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GENERAL AUDIT

REPORT OF A SPECIFIC AUDIT CARRIED OUT IN GERMANY FROM 22 TO 29 SEPTEMBER 2008 IN ORDER TO EVALUATE THE CONTROL OF RESIDUES AND CONTAMINANTS IN LIVE ANIMALS AND ANIMAL PRODUCTS, INCLUDING CONTROLS ON VETERINARY MEDICINAL PRODUCTS

PART B – SECTOR SPECIFIC ISSUES

Please note that factual errors in the draft report have been corrected. Clarifications provided by the Competent Authority of Germany are included as footnotes in bold italic.

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Abbreviations and definitions used in this report

AKS	*Staatliche Akkreditierungsstelle Hannover*	FIS-VL	*Fachinformationssystem Verbraucherschutz und Lebensmittelsicherheit* (Consumer Protection and Food Safety Technical Information System)
AMG	*Artzneimittelsgesetz* (the Federal Law on Medicines)	ISO	International Standardisation Organisation
BMVEL	*Bundesministerium für Verbraucherschutz, Landwirtschaft und Ernährung* (Federal Ministry for Food, Agriculture and Consumer Protection)	LC-MS/MS	Liquid chromatography – tandem mass spectrometry
BVL	*Bundesamt für Verbraucherschutz und Lebensmittelsicherheit* (Federal Office of Consumer Protection and Food Safety)	LALLF	*Landesamt für Landwirtschaft, Lebensmittelsicherheit und Fischerei* (State Office of Agriculture, Food Safety and Fisheries of Mecklenburg-Western Pomerania)
CCα; CCβ	Decision limit; Detection capability (defined in Comm. Dec. 2002/657/EC)	LU	*Ministerium für Landwirtschaft, Umwelt und Verbraucherschutz* (Ministry of Agriculture, the Environment and Consumer Protection of Mecklenburg-Western Pomerania)
CRL	Community Reference Laboratory	MLOD	(National) Minimum Limit of Determination
DG SANCO	Health and Consumers Directorate-General	MRL	Maximum Residue Limit
EC/ EU	European Community / European Union	MRPL	Minimum Required Performance Limit
EEC	European Economic Community	NOKO	North German cooperation management agreement
ELISA	Enzyme-Linked ImmunoSorbent Assay	NRCP	*Nationaler Rückstandskontrollplan* (National Residue Control Plan)
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC: A1 Stilbenes A2 Antithyroid agents A3 Steroids A4 Zeranol A5 β-agonists A6 Substances listed in Annex IV to Council Regulation (EEC) No 2377/90 B1 Inhibitors (antimicrobials) B2a Anthelmintics B2b Anticoccidials B2c Carbamates and pyrethroids B2d Sedatives B2e NSAIDs B2f Others (e.g. corticcosteroids) B3a Organochlorines including PCBs B3b Organophosphorus compounds B3c Chemical elements B3d Mycotoxins B3e Dyes B3f Others	NRL	National Reference Laboratory
		NSAID	Non-steroidal anti-inflammatory drug
		SAL	*Die Staatliche Anerkennungsstelle der Lebensmittelüberwachung*
		SOP	Standard Operating Procedure
		VLA	*Veterinär- und Lebensmittelüberwachungsamt* (Veterinary and Food Supervisory Office)
		ZLG	*Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten* (Federal Länder Office for Health Protection for Pharmaceutical Products and Medical Products)

1. FINDINGS AND CONCLUSIONS

1.1. Overall conclusion

The system of controls of residues and veterinary medicinal products in Germany is in line with the requirements of the Community legislation and overall is functioning well. Improvements have been made since the previous FVO residues mission in February/March 2005.

Each *Land* has the responsibility for planning, implementation and supervision of the official controls under Regulation (EC) No 882/2004 within its jurisdiction. The *Länder* themselves have established cooperation groups to harmonise related control activities. However, effectiveness of the system of controls is reduced to a certain extent as the central competent authority does not always have an overview of the follow-up procedures of non-compliant results in each of the *Länder* and by some shortcomings in laboratory performance which have yet to be addressed by the central competent authority and National Reference Laboratory as some national routine laboratories still use analytical methods, which are not fit for purpose and can not reach some Community and national limits laid down in the NRCP.

The procedures for controls of the distribution and use of veterinary medicinal products, in line with the requirements of Directive 2001/82/EC, have been harmonised between the *Länder*. In the *Land* visited well documented controls were implemented at all stages of distribution and in most production sectors, thus adding to the prevention of undesirable residues in food of animal origin.

1.2. Planning of the National Residue Control Plan (NRCP)

Legal Basis

The following Community legislation has a direct bearing on the elaboration of the NRCP.

Article 3 of Regulation (EC) No 882/2004 of the European Parliament and of the Council deals with the general obligations with regard to the organisation of official controls. Articles 3 to 7 of Council Directive 96/23/EC deal with the requirements for residue monitoring plans. Commission Decision 97/747/EC lays down levels and frequencies of sampling for residues. Council Regulation (EEC) No 2377/90 lays down Maximum Residue Limits (MRLs) for residues of pharmacologically active substances in food. Council Directive 86/363/EEC lays down Maximum Levels (MLs) for pesticides in food. 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 and have been elaborated for certain prohibited substances in Commission Decisions 2003/181/EC and 2004/25/EC.

Audit findings

A description of the structure of the competent authorities involved in carrying out controls on residues in live animals and animal products can be found in the Country Profile for Germany which has been published on the website of the Health and Consumers Directorate-General (DG SANCO), which can be accessed through: http://ec.europa.eu/food/fvo/country_profiles_en.cfm
At federal level *The Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz* - Federal Ministry for Food, Agriculture and Consumer Protection (BMELV) is the central competent authority for veterinary drug residues. Unit 106 of the *Bundesamt für Verbraucherschutz und Lebensmittelsicherheit* - Federal Office of Consumer Protection and Food Safety (BVL) carries out specific tasks on veterinary drug residues, sets up the National Residue Control Plan (NRCP), collects and analyses the data of the results of the *Länder* (federal states), summarises the data, reports them to the European Commission and publishes the data.
In the *Land* - federal state visited, *Mecklenburg–Vorpommern* - Mecklenburg-Western Pomerania, the NRCP is implemented by the *Ministerium für Landwirtschaft, Umwelt und Verbraucherschutz* - Ministry of Agriculture, the Environment and Consumer Protection (LU) of Mecklenburg-Western Pomerania and by the *Landesamt für Landwirtschaft, Lebensmittelsicherheit und Fischerei* - State Office of Agriculture, Food Safety and Fisheries (LALLF) of Mecklenburg-Western Pomerania. In the districts the *Veterinär- und Lebensmittelüberwachungsämter* - Veterinary and Food Supervisory Offices (VLÄ) are responsible for selection of samples and sampling, and the LALLF for live poultry.

The planning process for the forthcoming year starts in September with the annual meeting of all responsible and relevant authorities and performers of the German NRCP. At this meeting the results, relevant problems and proposals for the changes for the NRCP, including various risk factors, are discussed, also in the view of comments of National Reference Laboratory (NRL) and the Community Reference Laboratories (CRLs). On the basis of this meeting, the *Länder* agree on a sampling plan for the next year which is sent out from BVL at the end of the current year. Competent authorities in the Länder break it down to quarterly plans which are distributed to the relevant sampling authorities.
The mission team noted that:

- all relevant competent authorities are involved in the planning of the NRCP at federal level as well at regional level in Mecklenburg-Western Pomerania;
- sampling strategies and frequencies follow the requirements of Annex III-IV to Council Directive 96/23/EC and Commission Decision 97/747/EC. All substance groups are covered in the 2008 NRCP in accordance with Annex II to Council Directive 96/23/EC;
- for milk, eggs and poultry sampling, the total numbers of samples for the year were prescribed in Mecklenburg-Western Pomerania, although for other commodities quarterly plans specified which month or sometimes week each sample should be collected;
- all relevant risks are taken into account in the planning process for the NRCP. However, the competent authorities do not have access to veterinary medicinal products sales data but obtain information about use of veterinary medicinal products through e.g. targeted surveys. In Mecklenburg-Western Pomerania knowledge of use of veterinary medicinal products is also based on registrations made during official controls on farms but these data are not routinely forwarded to, or requested by, the central competent authority;
- due to the non-compliant results for malachite green/leucomalachite green (B3e) in recent years, all samples taken from aquaculture products in 2008 are tested also for these dyes;
- no aquaculture samples are planned to be analysed for chloramphenicol (A6) in 2008, even though there was one non-compliant case at the end of 2007. The central competent authority stated that the results from follow-up investigations did not indicate illegal use so it was not deemed necessary to add this substance to the then ongoing 2008 NRCP. However, the central competent authority stated that testing of chloramphenicol in aquaculture will be included in the 2009 NRCP[1];
- some relevant analyte/group/matrix/commodity combinations are missing in the 2008 NRCP, including some illegal substances and substances recommended by the CRLs. Several commodities are not tested for nitrofuran metabolites (A6) and nitroimidazoles (A6) are not tested for in *inter alia* farmed game, horses and rabbits;
- the scope of testing for certain authorised pharmacologically active substances e.g. benzimidazoles (B2a) and non-steroidal anti-inflammatory drugs (NSAIDs) (B2e) is limited and does not reflect what is on the market or take account of what has been recommended by CRL in Berlin. Benzimidazoles are not tested for in milk, the scope of testing for these is also limited in poultry and in farmed game. Regarding NSAIDs horses are tested only for phenylbutazone, although meloxicam and metamizol are authorised. In addition, ibuprofen, naproxen, and mefenamic acid are not tested for in milk;
- many relevant anticoccidials (B2b) are missing in *inter alia* poultry and rabbits;

[1] ***In their response to the draft report the German Competent Authority stated that cloramphenicol has been added to the 2009 NRCP for aquaculture.***

- sample numbers are mostly kept at the minimum numbers required by Council Directive 96/23/EC, with some exceptions e.g. poultry and aquaculture. Each *Land* can add samples according to the specific risk situation. *Länder* with small animal production are not included in the NRCP for certain commodities e.g. farmed game, aquaculture and honey. Nevertheless, in Mecklenburg-Western Pomerania, where according to the small aquaculture production, there is no sampling for malachite green (B3e) within the 2008 NRCP, additional residue checks on this unauthorised substance were established within other residue programmes;
- documentation provided by the NRL indicated that some routine national laboratories use analytical methods, which can not reach the minimum required performance limits (MRPLs) or national minimum limits of determination (MLODs) listed in the NRCP sent to the Commission. Examples are certain methods for screening of chloramphenicol (A6) and stilbenes (A1), for confirmation/screening of nitrofuran metabolites (A6), antithyroid agents (A2), nitroimidazoles (A6), phenylbutazone (B2e) and malachite green and leucomalachite green (B3e). The central competent authority and the NRL are aware of this problem, but have no power to demand corrective actions as this is a legislative obligation of the *Länder*.

Conclusions

All relevant competent authorities are involved in the planning of the NRCP and planning strategies follow Community legislation. Nevertheless, certain relevant analyte/group/matrix/commodity combinations are missing and some routine laboratories use analytical methods, which do not meet the standards listed in the NRCP submitted to the Commission, including MRPLs defined in Commission Decision 2002/657/EC. In addition, the NRL does not have the legal power to fulfil its obligation given by Article 14 of Council Directive 96/23/EC, i.e. to ensure that national laboratories observe the limits laid down. Thus, the central competent authority is not in a position to guarantee that the residue control system in Germany is capable of detecting all potential violations of Community residue limits and the consistency of official controls as required by Article 4(4) of Regulation (EC) No 882/2004.

Because the planning approach is based on production, certain commodities in particular *Länder* are never tested under the NRCP. Thus the central competent authority cannot ensure that residues in these commodities are monitored in these *Länder*.

1.3. Implementation of the NRCP

Legal Basis

Articles 4, 5 and 12 of Council Directive 96/23/EC deal with aspects pertaining to the implementation of the NRCP. Article 3 of Regulation (EC) No 882/2004 deals with the general obligations with regard to the organisation of official controls. Commission Decision 97/747/EC lays down levels and frequencies of sampling for residues and Commission Decision 98/179/EC lays down the rules for official sampling under the NRCP. Community methods of sampling for the official control of a wide range of residues in products of animal origin are laid down in several pieces of Community 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).

Audit findings

Implementation of the NRCP is the responsibility of the *Länder* competent authorities.
The sampling procedure follows the provisions of Commission Decision 98/179/EC, following Annex III to Council Directive 96/23/EC. From federal level general principles for implementation of sampling are listed in NRCP by giving special notes on sampling by individual species or by products.
The mission team noted that:

- financing of the NRCP is regulated by the legislation of the *Länder*. In Mecklenburg-Western Pomerania slaughter fees have been charged on the basis of the *Veterinärverwaltungskostenverordnung* - Veterinary administrative costs regulation. A new version of this pursuant to Annex IV Section B of Regulation (EC) No 882/2004 will come into force in 2008 and will contain fees also for milk, and aquaculture, which are not covered by the current legislation;
- the planning meeting between the *Länder* and the central competent authority in September 2008 has agreed on more comprehensive instructions to be included in the 2009 NRCP. These will include *inter alia* instructions for sampling without prior warning, sealing of samples, targeting and prevention of conflict of interest[2];
- in Mecklenburg-Western Pomerania there are uniform sampling procedures. All samples are accompanied by a standardised document. In addition, a suitable quality assurance procedural instruction is being drafted. It was seen that all samples on farm are taken unannounced. Sample collection and transport to the laboratory is handled by official staff;
- in Mecklenburg-Western Pomerania individual records of staff training were available. In the future training will be audited under the new Quality Management System;
- the NRL organises training however participation is not compulsory for staff from all relevant control laboratories. In Mecklenburg-Western Pomerania LALLF staff had taken part in workshops organised by the NRL, kept telephone contacts with the NRL, used the BVL's data base, applied NRL methods and had participated in specific training on the use of the BVL validation software and the use of liquid chromatography–(tandem) mass spectrometry (LC-MS/MS) analysis.

Conclusions

The implementation of the NRCP generally fulfils the requirements of Community legislation. In contrast to the findings of the 2005 FVO residues mission, the number of samples taken on a federal level for 2007 and in the *Land* visited for 2008 was in accordance with NRCP.
However, financing of the NRCP is regulated by the legislation of the *Länder* and in the *Land* visited fees are not yet pursuant to Annex IV Section B of Regulation (EC) No 882/2004.

1.4. Supervision of implementation of the NRCP

Legal Basis

Article 4 2(b) and (c) of Council Directive 96/23/EC lays down the requirements for central competent authorities in coordinating the activities of all bodies involved in residues controls. General principles governing the co-ordination of activities and

[2] ***In their response to the draft report the German Competent Authority stated that more comprehensive instructions have since been issued and are included in the 2009 NRCP.***

ensuring the co-operation between the various competent authorities are laid down in Articles 4.3., 4.4 and 4.5. of Regulation (EC) No 882/2004. Article 8 (3) of Regulation (EC) No 882/2004 places the obligation on competent authorities to *inter alia,* ensure that corrective action is taken when needed.

Audit findings

The supervision of implementation of the NRCP is the responsibility of the *Länder*. In Mecklenburg-Western Pomerania the Ministry of Agriculture, the Environment and Consumer Protection (LU) and LALLF are involved in supervision of sampling carried out under the NRCP.
A target maximum turnaround time of six weeks from the receipt of the sample in the laboratory to the report of analysis is prescribed in the NRCP. In Mecklenburg-Western Pomerania the competent authority stated that this target had been met for 90% of samples in 2007.

The mission team noted that:

- at a federal level the BVL monitors sampling within the framework of the NRCP. Results are entered in a common database half-yearly by the *Länder*. Once a year when the sampling year is over, a detailed evaluation is carried out by the BVL to establish whether the *Länder* have fulfilled their plans. Further assessments are undertaken as necessary. The "target and achievement" assessment is discussed with the *Länder* at the annual meetings concerning the NRCP;
- the central competent authority does not supervise and cannot influence the implementation of the NRCP in the *Länder* during the sampling year;
- actual sample numbers per substance groups for 2007 corresponded to those in the NRCP, although distribution between substances within a group was sometimes different from what had been planned;
- if district VLÄ in Mecklenburg-Western Pomerania cannot fulfil the targets, they report this to LALLF and the samples are re-allocated to another district. In the district visited, due to lack of staff for sampling on farm, the majority of the samples planned for 2007, had been transferred to other districts with risk approach consideration, so the annual plan for the *Land* was fulfilled as planned;
- the laboratories which cannot reach the respective MRPL and MLOD limits, laid down by either Community or national legislation, have not been excluded from the NRCP implementation.

Conclusions

In the *Land* visited, supervision of the NRCP was effective. However, in the event of a specific *Land* not implementing the NRCP as foreseen, the central competent authority has no mechanism to compel these *Länder* to comply with the requirements laid down in the NRCP, as evidenced by the continued use of laboratories using analytical methods which are not fit for purpose.

1.5. Other Residue Control Programmes

Legal Basis

In addition to the NRCP, Article 11 of Council Directive 96/23/EC gives Member States the option of conducting other residues testing, particularly in relation to detection of illegal treatment of food producing animals. Article 9 of Council Directive 96/23/EC foresees the application of own-checks by food business operators. Article 8.2. of Regulation (EC) No 882/2004 obliges Member States to have the legal provisions in place to allow competent authorities have access to such information. Competent authorities are obliged to examine *inter alia* records (of own checks) as laid down in Article 10. 2 (e) and (g) of Regulation (EC) No 882/2004. Article 19 of Regulation (EC) No 178/2002 obliges food business operators to inform the relevant competent authorities when non-compliances are detected, which may pose a risk to the consumers.

Audit findings

In addition to tests carried out under the NRCP, there is a national programme for residues of pharmacologically active substances for testing for antimicrobial inhibitors (B1) in meat under which 0.5% of all slaughtered animals (with the exception of poultry which are not tested and calves of which 2% are tested) are officially sampled. The central competent authority does not have information about which other official residue programmes, exclusive to the *Länder*, are implemented by the *Länder*. Under federal legislation it is not compulsory to include residue analyses in self-monitoring.

The mission team noted that:

- in Mecklenburg-Western Pomerania, results from self-monitoring programmes within the dairy industry are available to the competent authority and the past performance of dairy operators is taken into account at the NRCP planning;
- in Mecklenburg-Western Pomerania, there are in addition to the NRCP, other official residue control programmes, based on the *Land* specific situation, taking into account mainly non-compliant results from previous years;
- such programmes included *inter alia* intensified sampling of eggs for dioxin (B3f) and DDT (B3a) in 2006 and 2007. In 2007, eggs were also monitored for anticoccidials (B2b) and tetracyclines (B1). Aquaculture products were tested for *inter alia* malachite green (B3e), quinolones (B1), pesticides and PCBs (B3a), and chemical elements (B3c) and honey was tested for *inter alia* antimicrobials (B1), carbamates and pyrethroids (B2c) and amitraz (B2f). In 2008 official monitoring programmes covered wild and aquaculture fish (chemical elements), slaughtered animals in one particular geographical area (dioxin/furane and dioxin-like PCBs (B3f)), hen eggs (dioxin/furane and dioxin-like PCBs), piglets (antimicrobials (B1)) and rabbits (anticoccidials).

Conclusions

The existence of other official residue control programmes on a federal and state level (in the *Land* visited) enhance the effectiveness of the overall residue control system.

1.6. Follow up of non-compliant results

Legal basis

The measures to be taken by the competent authorities in response to the finding of non-compliant residues results are described in Articles 13, 16, 17, 18, 19, 23, 24, 27 and 28 of Council Directive 96/23/EC. In addition Article 54 of Regulation (EC) No 882/2004 lays down the principles to be followed in the application of national enforcement measures and actions to be taken in cases of non-compliance.

Audit findings

Follow-up procedures as required by Articles 16-19 of Council Directive 96/23/EC are included in national legislation, but the implementation is the responsibility of the *Länder* competent authorities. Additional details on the procedure following notification of non-compliant results are contained in the inter-state agreement "Residue monitoring for foodstuffs of animal origin". The *Länder* transmit non-compliant results and summarised descriptions of follow-up actions to the BVL using a uniform electronic form. The more comprehensive follow-up file is kept in the *Land*, and the *Länder* cooperate in cases involving more than one *Länder*.
In Germany 89 and 149 non-compliant samples were detected in 2006 and 2007, respectively. In 2006, from Group A (substances having anabolic effect and unauthorised substances), there were in total 9 cases of chloramphenicol, 2 cases of metabolites of nitrofurans and 3 cases of nitroimidazoles. In 2007, from Group A substances, there were in total 3 cases of chloramphenicol. Ten and 16 fish samples contained malachite green (B3e) residues in 2006 and 2007, respectively. In 2006 and 2007 respectively 17 and 29 analytically confirmed samples of steroids (A3) were found, including 17-β nortestosterone, α- and β-boldenone and 17-β estradiol.
The mission team noted that:

- the summarised follow-up information provided to the central competent authority from the *Länder* was not detailed enough to allow an evaluation of the effectiveness of follow-up activities;
- in Mecklenburg-Western Pomerania a follow-up strategy has been documented by clear flowcharts of follow-up actions. Detailed follow-up instructions were available at the district VLA;
- concerning follow-up investigations there had been no training organised at federal level, nor between the *Länder*, although draft instructions had been discussed at the annual NRCP meetings. In Mecklenburg-Western Pomerania, staff meetings on procedures with non-compliant results had taken place at a regional level;
- in 4 non-compliant cases of chloramphenicol (A6) in muscle, screening had been performed with a method having a detection capability (CCβ) of 0.75 µg/kg, exceeding the MRPL of 0.3 µg/kg;
- from the documentation provided, it can be concluded that a certain number of confirmatory analyses were performed with insufficiently validated methods e.g. no decision limit (CCα) had been calculated for malachite green (B3e);
- three complete follow-up files from 2007 were provided to the mission team from the responsible *Länder*. One case concerned chloramphenicol (A6) in fish and one concerned malachite green (A6) in fish occurred in Saxony. One case concerning dioxins in eggs occurred in Mecklenburg-Western Pomerania. In both Saxony cases, related to unauthorised substances, very detailed follow-up actions were documented, including prompt analytical testing, intensive on-farm investigations, food operator ban and legal proceedings. With regard to the dioxin (B3f) case in eggs, due to a very long turnaround time for the environmental investigation (soil samples), the follow-up investigation of the case took over 10 months after first sampling. However, in the mean time, eggs from the producer concerned were excluded from the market.

Conclusions

Follow-up of non-compliant results and co-ordination between competent authorities are the responsibility of the *Länder*. The central competent authority is not always fully informed of procedures and actions and is not in a position to ensure consistency of official controls and efficient and effective coordination between all the competent authorities involved as required by Article 4(3 and 4) of Regulation (EC) No 882/2004. Samples are sometimes analysed with methods which have not been validated in accordance with Commission Decision 2002/657/EC, or which can not meet the limits laid down in this Regulation, which may compromise effective legal action when non-

compliant results are detected. Follow-up actions in the checked cases were performed in line with the requirements of Council Directive 96/23/EC.

1.7. Laboratories

Legal Basis

Requirements for designating laboratories are laid down in Article 12(1) of Regulation (EC) No 882/2004 and Articles 14 and 15 of Council Directive 96/23/EC. Requirements pertaining to the capacity and capability of laboratories are described in Article 4 2c of Regulation (EC) No 882/2004. Requirements for accreditation of laboratories are laid down in Point 1.2. of the Annex to Commission Decision 98/179/EC and in Article 12(2) and (3) of Regulation (EC) No 882/2004. Requirements for the validation of analytical methods for residues of pharmacologically active substances and certain contaminants are laid down in Articles 3, 4, 5 and 6 of Commission Decision 2002/657/EC. Requirements for analytical methods are also laid down in the annexes to Commission Regulation (EC) No 1883/2006 (dioxins and dioxin-like PCBs in foodstuffs), Commission Regulation (EC) No 333/2007 (chemical elements in foodstuffs) and Commission Regulation (EC) No 401/2006 (mycotoxins).

The Laboratory Network

Audit findings

There are 29 national routine laboratories in Germany performing residue analysis under the scope of NRCP. They are all accredited according to ISO 17025 by one of the two accreditation bodies, *Staatliche Akkreditierungsstelle Hannover* (AKS) or *Die Staatliche Anerkennungsstelle der Lebensmittelüberwachung* (SAL).
NRL collects performance data from the routine national laboratories every second year. The summarised analytical data provided to the mission team were collected in the beginning of 2008.
The mission team noted that:

- there were many improvements in the performance of German residue laboratories since 2005 FVO residues mission. However, certain shortcomings were still observed;
- certain methods exceed MRPL and MLOD levels;
- in many cases, the MLOD levels specified in the 2008 NRCP exceeded the levels recommended by the CRLs including stilbenes (A1), antithyroid agents (A2), steroids (A3), β-agonists (A5) and some Group B substances with no MRL values. The central competent authority stated that Germany aims to adjust recommended concentration levels[3];
- Group A methods have in overall been validated according to Commission Decision 2002/657/EC, although in some cases there are gaps in validation regarding e.g. recovery, repeatability or intra-laboratory reproducibility. In some cases CCα/CCβ are missing e.g. for nitroimidazoles (A6) and nitrofurans (A6); in particular methods there were even no validation parameters presented;
- regarding pharmacologically active substances from Group B, the majority of the methods presented are still not fully validated according to Commission Decision 2002/657/EC as in general essential data are partly or completely missing, even though the deadline for validation passed in September 2007;
- in several cases, CCα values of confirmatory methods were below established maximum residue limit (MRL) values for B1, B2d and B3d groups of substances. This

[3] ***In their response to the draft report the German Competent Authority stated that the CRL recommended concentrations have been incorporated in the 2009 NRCP and are binding.***

does not comply with Commission Decision 2002/657/EC as CCα and CCβ for MRL compounds should be greater than the MRL.

National Reference Laboratory

Audit findings

Germany has one NRL for all commodities and all substance groups listed in Annex I to Council Directive 96/23/EC. The NRL resides under the BVL, which reports to the federal ministry BMVEL. NRL is also designated as a CRL and CRL personnel are jointly responsible for those NRL areas/tasks falling under their competence.

In accordance with Article 14 of Council Directive 96/23/EC, the role of the German NRL is mostly advisory and is related to the transmission of analytical information at conferences (presentation of new methods, transmission of information from the CRLs and the Commission, discussion of MRPL and MRL values, validation issues, interpretation of Commission Decision 2002/657/EC, assessment of measurement uncertainty, application of MRL totals), updating of information available in the laboratory data base (FIS-VL), dispatch of standard substances and in-house reference material, forwarding of method requirements, organisation of training courses, as well as implementation of proficiency tests, with the suitable follow-up support if requested or needed.

The mission team noted that:

- between 2006 and 2008 the NRL participated in a wide spectrum of proficiency tests for various analyte/matrix combinations available worldwide. In 2006 and 2007, for which the results were checked, the performance of the NRL in these proficiency tests was completely satisfactory;
- from the previous FVO residues mission reference, the NRL has introduced analytical methods for stilbenes (A1), antithyroid agents (A2), and recorcylic acid lactones including zeranol (A4). There are no methods for sedatives (B2d), organophosphorus compounds (B3b) and chemical elements (B3c). Development for a method for sedatives has started and is planned to be validated in 2009. For analysis of chemical elements, the NRL has no analytical experience and there is also a lack of staff;
- there is no requirement for compulsory participation for the national routine laboratories in the nationally organised proficiency test schemes. The NRL stated that in general these laboratories participate and achieve good results, if not, the NRL offers help to remedy the situation. In such a case, the central competent authority and the competent authority in the *Land* concerned are also informed. The latter has a legal opportunity to take action.

Control laboratories

In Mecklenburg-Western Pomerania the mission team visited national routine laboratory LALLF in Rostock.

Audit findings

The Department for the residue analysis (*Abteilung 5*) is divided into three parts, this is heavy metals, pesticides and organic contaminants, and pharmacologically active substances and mycotoxins.

Only official residue control samples are analysed in LALLF.

Sixty per cent of Mecklenburg-Western Pomerania NRCP analyses are performed in LALLF, the rest being mostly outsourced to the laboratories joined together under the North German cooperation management agreement (NOKO), which came to force in 2005 to share and rationalise residue analytical work of *Länder* Berlin, Brandenburg, Mecklenburg-Western Pomerania, *Niedersachsen* (Lower Saxony) and Schleswig-Holstein, and the cities Bremen and Hamburg.

The laboratory received technical accreditation in 1998 by the AKS, the last re-accreditation was in 2003, the next is pending at the end of 2008.

The mission team noted that:

- the laboratory has 22 suitably qualified and well trained staff. Training documentation including planning was provided;
- the laboratory was very well equipped with *inter alia* 3 LC-MS/MS. Instruments were state of the art and properly maintained;
- staff had attended all conferences organised by the BVL. One chemist had recently received training in the NRL for LC-MS/MS analysis;
- for the confirmatory methods, CCα estimates for residues of pharmacologically active substances (Group B) were below MRL values, as a consequence of taking ½ MRL instead of the MRL as the base value for calculation of this parameter, even though the prescribed approach in the standard operating procedure (SOP) for validation was in accordance with Commission Decision 2002/657/EC;
- participation in proficiency tests was successful. They were related mostly to environmental contaminants. Proficiency tests of pharmacologically active substances were limited, although the laboratory participated in all such tests organised by the NRL;
- samples received in laboratory were properly sealed, identified and stored with NRCP instructions;
- ownership anonymity was guaranteed onwards from sample receipt to the analytical staff, this being an improvement since the previous FVO residues mission;
- SOP for determination of nitroimidazoles (A6) in muscle, plasma and drinking water by LC-MS/MS was checked and one batch of respective samples. Quality assurance samples were included in the batch and four identification points were used for determination, which is in line with Commission Decision 2002/657/EC. Moreover, analytical acceptance criteria for approval of samples were also clearly defined;
- three validation files were checked, i.e. chloramphenicol (A6) in milk by enzyme-linked immunosorbent assay (ELISA), quinolones (B1) in meat and nitroimidazoles (A6) in plasma, both by LC-MS/MS analysis. Necessary validation parameters were properly evaluated, with the exception of determination of CCα for quinolones with MRL for the reason described above.

Conclusions

General analytical performance of German residue laboratories is good and has improved since last FVO mission. However the NRL is not able to fulfil its function according to Article 14 of Council Directive 96/23/EC, as it has no legal power to improve the shortcomings in the routine national laboratories, which are the responsibility of the *Länder*. In spite of all laboratories being accredited and, at central level, the collation of information on laboratory performance throughout Germany, the absence of any mechanism for the central competent authority to compel under-performing laboratories to improve performance weakens the effectiveness of the NRCP. In particular, the performance of some laboratories means that residue concentrations in excess of MRPLs may not be detected, thus compromising the effectiveness of the NRCP in these *Länder*. The absence of validation for certain analytical methods may potentially compromise enforcement actions taken in response to non-compliant results.

1.8. Veterinary medicinal products

1.8.1. Authorisation of veterinary medicinal products

Legal Basis

Conditions 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 of the European Parliament and of the Council and for certain products authorised on a Community-wide basis, Articles 30-40 of Regulation (EC) No 726/2004 of the European Parliament and of the Council. Veterinary medicinal products which are authorised for use in food producing animals may only contain pharmacologically active substances which

are listed in Annexes I, II, or III to Council Regulation (EEC) No 2377/90. The use of one specific category of veterinary medicinal product – medicated premixes – is governed by Council Directive 90/167/EEC. Council Directive 96/22/EC prohibits the authorisation of hormones and β-agonists for use as growth promoters in food producing animals.

Audit findings

The BVL is the central competent authority responsible for issuing marketing authorisations for veterinary medicinal products in Germany. The legal basis is *Artzneimittelsgesetz* - the Federal Law on Medicines (AMG).
The mission team noted that:

- an updated list of authorised veterinary medicinal products was available and was in line with Community legislation – no veterinary medicinal products containing pharmacologically active substances listed in Annex IV to Council Regulation (EEC) No 2377/90 are authorised for use in food producing animals;

- the legal provisions for use of veterinary medicinal products under the "cascade" are in line with Article 11 of Directive 2001/82/EC of the European Parliament and of the Council. If necessary, use of veterinary medicinal products under the cascade can also be applied to treatment of honeybees in line with the "Note to the members and observers of the Veterinary Pharmaceutical Committee" dated 24.07.2007 by DG Enterprise. However, the competent authority stated that in a questionnaire responded to by the *Länder* no need for use of veterinary medicinal products for bees under the cascade had been identified since there are authorised products for treatment of varroa mites and European foulbrood is treated by extermination of the infected colony;

- veterinary medicinal products containing active substances for which there are no MRLs listed for equidae in Council Regulation (EEC) No 2377/90 are authorised only for equines not intended for human consumption, which is also clearly indicated on the labels. Furthermore, veterinary medicinal products containing active substances for which no community MRLs have been set for any species are also required to have a label clearly stating that those veterinary medicinal products cannot be used for any food producing animal under the "cascade".

Conclusions

The available veterinary medicinal products are authorised in line with Community legislation.

1.8.2. Distribution and use of veterinary medicinal products

Legal Basis

Conditions governing the distribution and use of veterinary medicinal products are laid down in Article 65-71 of Directive 2001/82/EC and, in respect of medicated premixes, 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 of the European Parliament and of the Council and the production process must satisfy the conditions laid down in Annexes I and II to that Regulation.

Additional rules governing the availability of veterinary medicinal products (i.e. prescription status) are laid down in Commission Directive 2006/130/EC. With regard to the use of certain hormones and β-agonists for zootechnical and/or therapeutic purposes, the conditions governing such use are laid down in Articles 4, 5, 5a, 6, 8, 9 of Council Directive 96/22/EC.

Audit findings

Manufacturers, wholesalers and pharmacies need a permit from the competent authority in the *Land* in which they are located. Veterinary pharmacies have a duty to report their activities to this authority, which issues a certificate in accordance with § 67 AMG (pharmacy certificate) confirming that this duty has been discharged. Farmers may obtain veterinary medicinal products from pharmacies (on presentation of a veterinary prescription) or from their veterinary practitioner. Records, including *inter alia* batch numbers, must be kept at all levels of distribution and by the end user.
The mission team noted that:

- all veterinary medicinal products for food producing animals are "prescription only medicines". However, exceptions are laid down in the Third Ordinance amending the Ordinance on the Prescription of Medication [*3. Verordnung zur Änderung der Arzneimittelverschreibungsverordnung*] of 18.07.2007;

- in addition to being "prescription only medicines", medicated premixes are authorised only for the production of medicated feedingstuffs in registered feed mills which hold a manufacturing permit for production of medicated feedingstuffs pursuant to § 13 AMG. They cannot be prescribed or sold directly to a farmer for use on farm;

- in Mecklenburg-Western Pomerania, the permits for wholesalers and producers of medicated feedingstuffs, and certificates veterinary pharmacies are indefinite, but can be revoked or suspended by the competent authority. Pharmacy certificates may be declared null and void and need to be renewed should ownership or premises change. Prior notification must be given of any significant changes in wholesale activities or of any changes which could affect the permit (e.g. premises, person responsible). Examples of such renewed certificates/permits were seen in the veterinary pharmacy and in the wholesaler visited;

- a practicing veterinarian may delegate the administration of veterinary medicinal products to a farmer under certain conditions. Such treatments are to be made in agreement with the practitioner and under his or her specific instructions. Antimicrobials with a systemic effect may be handed out to farmers for a maximum treatment period of 7 days while other veterinary medicinal products, as well as antimicrobials with only local effect, may be delegated for a maximum period of 31 days;

- the private veterinary practitioner visited made visits 1-2 times per week to all farms to whom he had delegated treatments.

Conclusions

The distribution system for veterinary medicinal products is in line with Community legislation.

1.8.3. Controls on the distribution and use of veterinary medicinal products

Legal Basis

Competent authorities have a general obligation under Article 80 (1) of the Community code relating to veterinary medicinal products (Directive 2001/82/EC) to carry out inspections throughout the distribution chain of veterinary medicinal products in order to verify compliance with the provisions of the Directive 2001/82/EC. Specific obligations for competent authorities are laid down in Articles 65, 66, 68, 69 of the above 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.

The veterinary medicines record keeping requirements of stockowners are laid down in Article 10 of Council Directive 96/23/EC, Annex I, Section III, part 8 (b) to Regulation (EC) No 852/2004 and Annex II, Section III, part 3(c) to Regulation (EC) No 853/2004.

A list of substances many of which are not included in Annexes I, II or III to Council Regulation (EEC) No 2377/90 but which are deemed to be essential for the treatment of equidae has been drawn up in the Annex to Commission Regulation (EC) No 1950/2006. The conditions governing such use are described in Articles 1 to 4 of said Regulation and there is an obligation to record the use of these substances and other veterinary medicines a form which complies with that laid out in the Annex to Commission Decision 2000/68/EC (equine passport).

Audit findings

All establishments involved in the manufacture and storage of veterinary medicinal products are subject to inspections by the competent authorities in the relevant *Land*. There is no obligation for the *Länder* to inform the federal level of the results of controls of veterinary medicinal products but in practice relevant information is forwarded to other *Länder* and sometimes to the federal level. National legislation lays down a minimum inspection frequency for veterinary pharmacies of one inspection every two years. For the other establishments, including farms, the inspection frequencies are to be risk based and carried out regularly as deemed fit by each competent authority. In addition, *Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten* - Federal *Länder* Office for Health Protection for Pharmaceutical Products and Medical Products (ZLG) has issued a standardised quality system for medicine controls, including *inter alia* comprehensive procedural instructions, guidelines for risk based inspections on farms and templates for inspection reports.
The mission team noted that:

- in Mecklenburg-Western Pomerania controls on manufacturers and wholesalers of veterinary medicinal products were the responsibility of *Landesamt für Gesundheit und Soziales* (The Ministry for Health and Social Affairs) whilst LALLF was responsible for controls in veterinary pharmacies and farms and controls on the production of medicated feedingstuffs. However there is no such production in Mecklenburg-Western Pomerania;

- in Mecklenburg-Western Pomerania LALLF staff involved in controls of veterinary medicinal products had received regular and documented training and training had also been organised by LALLF for *inter alia* veterinary practitioners on the proper use of veterinary medicinal products;

- standardised inspection forms, based on the ZLG German Drug Control Quality System, had been used for all controls of veterinary medicinal products in the sites visited in Mecklenburg-Western Pomerania;

- inspection forms which had been filled out by hand were signed by the business operators and printed copies of these official control reports were subsequently sent out to the business operator concerned, as required under Article 9 of Regulation (EC) No 882/2004.

Controls on wholesale and retail premises including veterinarians
The mission team noted that:

- comprehensive record keeping in line with Community requirements was seen in the wholesaler and veterinary pharmacy visited;

- there were established channels of communication between the LALLF staff for control of veterinary medicinal products and the staff involved in residues control. Follow-up investigations on farm were to be conducted in co-operation, however so far no serious non-compliances had been observed in the controls of veterinary medicinal products or under the NRCP;

- in Mecklenburg-Western Pomerania criteria for risk-based inspections of wholesalers and farms had been developed and applied. In addition, a target inspection frequency of minimum one inspection every five years was applied in response to the legal obligation under national legislation to carry out inspections regularly;

- the wholesaler had been inspected in 1999 and 2004 by the competent authority, due to changes in both legislation and facilities, and comprehensive inspection reports were available. Only minor deviations had been observed and this wholesaler had been classified as "low risk" with a maximum inspection interval of once every 5 years;

- the veterinary pharmacy visited had been inspected prior to the issuing of the first certificate and then every two years by the competent authority and comprehensive inspection reports were available.

Controls on feed mills producing medicated feedingstuffs

In addition to a registration for the production of animal feedingstuffs, a feed mill needs a permit under § 13 AMG from the competent authority in the relevant *Land* for production of medicated feedingstuffs. In addition, medicated feedingstuffs cannot be produced for own use on farm unless the farm has a feedmill which has a manufacturing permit.

The mission team noted that:

- there are currently no feedmills which hold manufacturing permits for the production of medicated feedingstuffs in Mecklenburg-Western Pomerania since none of the existing feedmills applied for such a permit when this became a legal requirement. The competent authority stated that, after the legal requirement was introduced, feed produced in registered feedmills had been tested for antimicrobials to check that no medicated feedingstuffs had been produced illegally.

Controls on farms

The mission team noted that:

- the pig farm visited had been inspected in 2004 and 2006 and based on the results of these inspections and the type of production it had been classified by the competent authority as "low risk";

- farm treatment records are compulsory for all food producing species in Germany and comprehensive treatment records were kept at the pig farm visited. Copies of veterinary prescriptions, listing all relevant details, were filed in the farm and the treatment records were linked to the number of each prescription. A few discrepancies were observed between the veterinary prescriptions and the entries in the treatment records in that the target group of animals on the prescription was not the same as the one treated with the veterinary medicinal product prescribed;

- the food chain information had been implemented for pigs, as required under national and Community legislation (Regulation (EC) No 853/2004), in the slaughterhouses and on the pig farm visited using standardised forms defined in national legislation. In addition, both slaughterhouses visited had implemented own checks for other species, requiring the farmer to declare that the animals delivered for slaughter had not been treated with illegal substances and that withdrawal times for legal veterinary medicinal products had been respected;

- based on the results of inspections carried out in 2007, very few, if any, controls had been conducted in Mecklenburg-Western Pomerania on the use of veterinary medicinal products in rabbit farms, sheep/goat farms, egg production units, game

farms, apiaries and farms with more than 20 horses. The competent authority stated that this was the result of a risk-based targeting of controls of veterinary medicinal products.

Equine passport system

The central competent authority stated that the equine passport system has been fully implemented in Germany and is valid for all equidae in line with Commission Decision 93/623/EEC as amended by Commission Decision 2000/68/EC. Implementation and controls of the equine passport system are the responsibilities of the *Länder*. As the equine passport system is the responsibility of the *Länder*, the central competent authority stated that it was not responsible for ensuring that equine passports were required at slaughter of equines in all *Länder*.

The mission team noted that:

- in the slaughterhouse visited in Mecklenburg-Western Pomerania equine passports were checked by the official veterinarian before equidae were accepted for slaughter. When the animal had been slaughtered, the passports were sent back to the issuing body by the official veterinarian. The passports were marked as invalid by an official stamp and signature on the front page, however, the signature was not dated. The practice of placing an official stamp on the front page had been agreed upon in Mecklenburg-Western Pomerania and was not based on national legislation. This practice is partly in line with future requirements which will come into force with Commission Regulation (EC) No 504/2008;

- seven passports from recently slaughtered horses were available in the slaughterhouse and were all in line with Community legislation, e.g. all relevant identity data had been entered and none of the horses had been signed out of the food chain;

- in Mecklenburg-Western Pomerania training for official veterinarians on the proper implementation of the equine passport system had been organised by the competent authority. In addition, a comprehensive information brochure for owners of equidae had recently been produced by the competent authority. Both focused on current requirements and the amended requirements under Commission Regulation (EC) No 504/2008, which comes into force on 1 July 2009.

Conclusions

Veterinary medicinal products in Germany are authorised in line with the requirements in Community legislation. The control system for veterinary medicinal products is harmonised throughout Germany as it is based on a quality system which is agreed between the *Länder*. In Mecklenburg-Western Pomerania, controls of the distribution and use of veterinary medicinal products have been implemented at all stages of distribution of veterinary medicinal products and were well documented as required in Article 80(1) of Directive 2001/82/EC and Article 3(3) of Regulation (EC) No 882/2004, respectively. However, the risk based approach to controls on farm has led to very limited controls of use of veterinary medicinal products in certain smaller production sectors, some of which were not sampled under the NRCP in this *Land*, which may allow possible misuse of veterinary medicinal products to remain undetected in these sectors.

In Mecklenburg-Western Pomerania the equine passport system has been implemented in compliance with Commission Decision 93/623/EEC, thus preventing that equidae are accepted for slaughter if they have been treated with pharmacologically active substances not listed in Annexes I-III of Council Regulation (EEC) No 2377/90. The requirement for food chain information has been implemented for pigs as required under Annex II, Section III, part 1, 2 and 3(c) to Regulation (EC) No 853/2004.

2. RECOMMENDATIONS

The competent authority of Germany is recommended to:

1	Ensure that testing for illegal substances such as nitrofurans and nitroimidazoles is included in the NRCP for those commodities where the use of these substances is more likely to occur, e.g. nitroimidazoles in farmed game, horses and rabbits.
2	Expand the scope of the NRCP for residues of authorised pharmacologically active substances and feed additives (anticoccidials) taking account of the availability of such substances and the recommendations made by the Community Reference Laboratory in Berlin concerning the scope of the NRCP.
3	Ensure that the National Reference Laboratory fulfils all functions as laid down in Article 14 of Council Directive 96/23/EC to coordinate the work of the national laboratories and to ensure that these laboratories observe the Community limits (MRPLs) and national minimum limits of determination (MLODs) laid down in the NRCP.
4	Ensure geographical distribution of the NRCP sampling per certain commodities (e.g. farmed game, aquaculture, honey) also in *Länder* with small animal production in order to detect any possible violation or misuse in line with Article 3 (1) of Regulation (EC) No 882/2004.
5	Ensure that official residue controls are financed with fees as required in Article 27 and Annex IV to Regulation (EC) No 882/2004 in all *Länder*.
6	In relation to the follow-up of non-compliant residues results, for Germany to meet its obligations in respect of consistency in the application of official controls as required by Article 4(4) of Regulation (EC) No 882/2004, the central competent authority should have an overview of the procedures followed in each of the *Länder*.
7	Review national minimum limits of determination (MLODs) established for Group A substances and ensure that these are commensurate with the detection of abuse. The central competent authority is reminded that target values have been recommended by the Community Reference Laboratories.
8	Ensure that all laboratories meet national and Community requirements with respect to validation of analytical methods (Articles 3, 4, 5 and 6 of Commission Decision 2002/657/EC, Commission Regulation (EC) No 333/2007, Commission Regulation (EC) No 1883/2006, Commission Regulation (EC) No 401/2006) in particular demonstrating fitness for purpose.
9	Coordinate the risk based approaches applied for the geographical distribution of the NRCP samples and for controls on the use of veterinary medicinal products on farms to ensure that all sectors in all *Länder* are covered by adequate controls in line with requirements of Article 11 (1.c.) of Council Directive 96/23/EC and Article 3 (1) of Regulation (EC) No 882/2004.

ANNEX – LEGAL REFERENCES

Legal Reference	Publication details	Full Title
Audits by the Commission Services		
Regulation (EC) No 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Decision 98/139/EC	OJ L 38, 12.2.1998, p. 10-13	Commission Decision of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States
Food Law		
Regulation (EC) No 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Regulation (EC) No 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Regulation (EC) No 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Residues Monitoring and Sampling		
Directive 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
Decision 98/179/EC	OJ L 65, 5.3.1998, p. 31-34	98/179/EC: Commission Decision of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products
Decision 97/747/EC	OJ L 303, 6.11.1997, p. 12-15	97/747/EC: Commission Decision of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products
Validation of analytical methods for residues		
Decision 2002/657/EC	OJ L 221, 17.8.2002, p. 8-36	Commission Decision of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results
Bans on the use of hormones and beta-agonists for growth promotion in food producing animals		
Directive 96/22/EC	OJ L 125, 23.5.1996, p. 3-9	Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
Maximum Residue Limits for veterinary medicines in food of animal origin		
Regulation (EEC) No 2377/90	OJ L 224, 18.8.1990, p. 1-8	Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin
Directive 86/363/EEC	OJ L 221, 7.8.1986, p. 43-47	Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin
Minimum Required Performance Limits (for certain prohibited substances)		
Decision 2003/181/EC	OJ L 71, 15.3.2003, p. 17–18	2003/181/EC: Commission Decision of 13 March 2003 amending Decision 2002/657/EC as regards the setting of minimum required performance limits (MRPLs) for certain residues in food of animal origin
Decision 2004/25/EC	OJ L 6, 10.1.2004, p. 38-39	2004/25/EC: Commission Decision of 22 December 2003 amending Decision 2002/657/EC as regards the setting of minimum required performance limits (MRPLs) for certain residues in food of animal origin
Maximum levels for pesticides in food of animal origin		
Regulation (EC) No 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Authorisation of veterinary medicinal products		

Directive 2001/82/EC	OJ L 311, 28.11.2001, p. 1–66	Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products
Regulation (EC) No 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
Directive 2006/130/EC	OJ L 349, 12.12.2006, p. 15–16	Commission Directive 2006/130/EC of 11 December 2006 implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription
Medicated feedingstuffs and additives		
Directive 90/167/EEC	OJ L 92, 7.4.1990, p. 42–48	Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community
Regulation (EC) No 1831/2003	OJ L 268, 18.10.2003, p. 29–43	Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition
Regulation (EC) No 183/2005	OJ L 35, 8.2.2005, p. 1–22	Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene
Sampling methods and methods of analysis for contaminants in foodstuffs		
Regulation (EC) No 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
Regulation (EC) No 401/2006	OJ L 70, 9.3.2006, p. 12–34	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs
Regulation (EC) No 1883/2006	OJ L 364, 20.12.2006, p. 32–43	Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs
Sampling methods for pesticides in foodstuffs		
Directive 2002/63/EC	OJ L 187, 16.7.2002, p. 30–43	Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC
Horse identification (passport)		
Decision 2000/68/EC	OJ L 23, 28.1.2000, p. 72–75	2000/68/EC: Commission Decision of 22 December 1999 amending Commission Decision 93/623/EEC and establishing the identification of equidae for breeding and production
Medicines essential for the treatment of equidae		
Regulation (EC) No 1950/2006	OJ L 367, 22.12.2006, p. 33–45	Commission Regulation (EC) No 1950/2006 of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae