FINAL REPORT OF A MISSION
CARRIED OUT IN SWITZERLAND
FROM 30 APRIL TO 4 MAY 2007
CONCERNING THE EVALUATION OF THE CONTROL OF RESIDUES AND
CONTAMINANTS IN LIVE ANIMALS AND ANIMAL PRODUCTS,
INCLUDING CONTROLS ON VETERINARY MEDICINAL PRODUCTS

Please note that factual errors in the draft report have been corrected. Clarifications provided by the Swiss Competent Authorities are given as footnotes, in bold, italic, type, to the relevant part of the report.
EXECUTIVE SUMMARY

This report describes the outcome of a mission carried out by the Food and Veterinary Office (FVO) in Switzerland, from 30 April to 4 May 2007. The mission was part of a series of FVO missions on residue controls in third countries.

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 (VMPs) and feed additives, the use of which may give rise to residues in such products. The mission was based on the evaluation of the equivalence of Switzerland's standards to Council Directive 96/23/EC and other relevant Community legislation in this field, including legislation on the control and distribution of VMPs. The mission focused on the role of the competent authorities (CA), the legal and administrative measures in place to give effect to the relevant EU requirements with regard to import of food of animal origin into the EU, controls with regard to residues and VMPs and their operation, and the performance of residue laboratories.

In general, the residues control programme in Switzerland is operating in accordance with relevant Community legislation. The residues laboratories are in general functioning satisfactorily and there is an effective system of veterinary medicine authorisation and controls on the distribution and use of veterinary medicines. However, shortcomings observed in the implementation of the residue plan and the follow-up of non-compliant results, which are exacerbated by a lack of enforcement power of the central authorities upon the cantons, collectively weaken the effectiveness of the residues control system.

The report makes a number of recommendations to the Swiss competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.
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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>BVET</td>
<td>Federal Veterinary Office</td>
</tr>
<tr>
<td>C(CA)</td>
<td>(Central) Competent Authorities</td>
</tr>
<tr>
<td>CC alpha/beta</td>
<td>Decision limit/Detection Capability</td>
</tr>
<tr>
<td>DG(SANCO)</td>
<td>Health and Consumer Protection Directorate General</td>
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<tr>
<td>(E)EC</td>
<td>European (Economic) Community</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>ELISA</td>
<td>Enzyme-Linked ImmunoSorbent Assay</td>
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<tr>
<td>Group A, B</td>
<td>Categories of substances listed in Annex I to Council Directive 96/23/EC:</td>
</tr>
<tr>
<td></td>
<td>A1 Stilbenes</td>
</tr>
<tr>
<td></td>
<td>A2 Thyrostats</td>
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<td></td>
<td>A3 Steroids</td>
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<td></td>
<td>A4 Zeranol</td>
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<tr>
<td></td>
<td>A5 Beta-agonists</td>
</tr>
<tr>
<td></td>
<td>B1 Inhibitors (antimicrobials)</td>
</tr>
<tr>
<td></td>
<td>B2a Anthelmintics</td>
</tr>
<tr>
<td></td>
<td>B2b Coccidiostats</td>
</tr>
<tr>
<td></td>
<td>B2c Carbamates and pyrethroids</td>
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<tr>
<td></td>
<td>B2d Sedatives</td>
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<td></td>
<td>B2e NSAIDs</td>
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<tr>
<td></td>
<td>B2f Others (e.g. corticosteroids)</td>
</tr>
<tr>
<td></td>
<td>B3a Organochlorines including PCBs</td>
</tr>
<tr>
<td></td>
<td>B3b Organophosphorus compounds</td>
</tr>
<tr>
<td></td>
<td>B3c Chemical elements</td>
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<tr>
<td></td>
<td>B3d Mycotoxins</td>
</tr>
<tr>
<td></td>
<td>B3e Dyes</td>
</tr>
<tr>
<td></td>
<td>B3f Others</td>
</tr>
<tr>
<td>FVO</td>
<td>Food and Veterinary Office</td>
</tr>
<tr>
<td>HPLC</td>
<td>High Performance Liquid Chromatography</td>
</tr>
<tr>
<td>ISO</td>
<td>International Standardisation Organisation</td>
</tr>
<tr>
<td>LC-MS-MS</td>
<td>Liquid Chromatography-(Tandem) Mass Spectrometry</td>
</tr>
<tr>
<td>LoD</td>
<td>Limit of Detection</td>
</tr>
<tr>
<td>MRL</td>
<td>Maximum Residue Limit</td>
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<tr>
<td>NRCP</td>
<td>National Residue Control Plan</td>
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<tr>
<td>NRL</td>
<td>National Residue Laboratory</td>
</tr>
<tr>
<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
</tr>
<tr>
<td>Swissmedic</td>
<td>Swiss Agency for Therapeutic Products</td>
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<tr>
<td>VMP</td>
<td>Veterinary Medicinal Product</td>
</tr>
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</table>

### CONVENTIONS USED IN THE REPORT

Bullet points marked thus ➤ indicate findings made by the mission team on the basis of observations on the spot or assessment of information received.
1. **INTRODUCTION**

The mission took place in Switzerland from 30 April to 4 May 2007. The mission team comprised two 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 authorities (CCAs) accompanied the inspection team during the whole mission. An opening meeting was held on 30 April 2007 with the CCAs. At this meeting, the objectives of, and itinerary for, the mission were confirmed by the inspection team and the first discussions with the CCA officials were held.

2. **OBJECTIVES AND SCOPE 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 (VMPs) and feed additives, the use of which may give rise to residues in such products. The evaluation was made in order to assess the level of the equivalency of Switzerland's standards to Council Directive 96/23/EC and other relevant Community legislation in this field, including legislation on the control and distribution of VMPs. The mission focused on the role of the competent authorities (CA), the legal and administrative measures in place to give effect to the relevant EU requirements with regard to import of food of animal origin into the EU, controls with regard to residues and VMPs and their operation, and the performance of residue laboratories.

The following sites were visited and meetings were held with:

<table>
<thead>
<tr>
<th>Competent Authorities</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central</td>
<td>2 Opening and closing meetings with the CCAs responsible for residue control and VMPs</td>
</tr>
<tr>
<td>Regional</td>
<td>1 Cantonal CA responsible for implementation, supervision and follow-up of the NRCP and control of veterinarians and farms</td>
</tr>
<tr>
<td><strong>LABORATORIES</strong></td>
<td>1 1 main routine laboratory</td>
</tr>
<tr>
<td><strong>Farms</strong></td>
<td>1 1 dairy farm</td>
</tr>
<tr>
<td><strong>OTHER SITES</strong></td>
<td>2 1 feedmill; 1 wholesaler of VMPs</td>
</tr>
</tbody>
</table>

3. **LEGAL BASIS FOR THE MISSION**

The mission was carried out in agreement with the Swiss CCA under the general provisions of Community legislation and, in particular:

- Article 46 of 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;

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1 EU legal acts quoted in this report and included in the Annex refer, where applicable, to the last amended version.
– Commission Decision 98/140/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 third countries.

A full list of the legal instruments referred to in this report is provided in the Annex.

4. BACKGROUND

4.1. COUNTRY STATUS IN RELATION TO SUBMISSION OF RESIDUES CONTROL PLANS

Commission Decision 2004/432/EC, indicates that Switzerland's National Residues
Control Plan (NRCP) is approved in accordance with Council Directive 96/23/EC
for bovine, ovine/caprine, swine, equine, poultry, aquaculture, milk, eggs and
honey.

4.2. RAPID ALERT SYSTEM FOR FOOD AND FEED (RASFF) NOTIFICATIONS FOR
CONSIGNMENTS FROM SWITZERLAND CONCERNING RESIDUES

In 2005 five findings and in 2006 one finding of chloramphenicol in royal jelly
imported from Switzerland was reported under the RASFF. In most of the cases the
source of the royal jelly had been confirmed to be another third country.

4.3. PRODUCTION AND TRADE INFORMATION

Detailed information on quantities of food commodities of animal origin exported to
the EU in 2006 (listed in the table below) was supplied by the Swiss competent
authorities.

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Total amount (tonnes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beef</td>
<td>0.9</td>
</tr>
<tr>
<td>Pork</td>
<td>118</td>
</tr>
<tr>
<td>Poultry meat</td>
<td>12</td>
</tr>
<tr>
<td>Fish and fishery products</td>
<td>154</td>
</tr>
<tr>
<td>Dairy products</td>
<td>96 934</td>
</tr>
<tr>
<td>Eggs</td>
<td>26</td>
</tr>
<tr>
<td>Honey</td>
<td>188*</td>
</tr>
</tbody>
</table>

* According to CA, most of the honey exported to the EU originated from other
third countries.

5. MAIN FINDINGS

5.1. NATIONAL RESIDUE CONTROL PLAN

5.1.1. Planning

The Federal Veterinary Office (BVET) under the Ministry of Economic Affairs is
the responsible authority for the control of inter alia residues in animals and animal
products. BVET acts as central coordination body and is responsible for inter alia
the planning, coordination and supervision of the national residue control plan
(NRCP). The planning starts in the autumn of the previous year and it is finalised
before the end of the year.
The mission team noted that:

- the NRCP is based on Council Directive 96/23/EC for all commodities;
- there is a NRCP coordinator in BVET who is responsible for planning, implementation and supervision;
- there is the possibility to amend the plan during the sampling year and it could be seen that this had happened in 2006;
- all relevant bodies (i.e. laboratories and Swiss Agency for Therapeutic Products (Swissmedic)) are not involved in the planning process. However, the NRCP coordinator consults some of the cantons and some cantonal laboratories on an ad-hoc basis when planning the NRCP;
- national production data and results of residues control are taken into account for all commodities. The usage patterns and volumes of used veterinary medicinal products (VMPs) are not taken into account although some relevant information on the sale patterns of VMPs is available in Swissmedic;
- the following main observations were made on the 2007 NRCP:
  - the plans for rabbits, farmed and wild game have been included in the NRCP as new commodities;
  - all substance groups are covered for all commodities except Group B2b, B2c and B2d for equidae;
  - in general, the total number of samples is in accordance with Council Directive 96/23/EC. However, the number of tests is lower than required under Council Directive 96/23/EC for milk and eggs;
  - some matrix – substance combinations are not appropriate, e.g. thyrostats should be analysed in thyroid gland and urine instead of liver and blood and gestagens should be analysed in kidney fat instead of liver and blood;
  - the action limit is higher than the limit of detection (LoD) for some forbidden substances e.g. melengestrolacetate (2 µg/kg) and chloramphenicol (1 µg/kg while the Community Minimum Required Performance Limit (MRPL) is 0.3 µg/kg), nitrofurans (1 µg/kg) and dimetridazole (10 µg/kg);
  - the scope of testing is limited e.g. for Group A3 (steroids) and A4 (the main metabolite of zeranol – taleranol - is not tested for ), Group A5 (beta-agonists), Group B1 (antimicrobials) and Group B2e (non-steroidal anti-inflammatory – NSAIDs).

2 In their response to the draft report the Swiss Authorities stated that this data was not available at the time when the 2007 plan was developed. (See also action plan.)
3 In their response to the draft report the Swiss Authorities stated that these groups have already been added in the 2007 plan for equidae. (See also action plan.)
4 In their response to the draft report the Swiss Authorities stated that the number of tests will be increased in the 2008 plan. (See also action plan.)
5 In their response to the draft report the Swiss Authorities stated that these comments will be taken into account in the 2008 plan. (See also action plan.)
6 In their response to the draft report the Swiss Authorities stated that a working group is assigned to propose necessary amendments in order to bring Swiss legislation on residues into line with the Community law. (See also action plan.)
7 In their response to the draft report the Swiss Authorities stated that broadening of the scope of these substances will be discussed with the laboratories and will be taken into account in the 2008 plan.
• several VMPs authorised in the country for use in food producing animals, e.g. oxytetracycline and doxycycline are not included in the plan;

• for honey, the scope is limited as regards substances which, whilst not authorised in Switzerland, are known to be used worldwide in honey production e.g. Group B1 (e.g. tylosin is not included) and Group B3a (e.g. chlorobenzilate and bromopropylate are not included);

• action limits are set for some antimicrobials in honey while there are no maximum residue limits (MRLs) in Community legislation for antimicrobials. (Antimicrobials are not authorised for honey bees in Switzerland.)

5.1.2. Implementation

BVET directly organises the sampling for milk and eggs for all substance groups and the sampling of slaughtered animals for all groups except antimicrobials (B1). As regards the sampling of live animals and fish and the sampling of slaughtered animals for Group B1, BVET arranges this sampling via the 22 cantonal veterinary offices. BVET sends the sampling orders for all residues samples in which the species, analyte and type of sample are indicated. BVET decides the sampling ‘window’ during which most of the sampling should take place, while the cantons decide the time of B1 sampling in slaughterhouses. The samplers select the farms as well as individual animals at farms and slaughterhouses. All samples are tested in routine laboratories selected by BVET except slaughter-animal samples for Group B1 which are tested in laboratories selected by cantons (usually cantonal laboratories). Results are reported directly from these laboratories to the cantons.

The mission team noted that:

- BVET stated that it does not have the power to enforce residue sampling in cantons;
- in general, the total number of samples planned for 2006 was respected. However, some under sampling for some commodities was seen in particular for Group B1 which is solely the responsibility of the cantons;
- the sampling of new commodities in the NRCP, honey and wild game, had not been organised to date;
- official samples are in certain cases taken by non-officials e.g. the sampling of eggs is carried out by employees of egg companies. In addition, private veterinary practitioners took live animal samples in 2006 in the canton visited.

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8 In their response to the draft report the Swiss Authorities stated that oxytetracycline and doxycycline will be included in the 2008 plan.
9 In their response to the draft report the Swiss Authorities stated that substances which are not included in the plan for honey (e.g. B1 tylosin and B3a, chlorobenzilate, bromopropylate) will be tested for imported honey.
10 In their response to the draft report the Swiss Authorities stated that there are action limits for honey because in neighbouring countries the use of e.g. streptomycin is allowed as plant pesticides and therefore contamination of Swiss honey can occur.
11 In their response to the draft report the Swiss Authorities stated that the organization of sampling for honey is under preparation. The hunting season for wild game starts in September.
This is not equivalent to the standards laid out in Commission Decision 98/179/EC which requires that all sampling is carried out by officials;¹²

- sampling is not targeted and there are no centrally-issued targeting instructions or criteria. In addition, no training has been provided for samplers in this respect. Consequently, the samplers select the farms for live animal sampling as well as individual animals at slaughterhouses and on farms at random;
- small slaughterhouses covering 15% of total slaughter volume are sampled only for Group B1. Samples for all substance groups are taken from larger slaughterhouses;
- milk sampling is carried out in milk collection centres from the milk of individual producers. Farms whose milk is collected directly by dairy companies are never sampled under the NRCP¹³;
- fish are sampled only at the finishing stage, not at all production stages. Council Directive 96/23/EC requires that sampling takes place at all production stages for fish. According to the CA due to the small number of fish to be sampled it is not possible to cover all production stages;
- sampling of milk and fish in the 2007 NRCP had not started to date. Commission Decision 98/179/EC requires the even distribution of samples throughout the year¹⁴;
- there was clustering of sampling per species for antimicrobial substances in the canton visited i.e. all of the 2007 samples for slaughtered bovines had already been taken to date but no samples had been taken for slaughtered pigs. Furthermore, no live animal samples had been taken in this canton to date;
- sampling is unannounced.

5.1.3. Supervision of implementation

BVET is responsible for the over-all supervision of the implementation of the NRCP. The NRCP coordinator receives updated information concerning sampling and results of all commodities with the exception of antimicrobial sampling of slaughtered animals. Cantons select the laboratories for antimicrobial testing and these laboratories report to the cantons which in turn inform BVET.

The mission team noted that:

- evidence was seen that on a monthly basis BVET had supervised all sampling other than sampling for antimicrobial residues in slaughtered animals. As regards sampling for antimicrobials, the CA stated that all cantons do not inform BVET immediately of the results and BVET does not have power to enforce that such sampling actually takes place and is reported in a timely fashion to the CA¹⁵.

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¹² In their response to the draft report the Swiss Authorities stated that negotiations have been started so that all sampling will be carried out by officials. (See also action plan.)
¹³ In their response to the draft report the Swiss Authorities stated that this deficiency has already been corrected.
¹⁴ In their response to the draft report the Swiss Authorities stated that delay in milk sampling was due to the reorganization of sampling. Discussions to organise sampling are under way.
¹⁵ In their response to the draft report the Swiss Authorities stated that Food Act requires cantons to notify BVET of the results and follow-up measures when the case concerns the whole of Switzerland. In other cases results/measures are reported if BVET requests them. (See also action plan.)
internal supervision of the sampling was seen in the canton visited. This canton had also promptly reported the results of antimicrobial residue testing to BVET.

5.1.4. Other residues control programmes

Cantonal veterinary authorities also take residues samples outside the NRCP but this information is not communicated to BVET.

The CA stated that residue testing for imported honey/royal jelly will start in 2007. Testing in this programme will be limited to chloramphenicol.

5.1.5. Follow-up of non-compliant results

Cantons are responsible for all follow-up activities in their area.

The mission team noted that:

- there is no follow-up legislation in place equivalent to Council Directive 96/23/EC in Switzerland. Consequently, a uniform approach in different cantons cannot be guaranteed;
- under national legislation, owners must always be informed of sampling, even at slaughterhouses. This approach might weaken the possibility to find the source of residue during on-farm investigation;
- cantonal authorities carry out follow-up actions independently and BVET is not informed about the measures taken. Consequently, follow-up activities are not supervised or co-ordinated at the central level;
- the canton visited had developed its own procedures for follow-up including a checklist for on-farm investigations;
- several follow-up files of non-compliant antimicrobial residue results in slaughtered animals were studied in the canton visited. The cantonal veterinary authority had immediately initiated follow-up activities by asking slaughterhouse veterinarians about the origin of the animal. Subsequently the canton had informed the owners of the animals about the non-compliant result and requested an explanation within a set deadline. In all cases the explanation was considered sufficient and no further action was taken, except in one case where a small fine to cover analytical costs was set to the farmer;
- one follow-up file concerning a non-compliant result detected in an additional residue testing programme (outside the NRCP), carried out in another canton was studied. Chloramphenicol residues had been detected in three pigs originating from the same farm (0.5 µg/kg, 0.3 µg/kg and 0.2 µg/kg). The farmer had been notified of the result in writing, prior to an official on-farm investigation. The source of this illegal substance could not be found. As all pigs had already been slaughtered, feed samples were taken, and these were compliant. No other measures were taken and neither BVET nor Swissmedic was informed of the original non-compliant result. However, the national VMP legislation obliges cantons to report to the relevant bodies at central level of unwanted side-effects of VMPs, including non-compliant residue results.
5.2. LABORATORIES

5.2.1. General description

BVET has assigned five cantonal laboratories as national reference laboratories (NRL). Each NRL is responsible for a number of subgroups. Most residue analyses are performed in two (private) routine laboratories. Some of the antimicrobial substances are analysed in other laboratories which are appointed by cantonal authorities. All residues laboratories have to be accredited to ISO 17025. Private laboratories must have a contract with BVET which is renewed annually.

The mission team observed that:

- all laboratories are accredited to ISO 17025 and have regularly participated in internationally recognised proficiency tests;
- the main responsibilities of NRLs are to act as secondary opinion laboratories and keep analytical standards. This is a restricted range of functions in comparison to those detailed in Article 14 of Council Directive 96/23/EC in which NRLs are responsible for *inter alia* coordinating the work of national laboratories and organising comparative tests. Furthermore, there is no NRL in Switzerland for substance group B3;\(^{16}\)
- there have been some contacts with the Community reference laboratory (CRL) network but these contacts have been limited;
- although there is no requirement for the residue laboratories to validate the methods in accordance with Commission Decision 2002/657/EC, two laboratories had done so.

5.2.2. On the spot visits in the laboratories

One private routine laboratory was visited. This laboratory is responsible for testing all of Groups A, B2 and part of B1.

The mission team noted that:

- there was a satisfactory quality assurance system in place;
- the laboratory personnel were well trained and possessed sufficient expertise in residue analysis;
- modern adequate equipment was in place including one LC-MS-MS;
- the laboratory had regularly participated in proficiency tests and corrective actions had been taken in case of unsatisfactory performance;
- sample integrity was ensured. Criteria for the reception of the samples had been set by the laboratory, however samples were sometimes analysed even though these criteria had not been met;
- BVET has set a target turnaround time of 30 days from the arrival of the sample to the reporting of a result for all laboratories. In general, this target had been respected;

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\(^{16}\) *In their response to the draft report the Swiss Authorities stated that reference laboratory will be assigned for Group B3.*
there was a general SOP for validation. Several of the required criteria detailed in Commission Decision 2002/657/EC were in place for HPLC and LC-MS-MS methods. However, $\text{CC}_\alpha$ and $\text{CC}_\beta$ had not been calculated;

- for nitrofurans and sulphonamides, validation had been carried out in accordance with the general validation SOP and the performance of the methods satisfied the Community MRPL and MRL respectively;
- with regard to ELISA methods, only selectivity and recovery had been assessed;
- with regard to beta-agonists, there was no appropriate method for mapenterol, even though this analyte had been included in the 2007 NRCP. Furthermore, the spiking level used for the screening method was 0.5 µg/kg, which is higher than the LoD mentioned in the plan (0.2 µg/kg)\(^{17}\);
- for chloramphenicol, ELISA was used as a screening method for all matrices. Validation had been performed at a level of 0.5 µg/kg while an LoD of 0.2 µg/kg was noted in the 2007 NRCP. Consequently, a sample is reported as compliant below 0.5 µg/kg which is higher than the Community MRPL of 0.3 µg/kg\(^{18}\).

5.3. **Veterinary Medicinal Products (VMPs) and Medicated Feedingstuffs**

5.3.1. **Authorisation of VMPs**

Swissmedic which resides under the Ministry of Home Affairs is the competent authority responsible for the marketing authorisations of VMPs with pharmacologically active substances.

The mission team noted that:

- there is a central authorisation system for VMPs. A marketing authorisation is valid for five years after which it can be renewed;
- a list of all authorised VMPs is publicly available via the internet, including relevant information on *inter alia* pharmacologically active substances, target species and withdrawal periods;
- national legislation prohibits the use of stilbenes, thyrostats, chloramphenicol, nitroimidazoles and nitrofurans in food producing animals and the use of beta-agonists and steroids for growth promotion. This is in line with Council Directive 96/22/EC and Annex IV to Council Regulation (EEC) No 2377/90/EC;
- there are no VMPs containing malachite green or other dyes authorised for fish, other than ornamental fish, and there are no authorised products containing carbadox or olaquindox;
- off-label use is allowed and follows in general Community legislation;
- most of the VMPs which may cause residues, are "prescription-only" medicines. A topical product containing flumethrin is available without prescription.

\(^{17}\) *In their response to the draft report the Swiss Authorities stated a new method for mapenterol and other beta-agonists is the process of being validated and will reach LoD 0.2ppb. Method will be used in routine analysis in September 2007.* (See also action plan.)

\(^{18}\) *In their response to the draft report the Swiss Authorities stated that method has been updated and will reach EU MRPL 0.3 µg/kg.* (See also action plan.)
However, this bee medicine is distributed only via authorised bee inspectors and bee shops and thus is not freely available;

- maximum residue limits (MRLs) are set by the Ministry of Home Affairs. In several cases national MRLs are higher than Community MRLs laid down in Council Regulation (EEC) No 2377/90 (e.g. for gentamicin). For several substances, MRLs are listed for food producing animals or matrices where there are either no, or only very restricted Community MRLs (e.g. phenylbutazone – no Community MRL, gentamicin - Community MRL only for bovine and porcine)¹⁹;
- whilst there is an action limit (20 µg/kg) for some antimicrobial residues in honey e.g. tetracycline and streptomycin, the use of VMPs containing these active principles is not permitted under national legislation, which is in line with Community legislation¹⁰;
- national MRLs are set for several EU forbidden substances e.g. chloramphenicol and nitrofurans (0.1 µg/kg) as well as nitroimidazoles (dimetridazole 10 µg/kg). According to CA these limits are created for imported products, and if results below these limits are detected in domestic products, follow-up activities would be initiated (due to the illegal use of the substance) although products could not be withdrawn from the market¹⁹;
- there is no compulsory system of identification and registration of all horses. All horses are considered as food producing animals and if the owner wants to change the status of the horse, a horse passport similar to the EU horse passport, has to be acquired. In addition, horses are not slaughtered unless they are accompanied by either a horse passport or owner’s declaration indicating inter alia any treatment with VMPs.

5.3.2. Distribution of VMPs

Importers and manufacturers sell VMPs to wholesalers and feedmills. Wholesalers sell VMPs to veterinarians, pharmacies and feedmills. The majority of VMPs are distributed to farmers by veterinary practitioners.

Swissmedic has issued a uniform prescription model for medicated feed. There is no uniform prescription model as regards VMPs but the information which is required in the prescription has been specified.

The mission team noted that:

- distributors of VMPs, except veterinarians, are licensed by Swissmedic;
- distributors are required to keep records of purchased and sold VMPs. In contrast to the requirements of Directive 2001/82/EC of the European Parliament and of the Council, the recording of batch numbers is not compulsory under national legislation. According to the CA trace back is possible even though not always through batch numbers.

5.3.3. Controls on VMPs

Swissmedic is responsible for the authorisation and control of manufacturers, wholesalers and feedmills. Part of this control is delegated to regional VMP

¹⁹ In their response to the draft report the Swiss Authorities stated that a working group is assigned to propose necessary amendments (in line with EU legislation). (See also action plan.)
inspectorates under Swissmedic. These inspectorates are obliged to report inspections to Swissmedic.

The cantonal authorities are responsible for the control of veterinarians and for inspections at farm level.

The mission team noted that:

- Swissmedic has issued instructions for inspections of manufacturers, wholesalers and feed mills including target inspection frequencies and checklists;
- there are recently issued instructions and checklists by Swissmedic and BVET for inspections of farms and veterinarians including, for example, the target frequency for inspection.

5.3.3.1. At wholesale and retail level

Wholesalers are authorised by Swissmedic.

The mission team noted that:

- wholesalers are obliged to submit a report annually to Swissmedic concerning medicine (human and veterinary) sales, and in particular sales of antimicrobials. Part of this information is published and is publicly available on the Swissmedic website;
- there was evidence that controls in accordance with Swissmedic instructions had been performed in the wholesaler visited;
- whilst Swissmedic had stated that labelling requirements are in line with EU legislation, the medicine withdrawal period was printed only in the inner packaging of some VMPs at the wholesaler visited. Directive 2001/82/EC requires that this information is also printed on the outer packaging\(^\text{20}\).

5.3.3.2. In feed mills (medicated pre-mixes and medicated feedingstuffs)

Feed mills are authorised by Swissmedic. Feed mills manufacturing medicated feedingstuffs need a special approval. Medicated feedingstuffs are only produced after a prescription by a veterinarian. National legislation which is equivalent to Council Directive 90/167/EEC is in place regulating aspects such as homogeneity of mixing or prevention of cross contamination of feedingstuffs with VMPs.

The Federal Agricultural Office is responsible for the control of feed additives, including anti-coccidials. It has issued instructions for inspections including checklists.

The mission team noted that:

- on-farm mixing for farmers own use is allowed under the approval of a veterinarian without the approval of Swissmedic;
- top dressing of medicated premixes on farm is allowed on prescription;
- inspections had been carried out in the feed mill visited in accordance with instructions both for medicated feed and feed additives;
- in the feed mill visited, veterinary prescriptions were seen. Some procedures to control homogeneity and cross contamination were in place. In contrast to

\(^{20}\text{In their response to the draft report the Swiss Authorities stated that measures have been taken to rectify this.}\)
requirements of national legislation the stability of medicated feedingstuffs had not been assessed or controlled.\(^{21}\)

5.3.3.3. **On veterinary practitioners and farms**

The cantonal veterinary authorities are responsible for the control of veterinary practitioners and farms. Control of private veterinary practitioners had started in 2007. Veterinarians are allowed to sell VMPs to farms for the use covering 3-12 months (depending on the type of production) provided that they have a written contract with the farmer and they visit the farm twice a year. Beekeepers are inspected by authorised bee inspectors for animal diseases, but not for VMPs.

The mission team noted that:
- with the exception of bee keepers, it is compulsory for veterinarians and farmers, to keep records of medicinal treatments of food producing animals;\(^{22}\)
- all farms need to have a contract with a veterinarian. The canton visited had noted that twice a year visits by a contract veterinarian had not always been carried out and had initiated corrective actions;
- the target for on-farm inspections had not been reached for the whole country in 2006 (69%). However, in the canton visited, this target had been reached and follow-up actions had been taken where deficiencies had been found;
- inspections of veterinary practitioners had started in the canton visited;
- evidence of official inspections and inspections by the contracted veterinarian as well as correct record keeping of treatments and correct storage of VMPs were seen at the farm visited.

6. **CONCLUSIONS**

6.1. **National Residue Control Plan**

(1) The NRCP is designed in accordance with Council Directive 96/23/EC. However, the limited involvement of all relevant bodies in the planning phase and deficiencies noted in the plan e.g. limited scope of testing for some important substance groups and action limits higher than the detection limits for some forbidden substances weaken the effectiveness of the residue control system.

(2) The planned number of samples has in general been respected. However, the lack of central (targeting) instructions for sampling, the lack of power by BVET to issue sampling instructions to cantons and the use of non-officials for sampling, collectively militate against the possibility of detecting illegal use or misuse of pharmacologically active substances.

(3) Supervision of the implementation is satisfactory with the exception of sampling for antimicrobial residues at slaughterhouses. The deficiencies in this area reflect the fact that the central authority has no power to enforce sampling and reporting in the cantons.

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\(^{21}\) In their response to the draft report the Swiss Authorities stated that legislation requiring stability tests will come into force 1.1.2008.

\(^{22}\) In their response to the draft report the Swiss Authorities stated that all producers, including beekeepers are already required to keep treatment records. (See also action plan.)
There is framework legislation in place for follow-up. Follow up actions were carried out, though this was inconsistent. Current arrangements for follow-up are not effective and not at least equivalent to the requirements detailed in Council Directive 96/23/EC. This weakens the possibility to find the source of residues and prevent recurrence.

6.2. **Laboratories**

(1) The laboratories within the network are in general functioning satisfactorily. Accreditation, participation in proficiency tests and established validation procedures strengthen confidence with the laboratory system.

(2) Although third countries are not required to have NRLs, the restricted functions of the NRLs, in particular the absence of any requirement to coordinate the activities of the laboratory network, could hamper uniform implementation of testing within this network.

6.3. **Veterinary Medicinal Products and Medicated Feedingstuffs**

(1) A centralised procedure for authorisation of VMPs is in place. The control on distribution and use of VMPs is in general satisfactory with the exception of honey where there is no requirement of keeping treatment records or control on the use of VMPs at farm level which weaken guarantees on the residue status of this commodity.

(2) The discrepancy between the national and Community MRLs for pharmacologically active substances could mean that withdrawal times for VMPs containing such substances may not be sufficient to ensure that animal products exported to EU comply with Community MRLs in these cases.

6.4. **Overall Conclusion**

In general, the residues control programme in Switzerland is operating in accordance with relevant Community legislation. The residues laboratories are in general functioning satisfactorily and there is an effective system of veterinary medicine authorisation and controls on the distribution and use of veterinary medicines. However, shortcomings observed in the implementation of the residue plan and the follow-up of non-compliant results, which are exacerbated by a lack of enforcement power of the central authorities upon the cantons, collectively weaken the effectiveness of the residues control system.

7. **Closing Meeting**

A closing meeting was held on 4 May 2007 with representatives of the CA. At this meeting, the inspection team presented the main findings and preliminary conclusions of the mission. The CCA did not express disagreement.

8. **Recommendations**

The competent authorities were 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 25 working days of receipt of a draft of this mission report.
National Residue Control Plan

(1) Address all identified shortcomings in the structure, implementation and supervision of the NRCP in order to ensure that it will offer guarantees on the residue status of exported food commodities to the EU which are at least equivalent to the standards set out in Community legislation (Article 29 of Council Directive 96/23/EC and Commission Decision 98/179/EC).

(2) Ensure that, when non-compliant results are detected, follow-up procedures which have an effect at least equivalent to those laid out in Council Directive 96/23/EC, are carried out and supervised.

Laboratories

(3) Consider expanding the responsibilities of the NRLs with a view to co-ordinating the activities of the laboratory network in line with Article 14 of Council Directive 96/23/EC.

Veterinary Medicinal Products

(4) Given the discrepancy between national and Community MRLs for certain pharmacologically active substances, take measures to ensure that food of animal origin exported to the EU complies with Community MRLs.

(5) Take into account the requirements of Article 10 of Council Directive 96/23/EC which stipulates that veterinary medicines treatment records are kept on all farms.

9. COMPETENT AUTHORITY RESPONSE TO RECOMMENDATIONS

The competent authority’s response to the recommendations can be found at:
ANNEX: APPLICABLE COMMUNITY STANDARDS:

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