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FINAL REPORT OF A MISSION

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SWITZERLAND

FROM 17 TO 21 JANUARY 2011

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

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

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) mission in Switzerland, carried out between 17 and 21 January 2011, as part of the published programme 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, in order to assess whether these systems offer adequate assurance that the products and animals concerned are within the specified residue limits laid down in European Union (EU) legislation. Since residue controls are directly related to the national rules governing the authorisation, distribution and use of veterinary medicinal products and feed additives, the control systems in this area were also part of the mission. The mission assessed the performance of the competent authorities and other officially authorised entities involved in residues and veterinary medicinal product controls and the legal and administrative measures put in place to give effect to the relevant EU requirements.

For the commodities for which Switzerland is listed in the Annex to Commission Decision 2004/432/EC, the national residue monitoring plan is generally in line with the requirements of Council Directive 96/23/ EC. The planning process and dissemination of the plan to the cantonal authorities is timely, however, available information on non-compliant test results, on the use of veterinary medicinal products and on the analytical capabilities of the laboratory network has not been used to improve the effectiveness of the plan. Samples have been taken in accordance with the plan and the organisation and implementation of the plan has been effectively supervised by the central competent authority. Nevertheless several factors weaken the effectiveness of the plan including commodity-dependent differences in reporting protocols and the lack of follow-up of non-compliant residues results, an issue which was also highlighted in the 2007 FVO report.

With regard to laboratories, the central competent authority can generally have confidence in the analytical results of the laboratories which are all accredited according to ISO 17025. However, given that the network of National Reference Laboratories is not functioning as foreseen, this has the potential to weaken the overall performance of the laboratory network.

With regard to veterinary medicinal products, the conditions governing the authorisation, distribution and use of veterinary medicinal products are similar to EU requirements and there is a well elaborated and operational system in place for official controls on the distribution and use of veterinary medicinal products at each of the relevant points of the distribution chain. However, its effectiveness is reduced by inconsistencies in the performance of cantonal controls on the use of veterinary medicinal products. In relation to feed mills, the evidence seen suggests that the current approach to monitoring the implementation of corrective actions by feed mill operators may be insufficient to ensure compliance with national rules.

National requirements for the maintenance of medicinal treatment records on farms generally provide assurances that animals are not inadvertently sent for slaughter within drug withholding periods. However, given that not all treatments need to be recorded – in particular for honey where there are authorised medicines with MRLs – the competent authorities can not, in the absence of records, verify that these medicines have been used in accordance with label instructions.

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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Abbreviations and definitions used in this report

Abbreviation	Explanation
Agroscope	Organisation for research into agriculture, nutrition and the environment, also responsible for inspections in the animal feed sector, belonging to the Swiss Federal Office for Agriculture.
BVET	Das Bundesamt für Veterinärwesen, the Federal Veterinary Office
CCα, CCβ	decision limit, detection capability
DG(SANCO)	Health and Consumer Protection Directorate General
EU	European Union
EURL	European Union Reference Laboratory
FVO	Food and Veterinary Office
GDP	Good Distribution Practice
GMO	Genetically Modified Organism
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC
ISO	International Organisation for Standardisation
ISVET	Data recording and analysis system of the Swiss veterinary service
LC-HR-MS	Liquid Chromatography- High Resolution - Mass Spectrometry
LC-MS-MS	Liquid Chromatography-(Tandem) Mass Spectrometry
LC-TOF-MS	Liquid Chromatography- Time of Flight - Mass Spectrometry
MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
NRL	National Reference Laboratory
NSAID	Non-steroidal anti-inflammatory drug
PCB	Polychlorinated biphenyl
RASFF	Rapid Alert System for Food and Feed
Swissmedic	Swiss Agency for Therapeutic Products
SOP	Standard Operating Procedure

1 Introduction

The mission took place in Switzerland from 17 to 21 January 2011. The mission team comprised two inspectors from the Food and Veterinary Office (FVO) and one expert from a European Union (EU) Member State. The mission was undertaken as part of the FVO's mission programme, evaluating control systems and operational standards in the residues sector.

Representatives from the central competent authority responsible for control of residues in animals and animal products accompanied the mission team during the mission. An opening meeting was held on 17 January 2011 with the central competent authority and representatives of the competent authority responsible for the authorisation of veterinary medicinal products. At this meeting, the objectives of, and itinerary for, the mission were confirmed 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, in order to assess whether these systems offer adequate assurance that the products and animals concerned are within the specified residue limits laid down in EU legislation. Since residue controls are directly related to the national rules governing the authorisation, distribution and use of veterinary medicinal products and feed additives, the control systems in this area were also part of the mission.

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 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 undertaken in response to recommendations made in the report of a previous FVO residues mission to Switzerland (DG (SANCO)/2007-7319-MR Final) in April/May 2007. The table below lists sites visited and meetings held.

Meetings/Visits		**n**	**Comments**
Competent Authorities	**Central**	**2**	Opening and closing meeting with the Federal Veterinary Office, the Federal Office of Public Health, the Federal Food Chain Unit, Swissmedic, Agroscope and representatives from cantons and laboratories
	Regional	**2**	Cantonal veterinary offices in Bern and Brunnen
Laboratories		**1**	The reference laboratory in Zürich
Farms		**2**	A dairy farm and a farm with fattening pigs
Establishments		**1**	A dairy plant
Other sites		**2**	A feed mill and a distribution centre of veterinary medicinal products

3 Legal Basis for the Mission

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

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

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

4 Background

4.1 Country status in relation to submission of residue monitoring plans

Commission Decision 2004/432/EC indicates that Switzerland's residue monitoring plan is approved in accordance with Council Directive 96/23/EC for bovine, ovine/caprine, porcine, equine, poultry, rabbit, aquaculture, farmed game, wild game, milk, eggs and honey.

4.2 Previous fvo reports

The residues sector was inspected by the FVO in 2007 (DG(SANCO)/2007-7319 MR Final). The report (henceforth referred to as the 2007 FVO report) has been published on the website of DG (SANCO) here: http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=1794

That report concluded that in general the control of residues in Switzerland was operating in accordance with relevant EU legislation. The laboratories were in general functioning satisfactorily and there was an effective system for the authorisation of veterinary medicinal products and controls on the distribution and use of such products. However, shortcomings were observed in the implementation of the residue monitoring plan and the follow-up of non-compliant results. These were exacerbated by a lack of enforcement power of the central authorities on the cantons and these factors collectively weakened the effectiveness of the residue control system.

4.3 Rapid Alert System for Feed and Food (RASFF) notifications for products of animal origin from Switzerland concerning residues

Since the 2007 FVO report there have been no RASFF notifications for residues of veterinary medicinal products or contaminants in food of animal origin.

4.4 Production and trade information

National production data for 2009 provided by the Federal Veterinary Office (BVET) are summarised in the table below. Dairy products are the main commodity exported to the EU.

Commodity	Amount
Calves < 6 months	254,000 animals
Cattle 7 – 24 months	213,000 animals
Cattle > 24 months	180,000 animals
Pigs	2,711,000 animals
Sheep	238,000 animals
Goats	28,000 animals
Horses	3,200 animals
Poultry[1]	62,000 tonnes
Rabbits[1]	1,500 tonnes
Fish (farmed)[2]	1,100 tonnes
Game (farmed)	990 animals
Game (wild, except birds)[1]	100,000 animals
Game (birds)[3]	10,000 animals
Milk[1]	597,000 tonnes
Eggs[1]	40,000 tonnes
Honey[1]	2,600 tonnes

[1]Data for 2008; [2]Data for 2006; [3]Data for 2005

5 Findings And Conclusions

5.1 Residue monitoring

5.1.1 Competent authorities involved

Switzerland is a confederation composed of 26 cantons. The cantons exercise all the rights which are not conferred to the federal government.

BVET under the federal Ministry of Economic Affairs is the central competent authority responsible for the planning and coordination of the national residue monitoring plan, for reporting results to the European Commission, and for designating national reference laboratories for residue testing.

Cantonal veterinary services and food inspectorates under the cantonal administrations are the competent authorities for the implementation of the national monitoring plan and for the follow-up on non-compliant test results in their respective territories.

Agroscope, belonging to the Swiss Federal Office for Agriculture, is responsible for residue controls in animal feed.

The Federal Food Chain Unit, which is answerable to three federal ministries, audits control systems in the food chain and can assume a coordinating role in case of inter-cantonal food crises. Residue monitoring has not been subject to an audit so far.

The Swiss Agency for Therapeutic Products (Swissmedic) is the competent authority responsible *inter alia* for the authorisation of veterinary medicinal products.

5.1.2 Planning of the residue monitoring plan

Legal Requirements

Third countries which export live animals or animal products to the European Union are obliged to submit to the European Commission a specific plan setting out the guarantees which it offers as regards the monitoring of the groups of residues and substances referred to in Annex I to Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products.

The residue plan should take account of the results of monitoring from the previous year and should be revised annually and updated at the request of the Commission, particularly when checks carried out by the Commission render it necessary. Article 29 of said Directive states that guarantees must have an effect at least equivalent to those provided for in the Directive and must, in particular, meet the requirements of Article 4 and specify the particulars laid down in Article 7 and meet the requirements of Article 11(2) of Directive 96/22/EC. Articles 3 to 7 of Council Directive 96/23/EC deal with the requirements for residue monitoring plans. The levels and frequencies of sampling for residues are specified in Annex IV to Council Directive 96/23/EC and Commission Decision 97/747/EC.

Article 11 of Regulation (EC) No 178/2002, laying down the general principles and requirements of food law, specifies that food and feed imported into the EU for placing on the market within the EU shall comply with the relevant requirements of food law or conditions recognised by the EU to be at least equivalent thereto. In relation to maximum levels of residues and contaminants in food, Regulation (EC) No 470/2009 of the European Parliament and of the Council lays down Maximum Residue Limits (MRLs) for residues of pharmacologically active substances in food which are listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010. Regulation (EC) No 396/2005 lays down maximum residue levels of pesticides in or on food and feed of plant and animal origin. Commission Regulation (EC) No 1881/2006 lays down Maximum Levels (MLs) for contaminants in food. Minimum Required Performance Limits (MRPLs) are defined in Article 4 of Commission Decision 2002/657/EC.

In accordance with Article 29 of Council Directive 96/23/EC, Commission approval of every third country's residue monitoring plan is necessary if that country is to remain on the list of third countries from which EU Member States may import animals and animal products. The list of countries and commodities with approved residue monitoring plans is in the Annex to Commission Decision 2004/432/EC.

Findings

BVET starts the planning of the national residue monitoring plan for the following year in September of the preceding year. The plan is finalised by December and disseminated to each of the cantons.

The mission team noted that:

- the plan is based on Council Directive 96/23/EC for all commodities and the number of tests per commodity is based on national production data (see 4.4.);
- there is no formal involvement in the planning process of the cantons, the residue laboratories or Swissmedic. BVET consults, however, on an *ad-hoc* basis some cantons and laboratories;
- since 2007 the residue monitoring plan has not been modified in the light of non-compliant results and information on the use patterns of veterinary medicinal products in Switzerland;

- examination of analytical certificates demonstrated that some laboratories test for many more substances than are specified in the national residue monitoring plan;
- for many substance/species/matrix combinations specified in the plan the action level stated differs from that which is legally valid in Switzerland. Examples include tetracycline in honey (600µg/kg in the plan versus no Maximum Residue Limit (MRL) established in Swiss legislation, and enrofloxacin in cattle kidney (300µg/kg in the plan versus a national MRL of 200µg/kg);
- most relevant substance groups are included in the 2010 plan. However, the following substance groups are not covered:
  - anticoccidials (B2b), carbamates and pyrethroids (B2c) and sedatives (B2d) in equidae. The Swiss authorities stated in their action plan to the 2007 FVO report, that these substance groups had been added to the 2007 monitoring plan. However, this did not occur;
  - organochlorine compounds (B3a) in fish and anticoccidials (B2b) and sedatives (B2d) in goats;
- the scope of testing within certain groups is limited in relation to the veterinary medicinal products authorised and seen to be used on the farms visited by the mission team:
  - antibacterial substances commonly used in various animal species are not specified in the plan[1]: aminoglycosides, beta-lactams and macrolides (B1).[2] Residues of aminoglycosides and beta-lactams have however been found in a separate residue monitoring plan in the canton of Zürich (see 5.1.4.2);
  - only one non-steroidal anti-inflammatory drug (NSAID) (B2e) is included in the plan and no corticosteroids (B2f) have been included;

Conclusions on planning of the residue monitoring plan

For the commodities for which Switzerland is listed in the Annex to Commission Decision 2004/432/EC, the national residue monitoring plan is in generally line with the requirements of Council Directive 96/23/ EC. In some cases however - equidae, fish and goats - not all of the substance groups specified in Annex I to that Directive are included.

The planning process and dissemination of the plan to the cantonal authorities is timely. However, available information on non-compliant test results, on the use of veterinary medicinal products and on the analytical capabilities of the laboratory network has not been used to improve the effectiveness of the plan.

The fact that some action levels specified in the 2010 plan are not in line with national legislation could potentially lead to an incorrect interpretation of analytical results.

5.1.3 Implementation of the residue monitoring plan

Legal Requirements

1 In its response to the draft report the competent authority (BVET) stated that the focus for antimicrobial testing is on sulphonamides, tetracyclines and quinolones which account for 72% of total antibiotic consumption.

2 In its response to the draft report the competent authority stated that, although these substances are not specified in the residue monitoring plan, beta-lactams and macrolides are in fact covered by a multi-residue LC-MS/MS assay primarily used for anthelmintics. Furthermore aminoglycosides (while not specified in the plan) are detected by the microbiological growth inhibition test (four-plate test) used for screening purposes.

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive and must, in particular, meet the requirements of Article 4 and specify the particulars laid down in Article 7. Article 4(2)(b) and (c) of Council Directive 96/23/EC lays down the requirements for central competent authorities in co-ordinating the activities of all bodies involved in residues controls. Articles 5 and 12 of Council Directive 96/23/EC deal with aspects pertaining to the implementation of the residue monitoring plan. Sampling requirements are specified in Annex IV to Council Directive 96/23/EC and Commission Decision 97/747/EC and Commission Decision 98/179/EC lays down the rules for official sampling under the residue monitoring plan. EU methods of sampling for the official control a wide range of residues in products of animal origin are laid down in several pieces of EU legislation: Commission Directive 2002/63/EC (pesticides); Commission Regulation (EC) No 1883/2006 (dioxins and dioxin-like PCBs); Commission Regulation (EC) No 333/2007 (certain chemical elements); Commission Regulation (EC) No 401/2006 (mycotoxins).

Findings

The organisation of sampling, testing and reporting varies per commodity, as indicated below.

Red meat, substance groups A1 to A5, B2 and B3:

- BVET sends monthly sampling forms to the laboratory. The laboratory forwards the sampling forms to the meat inspector at the slaughterhouse designated by BVET. The meat inspector sends the samples and forms to the laboratory. The laboratory sends the analytical results to BVET.

Red meat, for substance groups A6 and B1:

- BVET sends monthly sampling forms to the veterinary service of the canton. The canton forwards the sampling forms to the meat inspector at the slaughterhouse designated by canton. The meat inspector sends the samples and forms to the laboratory. The laboratory sends the analytical results to the cantonal veterinary service and puts BVET in copy.

Poultry meat:

- BVET sends monthly sampling forms to the meat inspector at the slaughterhouse designated by BVET. The meat inspector sends the samples and forms to the laboratory. The laboratory sends the analytical results to BVET.

Live animals:

- BVET sends sampling forms before March, June and September to the veterinary service of the canton. The canton forwards the sampling forms to a veterinarian designated by canton. The veterinarian sends the samples and forms to the laboratory. The laboratory sends the analytical results to BVET.

Milk, eggs and honey:

- BVET sends sampling forms to the milk or food inspection service of the canton. The service sends the samples to the laboratory. The laboratory sends the analytical results to the canton and puts BVET in copy. Milk is sampled monthly, eggs five times per year and honey once per year.

The mission team noted that:

- samples are scheduled to be taken for every month of the year except December. This is to allow the laboratories time to finalise tests during the sampling year. As there is a low number of samples to be taken from live animals, sampling has been scheduled in March,

June and September only;

- samples were taken according to plan in 2009 and 2010 and BVET supervised this, reminding cantons or laboratories when samples were missing;
- sampling instructions are included in the sampling form. The instruction relates to the required matrix, the amount of sample, storage and transport conditions. Adequate sampling materials are used and samples are transported in tamper-proof sealed containers. All sampling is random - in the EU it is targeted;
- although the competent authority stated that sampling is included in the basic training of officials, sampling staff had not been specifically trained for residues sampling;
- in one of the Cantons visited, sampling of live animals was announced in advance to ensure that the farmer was present. Sampling at smaller slaughterhouses can also be announced in advance, in order to ensure that if animals are not being slaughtered on the intended day of sampling, resources are not wasted. In the EU the pre-announcement of sampling is not foreseen (see section 2.1. of the Annex to Commission Decision 98/179/EC);[3]
- sampling for eggs and red meat does not cover the complete national production. Egg samples are taken at four packing stations, which according to BVET pack approximately 90% the eggs produced in Switzerland. Red meat samples for testing substance groups A1-A5, B2, B3 are taken at the 32 largest slaughterhouses in the country, representing 85% of the national production;
- the work flows for the different commodities and substance groups as described above, and the differences in reporting responsibilities, were not clear to the cantonal veterinary services visited. Cantonal staff were not aware for which commodities they should receive the analytical test results from the laboratory and did not keep track of of test results, anticipating that they would be informed by BVET in case of non-compliances. In turn BVET would not inform cantons of non-compliant results on the assumption that they had already received the information from the laboratory[4]. Consequently, non-compliant test-results could remain unnoticed;
- in the cantons visited, samples from live animals were taken by private veterinary practitioners on their own clients' farms. One canton had drawn up contracts with the practitioners. For one of the nine veterinarians provisions were included in the contract that no official tasks could be performed on farms under his/her care. In the other canton there were no contracts, but annual letters requesting samples to be taken. It was considered an advantage that samples were taken by the veterinary practitioner in order to have the confidence and co-operation of the farmer, although such an arrangement presents a potential conflict of interest;
- for screening of antimicrobial residues by the four plate test, cantons have the freedom to choose the laboratory to which they will send samples. For other analytes, samples are sent to those laboratories designated by BVET in the national residue monitoring plan. All laboratories in question were accredited according ISO standard 17025.

3 In its response to the draft report the competent authority stated that advance notification is only done in exceptional cases.

4 In its response to the draft report the competent authority stated that as an immediate measure and pending the discussion of the issue with cantonal veterinary services, BVET would report any positive findings to the competent cantonal authorities, irrespective of whether BVET or the canton has received the original report. (See also the competent authority response to recommendation 5).

Conclusions on implementation of the residue monitoring plan

Samples have been taken in accordance with the plan and the organisation and implementation of the plan has been effectively supervised by BVET. Nevertheless several factors weaken the effectiveness of the plan. These include a lack of understanding of sampling staff at cantonal level of the commodity-dependent differences in reporting protocols and by using private veterinary practitioners which, in the absence of safeguards, may present a conflict of interest.

5.1.4 Other residues monitoring programmes

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive. Article 11 of Council Directive 96/23/EC gives the option of conducting other residues testing, particularly in relation to detection of illegal treatment of food producing animals. Article 9 of Council Directive 96/23/EC foresees the application of own-checks by food business operators.

5.1.4.1 Residues monitoring in milk

Findings

There is a national legal requirement that milk from each farm is tested fortnightly for antimicrobial residues. The test results go directly from the laboratory to the dairy plant and to the food/milk inspection service of the canton. The canton blocks milk deliveries from the farm in case of non-compliant results. In such a case the farmer has to submit follow-up samples and has to provide a statement regarding the cause of the non-compliant result. Only if the statement has been received and the follow-up sample has been tested negative, will the canton lift the blockage.

5.1.4.2 Residues monitoring in canton Zürich

Findings

Canton Zürich runs its own residue monitoring plan in addition to the national residue monitoring plan. The plan covers *inter alia* antibiotic residues in slaughtered animals. Non-compliant results for aminoglycosides, sulphonamides and beta-lactams have been detected in recent years.

5.1.4.3 Residues monitoring in animal feed

Findings

Agroscope implements a nationwide programme of testing of medication-free feed. The vast majority of results in 2010 were compliant.

5.1.4.4 Residues monitoring of the dairy plant

Findings

The dairy plant visited by the mission team checks each truck load (20,000 litre) of milk for

antimicrobial residues. The load contains mixed milk from multiple farms. However, from each farm a separate milk sample is kept for investigation should the bulk tank test non-compliant. Twice a year the dairy plant also checks butter and milk for *inter alia* residues of organochlorinated pesticides, PCBs, mycotoxins and heavy metals.

Conclusions on other residues monitoring programmes

The other residue monitoring programmes in place provide additional assurances to those provided by the national residue monitoring plan with regard to the residues status of food of animal origin. The confirmed findings of antibiotic residues in Zürich's standalone residue monitoring programme which are not specified in the national residue monitoring plan suggest that the effectiveness of the national plan could be improved by the addition of these substances.

5.1.5 Follow-up of non-compliant results

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive. Measures to be taken by competent authorities in response to the finding of non-compliant residues results are described in Articles 13, 16, 17, 18, 19, 23, 24, 27 and 28 of Council Directive 96/23/EC.

5.1.5.1 Non-compliant results in the 2009 and 2010 residue monitoring plan

Findings

The cantonal administration is the competent authority for carrying out follow-up in its territory in the event of non-compliant test results from either the national and/or cantonal residue monitoring plans and from the national milk testing programme. Federal law provides the cantons with the legal basis to carry out follow-up, such as the right for inspectors to enter premises, the right to seize goods, the possibility to stop production, the possibility to issue fines and to prosecute, and the obligation on the food business operator to cooperate.

Agroscope is the competent authority for the follow-up of non-compliant test results in feed throughout the confederation.

Food business operators are obliged to inform the canton if non-compliant products have been placed on the market.

The measures to be taken in the event of positive findings are established pursuant to Articles 27 - 31 of the Federal Act of 9 October 1992 on foodstuffs and commodities (LMG; SR 817.0). According to the competent authority any cantonal enforcement provisions are ancillary to this Act.

The mission team noted that:

- at federal level or in the cantons visited there was no procedure in place with an effect equivalent to all of the measures foreseen in Council Directive 96/23/EC for the follow-up of non-compliant residue results;
- with regard to the small number of non-compliant results in 2009 and 2010 it was confirmed that three cases were not followed-up and there was no evidence that any of the remaining six had been followed up;
- evidence was seen that when a non-compliant result was detected in a slaughterhouse in one

canton and the animal in question had been reared on a farm located in another canton, the second canton was not informed; [5]

– the central competent authority has not improved the co-ordination of follow-up, though this aspect was identified as a weakness in the 2007 FVO report and undertakings were given to address the issue in the action plan (response to recommendation 2). It was stated that under Article 36 of the federal food law the Federation could oversee and co-ordinate enforcement actions of cantons if there is a national interest and that implementation of this Article would be discussed in an interdepartmental working group in 2007.

5.1.5.2 Non-compliant results in the other programmes

Findings

The mission team noted that:

– non-compliant test results in milk had resulted in farm blockades and that the blockades had been lifted after the testing of follow-up samples taken by the farmer and the receipt of a statement on the cause of the residues by the farmer;

– the dairy plant destroys non-compliant batches of milk. The costs are billed to the farm that contaminated the bulk tank;

– the only non-compliant test result in feed in 2010 (tetracycline) was followed-up by Agroscope. The feed mill was ordered to establish an effective traceability system and to make an action plan to prevent cross contamination. The feed mill was also ordered to pay an administrative fine and costs of the investigation.

Conclusions on follow-up investigations/actions

The effectiveness of the national residue monitoring plan is undermined by a lack of follow-up of non-compliant residues results[6], an issue which was highlighted in the 2007 FVO report. With regard to the other residue monitoring programmes in milk and animal feedingstuffs, the follow-up actions observed were fit for purpose.

5.2 LABORATORIES

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive. Article 15 of Council Directive 96/23/EC requires that official samples are examined in approved laboratories. Requirements for accreditation of laboratories are laid down in Point 1.2. of the Annex to Commission Decision 98/179/EC. The rules for analytical methods to be used in the testing of official samples taken pursuant to Article 15(1) of Council Directive 96/23/EC are laid

5 In its response to the draft report the competent authority clarified that this could only occur in case of non-compliant test results for antibiotics (Group A6 and Group B1), where the cantons have been the receivers of the original test results. BVET has committed itself to inform the cantons of all positive results. (See footnote 5 and the competent authority response to recommendation 5).

6 In its response to the draft report the competent authority stated that BVET should consult the cantonal enforcement bodies for support. The issue should be included in training and further training for the cantonal authorities. (See also competent authority response to recommendation 5).

down in Commission Decision 2002/657/EC – in particular Articles 3, 4, 5 and 6 which cover inter alia, validation requirements and quality control. More specific requirements for analytical methods for certain substances are laid down in the annexes to Commission Regulation (EC) No 1883/2006 (dioxins and dioxin-like PCBs in foodstuffs), Commission Regulation (EC) No 333/2007 (chemical elements in foodstuffs) and Commission Regulation (EC) No 401/2006 (mycotoxins).

5.2.1 General description

Findings

BVET contracts laboratories for testing of samples under the residue monitoring plan on an annual basis. Eleven laboratories were contracted in 2010 and ten in 2011. Of these, four laboratories have been designated by BVET as National Reference Laboratories (NRLs). Interlabor Belp is the NRL for substance groups A1 to A5 and part of A6. The cantonal laboratory St. Gallen is the NRL for substance groups B2a to B2f, and the cantonal laboratories of Geneva and Zürich are the NRLs for B1 and part of A6. The NRLs in Geneva and Zürich have divided between themselves the responsibility for the different substances within the substance groups B1 and A6, so there is no overlap of work.

The mission team noted that:

- all BVET-contracted laboratories are accredited to ISO 17025;
- no NRL has been designated for group B3 substances. (The competent authority stated in its response to the 2007 FVO report that this would be done but during the present mission clarified that to date, there has been no legal basis to assign a NRL for group B3 substances, but that a legal basis for so-doing is being prepared at present);
- the existing NRLs do not perform most of the tasks as foreseen in Article 14 of Council Directive 96/23/EC. They do not co-ordinate the work of other laboratories involved in residue monitoring plan, they do not assist the competent authority in organising the plan, they do not periodically organise comparative tests[7], they do not ensure that other laboratories observe the limits laid down and they do not disseminate information to other laboratories;
- in its response to the 2007 FVO report, BVET indicated that it did not see a need for a co-ordination role for NRLs since (at that time) only two laboratories were involved in the residue monitoring plan and that the matter would be reconsidered should more routine laboratories become involved;
- contact of the NRLs with the EU reference laboratories (EURL) is limited;[8]
- there is no structure through which the BVET-contracted laboratories can meet and exchange information;[9]
- the contracts with laboratories stipulate the number of samples (matrices) to be tested for which substances, the turnaround time of samples, and that the laboratory has to use a

7 In its response to the draft report the competent authority indicated that the organisation of a collaborative study is costly and in any case the laboratories participate several times a year in collaborative studies tendered on an international scale.

8 In its response to the draft report the competent authority indicated that it will try to ensure that access for national reference laboratories to the European Union reference laboratories is improved.

9 In its response to the draft report the competent authority indicated that the cantonal laboratories meet several times a year in the Association of cantonal chemists in Switzerland (VKCS) and can exchange views and information in this forum. .

scientifically recognised method. The contract does not specify the required level of performance in relation to criteria including *inter alia,* the ability of the analytical method to detect the substance(s) in question at the appropriate limit (MRL, MRPL, CCα, CCβ), the validation and accreditation of methods and participation in proficiency tests. The substances to be tested for within a substance group have not been specified and there is no information as to whether and when a screening and/or confirmatory method should be used.

5.2.2 On the spot visits in the laboratories

Findings

The mission team visited the cantonal laboratory in Zürich. In addition to its role as an NRL, this laboratory performs routine analyses in the framework of the national residue monitoring plan for chloramphenicol, nitrofurans and nitroimidazol (A6), for sulphonamides, tetracyclines, quinolones (B1), for carbamates (B2c), for tranquilisers (B2d), for NSAIDs (B2e), for chlorinated hydrocarbons, PCBs and organophosphates (B3) in cattle, pigs, sheep, chicken, milk, honey and eggs. The laboratory also does a number of residue tests for the cantonal residue monitoring program (see 5.1.4.2).

The laboratory analyses approximately 2400 samples for veterinary drugs, 2900 samples for contaminants, 1000 samples for pesticides and 1200 samples for elements annually.

The mission team noted the following:

- the laboratory has a contract with BVET for its NRL task and the contract refers to Council Directive 96/23/EC. However, the laboratory does not perform all of the NRL tasks foreseen in Article 14 of said Directive [9] with the exception of ensuring that its staff are able to take part in training courses;
- the laboratory sends an annual report on its NRL activities to BVET. Information with regard to method development and proficiency test participation are included in this report. The laboratory also sends every year a list of available reference standards to BVET;
- the laboratory is well equipped with modern, state of the art equipment, including LC-MS/MS, LC-TOF-MS and LC-HR-MS. Records on maintenance of equipment and checks were kept;
- the last ISO 17025 mission took place in February 2007 and the report of that mission concluded that the laboratory was performing in a manner consistent with the ISO standard;
- staff training files were available in laboratory and all of the staff interviewed were knowledgeable on issues such as method development, method validation and quality control;
- there was no Standard Operating Procedure (SOP) in place for sample reception. However, there was documentary evidence that action had been taken when samples were not received in a suitable condition for analysis. Information on received samples was stored electronically;
- the responsible scientist checks the results and signs the raw data. Interpretation of the results is performed according to the MRLs in the latest version of Regulation (EU) No 37/2010. The sample is declared as non-compliant when the quantitative results (plus the added uncertainty of the method) exceed the MRL;
- samples for the national residue monitoring plans were generally analysed within the contractual deadline of 30 days;

– for the validation of each method a dedicated validation plan is drawn up. Several validation files examined by the mission team (a multi-residue method for antibiotics and a method for chloramphenicol), were well documented and adequately validated;
– the laboratory has participated in a number of proficiency tests between 2007 and 2010. The results (*z*-scores) of several proficiency tests for sulphonamides were not satisfactory in this period. The matter has been investigated by the laboratory (as is required in any case by ISO 17025). Correction for signal reduction in the instrument and quality assurance checks were made using different matrices. A subsequent satisfactory *z*-score was produced for sulphonamides with a different proficiency test organiser in May 2010.

Conclusions on laboratories

The competent authority can generally have confidence in the analytical results of the laboratories which are all accredited according to ISO 17025. However, given that the Swiss authorities have implemented a network of NRLs which should function based on the requirements outlined in Article 14 of Council Directive 96/23/EC, the fact that this network is not functioning as foreseen has the potential to weaken the overall performance of the laboratory network.

5.3 Veterinary medicinal products and medicated feedingstuffs

5.3.1 Authorisation distribution and use of veterinary medicinal products

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive and must, in particular, meet the requirements of Article 4 and specify the particulars laid down in Article 7 and meet the requirements of Article 11(2) of Directive 96/22/EC.

Article 7 of Council Directive 96/23/EC provides for legislation on the use of (pharmacologically active) substances listed in Annex I to the Directive and, in particular, provisions on their prohibition or authorisation, distribution and placing on the market and the rules governing their administration. Articles 4, 5 and 7 of Council Directive 96/22/EC establish conditions for the administration of substances, referred to in its Annex II, List B and Annex III, to farm and aquaculture animals.

According to Article 11(2) of Council Directive 96/22/EC, Member States may not import live animals or animal products from third countries which authorise the use of stilbenes or thyrostats in food producing animals. Member States are also prohibited from importing products of animal origin for human consumption if the animals from which such products have been derived have been treated at any time with either thyrostatic substances, stilbenes, stilbene derivatives, their salts and esters, oestradiol 17β and its ester-like derivatives, and beta-agonists if administered for the purposes of growth promotion.

The relevant provisions in EU law governing the marketing authorisation of veterinary medicinal products are laid down in Articles 5-15, 21-30, 58-62 and 83 of Directive 2001/82/EC and for certain products authorised on an EU-wide basis, in Articles 30-40 of Regulation (EC) No 726/2004. Provisions governing the distribution and use of veterinary medicinal products are laid down in Articles 65-71 of Directive 2001/82/EC. Veterinary medicinal products which are

authorised for use in food producing animals may only contain pharmacologically active substances which are listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010. Article 67(aa) of Directive 2001/82/EC requires that veterinary medicinal products for food producing animals are only dispensed to the public under a veterinary prescription unless exempted under the conditions laid down in Article 2 of Commission Directive 2006/130/EC.

In respect of medicated premixes conditions governing the distribution and use are laid down in Articles 2, 8 and 9 of Council Directive 90/167/EEC. Production of medicated feedingstuffs can only take place in establishments which have been authorised for the production of feedingstuffs containing additives in accordance with Articles 9, 10, 11 and 13 of Regulation (EC) No 183/2005 and the production process must satisfy the conditions laid down in Annexes I and II to that Regulation.

Findings

There is a comprehensive body of federal legislation and guidelines in place dealing with the authorisation, distribution and use of veterinary medicinal products. The following information complements the description from 2007 FVO report.

Veterinary medicinal products intended for food producing animals can only be granted a marketing authorisation if the pharmacologically active substances either have a national MRL, or do not require a MRL. All veterinary medicinal products containing substances with MRLs are categorised as prescription-only medicines, except some topical products and medicines intended for use in honey bees.

Feed mills producing medicated feed are legally considered manufacturers and wholesalers of veterinary medicinal products and have to be licensed by Swissmedic. This does not apply to farms where medicated feed may be produced in amounts which do not exceed one day's consumption for the farmer's own animals.

Veterinary practitioners who have obtained a wholesale license are permitted to supply feed mills with premixes for the production of medicated feed. Feed mills supply medicated feed to farms based on a veterinary prescription, for which a uniform model has been established.

For other veterinary prescriptions there is no prescribed model, but the content is based on recognised rules of the pharmaceutical and medical professions.

Manufacture and distribution of veterinary medicinal products has to be carried out in accordance with the rules of Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP), respectively. All distributors and persons who administer medicines are required to keep records of incoming and outgoing products.

Marketing authorisation holders have to report annually to Swissmedic on the sales of antimicrobial drugs. Summaries of these data are published on the Swissmedic website.

The mission team noted that:

- national MRLs for residues of pharmacologically active substances are harmonised with the EU limits listed in Regulation (EU) 37/2010. This has eliminated the discrepancy between national and EU MRLs identified in the 2007 FVO report;
- off-label use is explicitly forbidden for the treatment of honey bees;
- the distributor of veterinary medicinal products and feed mill visited were authorised in accordance with national rules. Records of incoming and outgoing veterinary medicinal products were kept in good order at the distributor, including batch numbers which were

recorded in line with the GDP requirements on traceability.

Conclusions on authorisation, distribution and use of veterinary medicinal products

In general, conditions governing the authorisation, distribution and use of veterinary medicinal products are similar to EU requirements and provide guarantees equivalent to those.

5.3.2 Controls on the distribution and use of veterinary medicinal products

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive and must, in particular, meet the requirements of Article 4 and specify the particulars laid down in Article 7 which provides for legislation on the use of (pharmacologically active) substances listed in Annex I to the Directive and, in particular, provisions on their prohibition or authorisation, distribution and placing on the market and the rules governing their administration. Article 10 of Council Directive 96/23/EC lays down the veterinary medicines record keeping requirements for stockowners.

The relevant provisions in EU law governing competent authorities' obligations to carry out inspections throughout the distribution chain of veterinary medicinal products in order to verify compliance with the provisions of the EU code relating to veterinary medicinal products (Directive 2001/82/EC) are laid down in Articles 65, 66, 68, 69 of that Directive. With regard to ensuring that the production of medicated feedingstuffs is in accordance with Council Directive 90/167/EEC, the rules governing control functions by the competent authorities are laid down in Articles 4, 9 and 13 of said Directive.

Findings

The following information complements the description from 2007 FVO report.

Swissmedic is responsible for the control of manufacturers, including feed mills producing medicated feed, and distributors (except retailers) of veterinary medicinal products. In addition to instructions already in place, in 2008 specific instructions for implementation of official controls on production and distribution of medicated feed were issued.

Regular inspections are normally announced in advance, however inspections without prior warning may be carried out if deemed necessary, e.g. in case of suspected illegal distribution of medicines. Wholesalers have to be inspected at least every four years, or every two years if they hold a marketing authorisation for a veterinary medicinal product. The minimum inspection interval for feed mills producing medicated feed is three years. Based on a risk assessment of individual companies, minimum inspection intervals may be prolonged (for one year at the most) or shortened.

Cantonal veterinary offices inspect veterinary practitioners and farms, including on-farm feed mills for production of medicated feed which are not subject to Swissmedic authorisation.

The minimum inspection frequency of veterinary practitioners and farms has been set in national legislation. Veterinary practitioners dealing with food producing animals have to be checked at least every five years. Just over eight per cent of farms should be checked on a random basis every year and an additional two percent based on a risk assessment.

There is an agreement in place between Swissmedic and Agroscope, according to which Agroscope samples medicated feed during inspections of feed mills, along with the samples of non-medicated

feed taken in accordance with Agroscope programmes. Samples of medicated feed are then forwarded to Swissmedic for analysis.

All bodies involved in official controls on the distribution and use of veterinary medicinal products and all regional GMP/GDP inspectorates are accredited (to ISO 17020) as required by national legislation.

The mission team noted that:

- controls were carried out by Swissmedic in line with the national requirements at the distributor visited. Action plans aimed at addressing the shortcomings identified by Swissmedic had been submitted by the company;
- the feed mill visited was inspected by Swissmedic in 2009 and several shortcomings were identified including cross-contaminated feedingstuffs, a lack of acceptance criteria for own-checks results, problems with homogeneity of mixing and the acceptance of veterinary prescriptions which were not written on the compulsory uniform model. The feed mill had submitted an action plan to rectify the problems within the set deadline, however, the mission team observed that there were still no acceptance criteria in place, that homogeneity checks were still not carried out in accordance with Swissmedic instructions and that incorrect prescriptions continued to be accepted. It was also noted that the tests on medicated feed showed active substance concentrations outside the prescribed values, and that these batches of feed had been accepted with no investigation by the company. Swissmedic indicated that the verification of corrective actions is normally carried out during the next regular inspection, which for the feed mill in question, is 2012;
- keeping of medicine treatment records for all food producing animals is compulsory for farmers and veterinarians when animals are treated with prescription-only medicines or medicines with established withdrawal periods;
- none of the authorised medicines for bees are classified as prescription-only in spite of the fact that two authorised products contain coumaphos, a substance for which there is a national MRL. Bee-keepers are therefore not required to keep treatment records. (This issue was also highlighted in the 2007 FVO report and the recommendation 5 to that report has not been fully addressed);
- according to the Law on Epizootics, cantons have to designate bee inspectors who are responsible for controls on bee-keepers. Official controls on the use of veterinary medicinal products had not been carried out on bee farms in the canton visited. A similar situation was noted in the 2007 FVO report;
- on the farms visited by the mission team, treatment and stock records were kept in good order. Both farms had been regularly controlled by the contracted veterinary practitioners and the check lists used for these controls were available. There was also evidence that official inspections, using check-lists issued by BVET, had been carried out by cantonal veterinarians on these farms;
- significant differences were noted between the two cantons visited in relation to the implementation of controls of veterinary practitioners and on farms. In one canton, controls had been carried out as planned and with the frequency required under national rules. A well elaborated system was in place for organisation of controls and for taking follow-up actions in case of identified deficiencies. Examples of a range of administrative measures taken were available, depending on the severity of non-conformities. In contrast, in the other canton visited, approximately half of the planned controls on farms had been implemented in 2010 whilst official controls of veterinary practitioners had not been carried out. In this

canton the follow-up of non-compliances identified during on-farm controls was mainly informal and not documented;

- private veterinary practitioners have been contracted to carry out on-farm inspections in one of the cantons visited. In one canton measures were in place to prevent a conflict of interest. Official controls on veterinary practitioners were delegated by one canton to another canton, also to ensure greater impartiality;
- countrywide the target numbers of on-farm inspections was not achieved in 2010. Overall, controls were carried out on 41% of the farms that should have been inspected according to national rules. The situation was slightly better in 2007 (69%);
- food chain information has to be provided for hoofed animals for sale and for slaughter. A compulsory form has been issued by BVET;
- according to national rules, the outcome of controls on veterinary medicinal products carried out at retailers (including veterinary practitioners) and farms should be reported to Swissmedic. In practice, controls on farms are reported from cantonal veterinary offices to BVET via the national database ISVET whilst data on controls carried out on veterinary practitioners are not systematically collated at federal level.

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

There is a well elaborated and operational system in place for official controls on the distribution and use of veterinary medicinal products at each of the relevant points of the distribution chain. However, its effectiveness is reduced by inconsistencies in the performance of cantonal controls on the use of veterinary medicinal products. In relation to feed mills, the evidence seen suggests that the current approach to monitoring the implementation of corrective actions by feed mill operators may be insufficient to ensure compliance with national rules.

In relation to the issue of the maintenance of medicinal treatment records on farms, the fact that there are national requirements in this regard provide assurances that animals are not inadvertently sent for slaughter within drug withholding periods. However, given that not all treatments need to be recorded – in particular for honey where there are authorised medicines with MRLs – the competent authorities can not, in the absence of records, verify that these medicines have been used in accordance with label instructions.

6 Overall Conclusions

For the commodities for which Switzerland is listed in the Annex to Commission Decision 2004/432/EC, the national residue monitoring plan is generally in line with the requirements of Council Directive 96/23/ EC. The planning process and dissemination of the plan to the cantonal authorities is timely, however, available information on non-compliant test results, on the use of veterinary medicinal products and on the analytical capabilities of the laboratory network has not been used to improve the effectiveness of the plan. Samples have been taken in accordance with the plan and the organisation and implementation of the plan has been effectively supervised by the central competent authority. Nevertheless several factors weaken the effectiveness of the plan including commodity-dependent differences in reporting protocols and, in particular the lack of follow-up of non-compliant residues results, an issue which was also highlighted in the 2007 FVO report.

With regard to laboratories, the central competent authority can generally have confidence in the

analytical results of the laboratories which are all accredited according to ISO 17025. However, given that the network of National Reference Laboratories is not functioning as foreseen, this has the potential to weaken the overall performance of the laboratory network.

With regard to veterinary medicinal products, the conditions governing the authorisation, distribution and use of veterinary medicinal products are similar to EU requirements and there is a well elaborated and operational system in place for official controls on the distribution and use of veterinary medicinal products at each of the relevant points of the distribution chain. However, its effectiveness is reduced by inconsistencies in the performance of cantonal controls on the use of veterinary medicinal products. In relation to feed mills, the evidence seen suggests that the current approach to monitoring the implementation of corrective actions by feed mill operators may be insufficient to ensure compliance with national rules.

National requirements for the maintenance of medicinal treatment records on farms generally provide assurances that animals are not inadvertently sent for slaughter within drug withholding periods. However, given that not all treatments need to be recorded – in particular for honey where there are authorised medicines with MRLs – the competent authorities can not, in the absence of records, verify that these medicines have been used in accordance with label instructions.

7 Closing Meeting

A closing meeting was held on 21 January 2011 with representatives of the central competent authority. At this meeting, the inspection team presented the main findings and preliminary conclusions of the mission. The authorities did not express disagreement with the preliminary findings and conclusions, but indicated their desire to apply a risk-based approach in establishing future residue monitoring plans.

8 Recommendations

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

N°.	Recommendation
1.	As the Swiss national residue monitoring plan is based solely on Council Directive 96/23/EC, ensure that for all commodities for which the country is listed in the annex to Commission Decision 2004/432/EC, testing includes all of the substance groups listed for each of those commodities in Annex I to the above Directive.
2.	Taking into account the use patterns of veterinary medicinal products, analytical results from previous years' residue monitoring plans and the analytical capabilities of the laboratories, consider adjusting the scope of testing under the national residue monitoring plan in order to increase the overall effectiveness of that plan in line with

N°.	Recommendation
	Article 6 (1) of Council Directive 96/23/EC.
3.	Ensure that action levels for residues of pharmacologically active substances which are specified in the national residue monitoring plan, correspond with national levels (which are already in line with Regulation (EU) No 37/2010).
4.	Ensure that sampling under the national residues monitoring plan is unforeseen, unexpected and effected at no fixed time and on no particular day of the week and that all precautions necessary are taken to ensure that the element of surprise in sampling is constantly maintained, in order to provide guarantees with an effect equivalent to Article 12 of Council Directive 96/23/EC and point 2.1 of the Annex to Commission Decision 98/179/EC.
5.	Ensure that in the event of non-compliant test results in the national residue monitoring plan, follow-up is carried out which has an effect equivalent to the measures foreseen in Articles 15-19 and 22-29 of Council Directive 96/23/EC.
6.	Ensure that the National Reference Laboratories contracted by BVET pursuant to Article 14 of Council Directive 96/23/EC carry out the functions specified in that Article.
7.	Ensure that records are kept of treatments with all veterinary medicinal products, for all food producing species (including honey bees) in order to provide guarantees with a standard equivalent to that required by Article 10 of Council Directive 96/23/EC.

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

http://ec.europa.eu/food/fvo/ap/ap_ch_2011-8907.pdf

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Audits by the Commission Services		
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Food Law		
Reg. 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
Monitoring and sampling of residues in food of animal origin		
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
Dec. 97/747/EC	OJ L 303, 6.11.1997, p. 12-15	97/747/EC: Commission Decision of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products
Dec. 98/179/EC	OJ L 65, 5.3.1998, p. 31-34	98/179/EC: Commission Decision of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products
Approval of residue monitoring plans submitted by third countries		
Dec. 2004/432/EC	OJ L 154, 30.4.2004,	2004/432/EC: Commission Decision of 29 April

Legal Reference	Official Journal	Title
	p. 44-50, corrected and re-published in OJ L 189, 27.5.2004, p. 33	2004 on the approval of residue monitoring plans submitted by third countries in accordance with Council Directive 96/23/EC
Validation of analytical methods for residues		
Dec. 2002/657/EC	OJ L 221, 17.8.2002, p. 8-36	2002/657/EC: Commission Decision of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results
Bans on the use of hormones and beta-agonists for growth promotion in food producing animals		
Dir. 96/22/EC	OJ L 125, 23.5.1996, p. 3-9	Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
Maximum Residue Limits for veterinary medicinal products in food of animal origin		
Reg. 470/2009	OJ L 152, 16.6.2009, p. 11-22	Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council
Reg. 37/2010	OJ L 15, 20.1.2010, p. 1-72	Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin
Maximum Residue Levels for pesticide residues in food of animal origin		
Reg. 396/2005	OJ L 70, 16.3.2005, p.	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005

Legal Reference	Official Journal	Title
	1-16	on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
Maximum Levels for contaminants in food		
Reg. 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Authorisation of veterinary medicinal products		
Dir. 2001/82/EC	OJ L 311, 28.11.2001, p. 1-66	Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products
Dir. 2006/130/EC	OJ L 349, 12.12.2006, p. 15-16	Commission Directive 2006/130/EC of 11 December 2006 implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription
Reg. 726/2004	OJ L 136, 30.4.2004, p. 1-33	Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
Medicated feedingstuffs and additives		
Dir. 90/167/EEC	OJ L 92, 7.4.1990, p. 42-48	Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community
Reg. 1831/2003	OJ L 268, 18.10.2003, p. 29-43	Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition

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