other sulphonamides. Problems with identification and quantification were exacerbated due to a lack of analytical standard substances. There has been no participation in either 2004 or 2005 in any other international PT schemes;
In its role as a provider of analytical services for the NRCP, the mission team noted that:

- there is a quality manager in place and a quality manual is available including *inter alia* standard operating procedures (SOPs) for the calibration of instruments and general validation procedures for analytical methods;
- facilities and equipment are old and not sufficient for the purpose. A lack of analytical instruments hinders the development of mandatory methods. The only GC-MS system available within the NRL and the official laboratory network for residues analysis is 11 years old. It is not used on a regular basis and was last serviced in 1999. At the moment there is no strategic plan for the purchase of necessary equipment (especially mass spectrometers and HPLC systems);
- staff demonstrated limited competence and expertise in residue chemistry, especially in development and validation of new analytical methods;
- there are no confirmation methods (by mass spectrometry) available for any group A substances;
- for several Group A substances, the analytical methods used are either limited in scope (e.g. nitroimidazoles), are insensitive and incapable of meeting Community requirements or can not detect the correct marker residue and are therefore of limited value in detecting abuse of these substances. Examples include the test for malachite green which is five times less sensitive than required and does not detect the major marker residue, leuco-malachite green; CAP by GC-ECD which is seven times less sensitive and the chemical test for nitrofurans in meat, eggs and milk which is fifty times less sensitive;
- only some analytical methods are validated, however, the validation data are neither complete nor well documented. No methods are validated according to (the transposed) Commission Decision 2002/657/EC. No strategic plan or timetable was available for the validation of Group A methods to this standard;
- the microbiological tests for the screening of Group B1 substances (antibacterial substances) are not validated. There are no confirmation methods nor procedures available in order to verify screened non-compliant samples;
- for ELISA tests the information from the manufacturers are copied directly into the SOPs, without any in-house validation. Almost all ELISA results for nitrofuran metabolites in honey exceeded the LODs given in the SOP, however no re-analysis or confirmation was performed on these non-compliant results in order to initiate possible follow-up measures. Furthermore, control samples (blanks, fortified samples) are not used routinely during ELISA tests;
- the actual performance of the NRL in respect to analytical methods and LODs is not always reflected in the NRCP presented to the Commission Services; several methods listed in the NRCP 2005 are not actually in place in the laboratory.

### 5.3. Veterinary medicinal products and medicated feedingstuffs

#### 5.3.1. Authorisation of VMPs

The Institute for Biological and Veterinary Medicinal Products Control (IBVMP) belonging to the Directorate for Inspection, Control, Border Inspection Posts and
Coordination of Veterinary Institutes of the NSVFSA is the national authority responsible for the national marketing authorisation of VMPs. It was noted that:

- Council Regulation (EEC) No 2377/90 has been transposed into Romanian legislation since 2001 and a list of VMPs with marketing authorisations, containing product information, is available via the intranet of NSVFSA. A public webpage with a list of authorised VMPs is under construction;
- several VMPs, authorised for external application to food producing animals, contain substances listed in Annex IV of Council Regulation (EEC) No 2377/90, e.g. nitrofurans and CAP. In addition, VMPs for non-food producing animals containing Annex IV substances are authorised in large package sizes, giving rise to a risk of misuse for food producing animals;
- VMPs containing several substances not listed in Annexes I, II or III of Council Regulation (EEC) No 2377/90 have a marketing authorisation for food producing animals (e.g. phenylbutazone, nitrofonate, trichlorfon, propionylpromazine, acepromazine, norfloxacin, gentian violet);
- several VMPs are authorised for species other than those indicated in Annexes I, II or III of the transposed Council Regulation (EEC) No 2377/90 (e.g. gentamicin);
- withdrawal periods for several VMPs authorised for food producing animals are either not listed or are incomplete;
- Commission Decision 2000/68/EC has been transposed since 2003. However, a horse identification and horse passport system is not yet implemented. A deadline for the implementation of the transposed Decision could not be provided (Romania is leading exporter of live horses to the EU).

5.3.2. Distribution of VMPs

The IBVMP is the national authority responsible for regulation and surveillance inter alia the distribution of medicinal products, including for the manufacturing of medicated feedingstuffs. Wholesale distribution of VMPs and operation of pharmacies is regulated by national legislation. Wholesalers distribute VMPs to the pharmacies, veterinarians and farms where a veterinarian is present. VMPs are sold by veterinary pharmacies to animal holders. Since 1 January 2005 it is not possible anymore to sell raw active substances to wholesalers, pharmacies or feed mills. The mission team noted that:

- there is no prescription system for VMPs though animal owners are legally obliged to keep a record of drug-use, including withdrawal time;
- the last printed official version of the list of authorised VMPs distributed to the stakeholders dates from 2003;

5.3.3. Controls on VMPs

The CSVFSD carries out regular unannounced inspections on all levels within the distribution chain of VMPs within the county. Since 2005 an inspection plan has been communicated by every county to the CCA indicating the number of inspections to be performed at the different levels of distribution. The mission team noted that:
there are no harmonised inspection guidelines/instructions, to guarantee a consistent approach throughout the country. However, there is some regular training of inspectors by the CCA;

- an inspection report is always made in duplicate, including a copy for the inspected establishment.

5.3.3.1. Wholesale and retail level

CSVFSD is responsible for authorising wholesalers and pharmacies. The mission team noted that:

- at the wholesaler visited, although regular official inspections had been performed, several VMPs authorised for use in non-food producing animals containing Annex IV substances were found to bear a label allowing their use in food producing animals (e.g. furazolidone for turkeys; CAP for cattle, pigs, horses). In these cases, the conditions of the marketing authorisation of the products were not respected;

- at the wholesaler visited, in many cases, the labelling of VMPs did not always fulfil the transposed EU requirements (missing leaflets, labels not always in the national language, without authorisation number or details of species or withdrawal time).

5.3.3.2. Medicated pre-mixes and medicated feedingstuffs

The CSVFSD carries out regular unannounced inspections in the area of animal nutrition including the control and approval of establishments. 26 feed mills and 37 on-farm mixers are authorised to manufacture medicated feedingstuffs. Feed mills manufacturing medicated feedingstuffs are regularly checked. The mission team noted that:

- whilst the use of, inter alia, nitroimidazoles and nitrofurans has been banned since 2001, despite regular inspections in the feed mill visited, the routine manufacturing of medicated feed using these pharmaceutical raw substances was not detected by the CA until February 2005.

5.3.3.3. Veterinary practices and farms

The CSVFSDs perform inspections on farms and on veterinary practices. Records of medical treatment must be kept, including the withdrawal periods. The mission team noted that:

- the only farms that are inspected are the major production farms which have a veterinarian employed on the farm. So called (small) “backyard farms” are not inspected.

6. Conclusions

6.1. National Residue Control Plan

The design of the NRCP is in general in line with the EU requirements, as regards the coverage of commodities. However, residue controls and resultant guarantees on the residues status of exports are weakened by several deficiencies in the NRCP design; the situation is exacerbated by the lack of central co-ordination, supervision of implementation of the programme and consistency with regard to follow-up of residue violations.
6.2. Laboratories

The performance of the laboratories is insufficient, with a limited scope of testing, use of insensitive analytical methods, insufficient or un-validated analytical methods, a lack of adequate analytical equipment and limited analytical expertise. These serious shortcomings make it impossible for the CA to detect residues of most unauthorised and authorised substances, weakening guarantees on the residue status of exports to the EU.

6.3. Veterinary medicinal products and medicated feedingstuffs

1. The general process of marketing authorisation is in line with EU requirements. However, the marketing of several VMPs for use in food producing animals which contain active substances not listed in Annexes I, II, or III or which are listed in Annex IV to Council Regulation (EEC) No 2377/90, contravene Community and Romanian legislation. In addition, the free availability of VMPs, which are often not labelled in accordance with the national authorisation specifications demonstrates that the inspection system is ineffective and raises concerns over the residue status of animals and animal products destined for export to the EU.

2. Failure to implement the horse passport system contravenes transposed Community legislation, weakening the controls on traceability and residue status of horses that enter the food chain for export to the EU.

6.4. Overall conclusion

A framework for residues controls following EU requirements is in place. Its current performance is adversely affected by a number of deficiencies related to the analytical capability of the laboratories and the availability of VMPs. Cumulatively, deficiencies in controls on VMP availability and distribution, allied with insufficient laboratory capability weaken CA guarantees on the residue status of animals and animal products which are liable to be exported to the EU.

7. Closing meeting

A closing meeting was held on 27 May 2005 with representatives of the CCA. At this meeting, the inspection team presented the main findings and preliminary conclusions of the mission. The CCA did not express major disagreement. The inspection team was provided with additional documentation; in particular some details of proposed actions to be taken with regard to the authorisation of veterinary medicinal products. Moreover, the CCA issued an Order whereby only officials are responsible for on farm sampling in the counties. After the mission, a document with proposed actions on the laboratory performance and the NRCP design was received from the NRL.

8. Recommendations

The competent authorities are invited to provide an action plan containing detailed information, including a timetable, regarding the actions planned or taken in order to address the recommendations set out below in relation to exported commodities to the EU and to submit this plan to the Commission services within 20 working days after receipt of this report.
National Residues Control Plan

1. Ensure that the NRCP covers all relevant substances insofar as they relate to exported commodities. As a matter of urgency particular attention should be paid to ensuring that analyses are carried out in order to guarantee exported commodities do not contain detectable residues of those substances presently listed in Annex IV to Council Regulation (EEC) No 2377/90 or not listed in annexes I, II, or III of said Regulation.

Laboratories

2. Ensure that in respect of guarantees on the residue status of animals and animal products exported to the EU, laboratory analytical methods should be: properly validated (fit for purpose); preferably carried out within the scope of accreditation to ISO 17025; and capable of demonstrating compliance with Community limits.

VMPs and medicated feedingstuffs

3. To immediately rectify the observed deficiencies in relation to the availability and marketing of VMPs and improve existing controls on all stages of the VMP distribution chain in order to:
   a. comply with national (i.e. transposed Community) legislation;
   b. detect illegal or unauthorised treatment of animals liable to be exported to the EU and;
   c. ensure that residues of substances not authorised in the EU are not present in animals and animal products exported to the EU.

4. Implement without delay the (already transposed) equine passport system in respect of all equidae liable to be exported to the EU in order to ensure the traceability and provide the necessary information on residue status of such animals.


In their letter of 5 August 2005 in response to the draft report, the Romanian CA did not comment on the content of the report, nevertheless they provided already an action plan on the recommendations made in the draft report. The response can be summarised as follows:

With regard to NRCP:

Recommendation 1: It is planned to increase the scope of analysis for several substance groups in 2006 (e.g. for A3, A5, A6 (nitroimidazoles), B1, B2a, B2b, B2c, B2e and B3e).

With regard to laboratories:

Recommendation 2: A time table has been provided in order to have all laboratories accredited at the latest in 2006. This table also includes an indication of the completion of the validation studies, according to Commission Decision 2002/657/EC, and the accreditation for a number of methods. Furthermore, reinforcement of additional qualified laboratory staff and analytical equipment is intended in IHVPH.
With regard to VMPs and medicated feedingstuffs:

Recommendation 3:

a. An action plan has started in order to review the labels and the usage conditions of the VMPs. The implementation of this review will be finalised by 1 October 2005.

b. Elaboration of legal acts will take place before 1 September 2005. The implementation of these measures will be done until 1 June 2006. Supervision of the implementation measures is also foreseen, together with a reporting per trimester.

c. The control is carried out by the veterinarians taking care of pharmacovigilance, within county DSVA and will be reported each trimester, in accordance with the inspection calendar.


____________________
ANNEX I: Applicable Community standards:

Residues monitoring and sampling


Residues monitoring and sampling - financing


Laboratories


Laboratory analytical methods


Bans on the use of hormones and beta-agonists for growth promotion


Maximum residue limits for veterinary medicines in foodstuffs of animal origin


Maximum Residue Limits for pesticides in foodstuffs of animal origin


Maximum Limits for Contaminants


Authorisation of veterinary medicinal products


Medicated feedingstuffs and additives


Sampling methods and methods of analysis for contaminants in foodstuffs


Sampling methods for pesticides in foodstuffs


Horse identification (passport)