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Directorate F - Food and Veterinary Office

DG(SANCO) 2013-6765 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

GUATEMALA

FROM 12 TO 22 MARCH 2013

IN ORDER TO EVALUATE THE CONTROL 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) audit in Guatemala, carried out from 12 to 22 March 2013, as part of the published FVO audit programme on residue controls in Member States and third countries.

The objective of the audit 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 audit. The audit 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.

Guatemala is listed in Commission Decision 2011/163/EU as having an approved residue monitoring plan (RMP) for aquaculture products and honey, the latter with an export volume comparable to that of India or Australia. Guatemala has never had a residue audit.

While planning and implementation of the RMPs for aquaculture crustacean products and honey are generally in line with Directive 96/23/EC, planning of the RMPs is somewhat weakened by the fact, that not all nationally prohibited dyes or nationally authorised pharmacologically active substances for which MRLs have to be respected, are included in the respective RMPs. Current procedures in place to identify and seal residue samples cannot fully ensure their integrity which has potential to weaken the effectiveness of follow-up investigations. In line with EU requirements, traceability to the farm of origin in case of non-compliant residue results is possible and follow-up investigations for the few non-compliant results so far ensured that non-compliant products were not exported to the EU; however, official follow-up sampling has not been undertaken so far.

The two contracted foreign laboratories are accredited and use validated methods and can therefore provide reliable analytical laboratory results.

Although in general, national requirements with regard to authorisation, distribution and use of veterinary medicinal products are similar to EU legislation, inconsistent information with regard to the required withdrawal periods has the potential to weaken the system in place. While official controls on the distribution and use of veterinary medicinal products relevant for crustaceans and honey bees are implemented and farmers/bee-keepers maintain the nationally required treatments records, findings observed during this audit, but not recorded in the reports of official controls indicate that effectiveness of official controls in the area of distribution and use of veterinary medicinal products is not fully ensured.

It is therefore concluded, that the Guatemalan competent authority has implemented residue control systems for aquaculture crustacean products and honey which since 2012, are largely equivalent to EU legislation and where only some areas require further improvements.

The report makes a number of recommendations to the Guatemalan competent authority, 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
CCα / Ccβ	Decision Limit / Detection Capability
DG(SANCO)	Health and Consumers Directorate-General
DRIPUA	Department of Registration of Supplies for Use in Animals (*Departamento de Registro de Insumos para Uso en Animales*)
EC	European Community
ELISA	Enzyme-linked immuno-sorbent assay
EU	European Union
FSD	Food Safety Directorate (*Dirección de Inocuidad*)
FVO	Food and Veterinary Office
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC
ISO	International Organisation for Standardisation
LC-MS/MS	Liquid Chromatography-(Tandem) Mass Spectrometry
LoD	Limit of Detection
LoQ	Limit of Quantification
MAGA	Ministry of Agriculture, Livestock and Food (*Ministerio de Agricultura, Ganadería y Alimentación*)
ML	Maximum Level
MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
RASFF	Rapid Alert System for Food and Feed
RTCA	Central American Technical Regulation
SOP	Standard Operating Procedure
VISAR	Deputy Minister for Animal and Plant Health and Regulations (*Viceministerio de Sanidad Agropecuaria y Regulaciones*)

1 Introduction

The audit took place in Guatemala from 12 to 22 March 2013. The audit team comprised one auditor from the Food and Veterinary Office (FVO). The audit was undertaken as part of the FVO's planned audit 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 auditor during the audit. An opening meeting was held on 12 March 2013 with the central competent authority responsible for implementing residue monitoring in live animals and animal products and representatives of the competent authority responsible for the authorisation of veterinary medicinal products. At this meeting, the objectives of, and itinerary for, the audit were confirmed and the control systems were described by the authorities.

2 Objectives

The objective of the audit 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 audit. The audit focussed on the roles of the competent authorities, the legal and administrative measures in place to give effect to the relevant EU requirements, controls with regard to residues and veterinary medicinal products and their operation, and the performance of residue laboratories. The table below lists sites visited and meetings held in order to achieve that objective.

Meetings/Visits		N	Comments
Competent Authorities	Central	2	Opening and closing meetings with the relevant Units of the Ministry of Agriculture, Livestock and Food (MAGA)
Laboratories		1	Governmental laboratory in Guatemala City
Farms		4	Aquaculture shrimp farms (2) with veterinary practitioner and bee-keepers (2)
Establishments		4	Shrimp processing plants (2) and honey collection centres/processing plants (2)
Other Sites		4	Feed mills producing medicated feeding stuff for aquaculture (2); wholesaler (1) and retailer (1) for veterinary medicinal products

3 Legal Basis

The audit 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 audit report is provided in the Annex and refers, where applicable, to the last amended version.

4 Background

4.1 Country status in relation to EU-approval of residue monitoring plans

Commission Decision 2011/163/EC indicates that Guatemala's residues monitoring plan (RMP) is approved in accordance with Council Directive 96/23/EC for aquaculture products and honey.

4.2 Summary of previous FVO audit reports

Residue controls have never been audited by the FVO. The last FVO audit took place in 2012 and relates to the control systems in place governing the production of fishery products intended for export to the EU – DG(SANCO) 2012-6465 - MR Final. This report has been published on the website of the Directorate – General for Health and Consumers here: http://ec.europa.eu/food/fvo/ir_search_en.cfm.

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

From 1 January 2007 to 31 December 2012, there have been no notifications for aquaculture (crustaceans). With regard to honey, there were two notifications, one in 2009 for oxytetracycline and one in 2011 for metronidazole (a substance prohibited in the EU for use in food producing animals).

4.4 Production and Trade Information

Guatemala exports aquacultured crustaceans and honey to the EU.

Four out of seven aquaculture processing plants are approved for export to the EU (sanitary license which is valid for one year). These four plants source their shrimps from seven registered aquaculture farms (registration is valid for one year). Two of the four plants only source from company owned farms. In 2011, registered farms produced 7913 tonnes of shrimps and based on this volume, the number of samples under the 2012 RMP for aquaculture was calculated.

Aquaculture processing plants approved for export to the EU, also import shrimps from other countries. Ministerial Agreement No 14-2013 requires such imports to originate exclusively from plants which are on the respective national list for EU approved processing plants of the exporting country. In addition, these foreign plants have to be approved nationally to be eligible for importation.

At present, 27 honey processing plants are registered, of which 19 have a valid sanitary license (valid for one year) and 11 (out of the 19) plants are approved for export to the EU. Nine of them have exported in the last two years. Since September 2012, exporting plants can only source from registered bee-keepers and at present, about 800 are registered in line with Ministerial Agreement 169-2012 in the Guatemalan Apiary Registry “REGAPI”. The registration is valid for two years and then needs to be actualised. Registration/authorisation of honey collection centres and processing

plants requires an official control by the competent authority before the "operating health licence" is issued, which is valid for one year. Good Manufacturing Practice and a HACCP system are a pre-requisite for exporting plants to be registered/authorised.

In 2011, 2125 tonnes of honey were exported to the EU (90% of the exports are destined to the EU). It is estimated that 80% of the national honey production is exported and based on this estimation, 2657 tonnes were the calculated volume of the national production in 2011, and the number of samples under the 2012 RMP for honey was based on this production volume.

5 Findings And Conclusions

5.1 Residue monitoring

5.1.1 Competent authorities involved

The Department of Products of Animal Origin and Fishery within the Food Safety Directorate (*Dirección de Inocuidad*, FSD) under the Deputy Minister for Animal and Plant Health and Regulations (*Viceministerio de Sanidad Agropecuaria y Regulaciones* -VISAR-) of the Ministry of Agriculture, Livestock and Food (*Ministerio de Agricultura, Ganadería y Alimentación* – MAGA) is the competent authority for planning and implementation of the national RMPs for aquaculture (Section for Aquaculture) and honey (Section for Honey).

FSD is also responsible for registration/authorisation and official controls of aquaculture farms and bee-keepers as well as for the respective processing plants.

At present, FSD carries out all official tasks with five officials for aquaculture and two officials for honey. FSD has no offices at regional or local level.

5.1.2 Planning of 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 2011/163/EU.

Findings

Article 17 of the MAGA Agreement No 665-2007 provides for the legal basis to establish an annual RMP for aquaculture.

While Section V of Ministerial Agreement No 169-2012 provides the legal basis for the implementation of a national RMP for honey, MAGA Decree 02-2012 contains the conceptual framework for an annual RMP for honey, and defines the responsibilities of the competent authority.

Based on the respective relevant annual domestic production (see 4.4), FSD plans the RMPs for aquaculture and honey on the requirements of the Annex I to Directive 96/23/EC and the Annex to Decision 97/747/EC, and the RMPs comply with these requirements with regard to the number of samples to be taken for the relevant substance groups.

It was noted that:

- For aquaculture products, the 2012 RMP covers crustaceans. The plan includes all substance groups listed in Annex II to Council Directive 96/23/EC, except Group B2a (anthelmintics). The reason for not including anthelmintics in the national RMPs is that so far in Guatemala, anthelmintics have not been reportedly used for aquacultured crustaceans.
- With regard to Group B1 (antibiotics) testing covers three of the four authorised substances: florfenicol, enrofloxacin and oxytetracycline (see also 5.3.1). The level of action indicated in the RMP (100 µg/kg) for these substances is in line with the maximum residue limits (MRLs) established in the Annex to Regulation (EU) No 37/2010 (see also 5.3.1). Phosphomycin, which is also authorised in Guatemala for use in aquaculture (see 5.3.1), but not listed in Annex to Regulation (EU) No 37/2010, is not included in the RMP. At present, phosphomycin is not used in aquacultured shrimps in Guatemala (see 5.3.2).
- With regard to Group B3e (dyes) testing is limited to (leuco)malachite green and does not include (leuco)crystal violet, although both dyes – equivalent to EU legislation - are nationally prohibited for use in aquaculture (see also 5.3.1).
- The limit of detection (LOD) indicated in the 2012 RMP for the ELISA screening method (0.01 µg/kg) and the LC-MS/MS method (0.06 and 0.01 µg/kg) used to analyse chloramphenicol and nitrofuran metabolites are more sensitive than the minimum required performance levels (MRPLs) provided for in Decision 2003/181/EC (0.3 µg/kg for chloramphenicol and 1 µg/kg for nitrofurans). However, the levels of action indicated in the 2012 RMP are 0.3 µg/kg for chloramphenicol and 1 µg/kg for nitrofurans, although national legislation – as does EU legislation - prohibits the use in food producing animals for both substances. FSD plans to amend in the 2013 RMP these levels of action to non-detectable, in order to be equivalent to EU legislation.

- For honey, in the 2013 RMP, all substance groups are covered with many different substances tested for, including substances, of which the use is authorised in the EU with no MRL required (e.g. flumethrin or tau-fluvinate).
- FSD had taken risk criteria into account when planning the 2012 RMP by including nitroimidazoles (metronidazole) in the scope of substances to be analysed in Group A6 (see also 5.1.5.3).
- Amitraz is not included in the RMP, although a national MRL is established for this substance, which is the same as the MRL listed in the Annex to Regulation (EC) No 37/2010. At present, there are no veterinary medicinal products registered which contain amitraz (see also 5.3.1).
- While Ministerial Agreement No 169-2012 establishes a national MRL for coumaphos of 100 µg/kg for honey, in line with the MRL listed in Table 1 of the Annex to Regulation (EC) No 37/2010, the Manual for Good Apiary Practice (edited in 2006) has not been updated accordingly and contains previously established national MRLs for coumaphos of 0.1 µg/kg and for cyamizol of 100 µg/kg, the latter now reduced to the value of 0.1 µg/kg. Cyamizol – a pharmacologically active substance not listed in the Annex to Regulation (EC) No 37/2010 - is not included in the RMP.

Conclusions on planning of the residue monitoring plan

In general, the RMPs for aquaculture and honey are designed in line with the requirements of Directive 96/23/EC. The planning of the RMPs is somewhat weakened by the fact, that not all nationally prohibited dyes - which are also prohibited in the EU – or nationally authorised pharmacologically active substances for which MRLs have to be respected, are included in the respective RMPs.

5.1.3 Implementation of the residue monitoring plan

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. 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 252/2012 (dioxins and dioxin-like PCBs); Commission Regulation (EC) No 333/2007 (certain chemical elements); Commission Regulation (EC) No 401/2006 (mycotoxins).

Findings

The budget of MAGA covers costs for the implementation of the 2013 RMPs for aquaculture and honey.

Ministerial Agreement No 3-2012, dated 6 January 2012, on the sampling procedure of aquaculture shrimp in the framework of the national residues monitoring programme contains instructions for sampling, packaging, and transportation of samples. The MAGA Manual for implementation of the 2013 RMP for aquaculture, drafted in January 2013, provides further instructions on sampling and a calculation of the budget needed for the analyses of the planned samples.

With regard to honey, the MAGA Manual for implementation of the 2013 RMP for honey, drafted in December 2012, and the Manual for sampling of honey, drafted in January 2012, provide comprehensive instructions on sampling, packaging, and transportation of honey samples, as well as a calculation of the budget needed for their analyses.

National legislation provides for the option to contract staff for taking samples, but so far, only official staff of the two respective Units of the FSD have taken samples under the RMPs (see 5.1.1).

FSD takes samples of crustaceans in the final stage of fattening from different ponds, on all registered farms and from each production cycle (one to three per year).

Sampling of honey is seasonal (mainly January and February). Half of the planned samples are taken at exporting honey collection centres and the other half at apiaries and local collection centres. The decision how many samples to take in each geographical area is based on the density of beehives in the different areas.

The respective Units of FSD receive the laboratory results and decide if results are compliant or non-compliant. FSD forwards a copy of the laboratory results to the responsible person of the farm or establishment where the sample had been taken.

It was noted that:

- With regard to aquaculture, in 2009, 2010, and 2011, the planned number of samples (exactly the minimum number of samples required in Annex IV to Directive 96/23/EC) was not fully achieved, in particular for substances of the Groups A6 and B1 (69% in 2009, 92 % in 2010 and 96% in 2011). FSD stated that this under-sampling was caused by natural catastrophes (flooding) which forced farms to close production sites.
- With regard to honey, in 2012 and 2011, all samples had been analysed as planned and the minimum number of samples required in the Annex to Directive 97/747/EC was achieved. In 2010, however, for Group B3a, only 59% of the planned samples had been analysed.
- Staff took the samples and drafted sample reports in line with the national instructions. These instructions and manuals, provide instructions or sampling, packaging and transport of samples and sampling reports which are in general equivalent to the respective requirements of EU legislation.
- At the governmental laboratory visited (see 5.2.2), recently collected honey samples in stock had not been sealed in such a way, that the integrity of the samples during their transport to the contracted laboratory could be ensured (jars could be opened without destroying the tape used for sealing).
- The different aquaculture samples taken at farms, are not immediately labelled and information of the origin of the samples is only recorded in the sample reports. Aquaculture samples are divided into a sample and counter sample at the governmental laboratory and the possibility of errors in linking the different sampling reports to the respective samples cannot be excluded. As a consequence, the current procedure to seal and identify samples does not provide equivalent guarantees to the requirement of point 2.6 of the Annex to Decision 98/179/EC.

- Before transport to the contracted laboratories (see 5.2.1), samples were stored for up to four weeks in the governmental laboratory (aquaculture samples in a freezer, honey samples at ambient temperature).

Conclusions on implementation of the residue monitoring plan

In general, the RMPs for aquaculture and honey are implemented as planned and provided for in the national instructions and manuals, which are equivalent to EU legislation. Nevertheless, the fact that the integrity of samples during their transport to the laboratories is not sufficiently ensured has the potential to weaken the effectiveness of follow-up investigations in the event of non-compliant results being found.

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 Other official residues monitoring programme

Findings

There are no other official residue monitoring programmes for aquaculture or honey.

5.1.4.2 Establishment own-checks

Findings

National legislation does not require establishment own-checks in aquaculture processing plants authorised for export to the EU.

With regard to honey, Ministerial Agreement 169-2012 requires that the authorised exporting honey processing plant provides the laboratory results of pre-export testing to MAGA for the batches which are planned to be exported. However, national legislation does not require that food business operators have to inform FSD about all non-compliant results obtained from establishment own-samples.

At the honey exporting establishments visited, it was noted that:

- The food business operator decides, based on the requirement of his trading partners, for which residues and/or contaminants establishment own-samples are analysed.
- The operators of the plants visited, had chosen laboratories in EU Member States which were accredited under ISO 17025. The respective laboratory reports indicated - in addition to the results - that the methods used for the analyses were validated in line with EU requirements.
- The establishment own-checks covered at least substances of the Groups A6 and B1 and the LODs for chloramphenicol and nitrofurans indicated in the laboratory reports were fully in

line with the respective MRPLs required in EU legislation.

Conclusions on other residues monitoring programmes

The extensive pre-export testing within establishment own-checks, with results to be provided to FSD, provides added confidence in the residue control system implemented to ensure that harmful residues are not present in honey exported to the EU. The effectiveness of establishment own-checks for the national residue control system in place is partly compromised by the fact that national legislation does not require food business operators to inform FSD about all non-compliant results obtained from establishment own-checks.

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.

Findings

Various national legislation, (Health Code 90-97, Articles 47 and 71 of the Food Safety (Hygienic) Practices Regulation 969-99, Decree 36-98) provide for general instruction for follow-up investigations and Articles 119 to 124 of the Plant and Animal Health Regulation 745-99 provide for sanctions (fine, detention/destruction of animals or products and exclusion from business). In addition, with regard to aquaculture products, Article 9 of MAGA Decree 173-2008 provides more detailed instructions for the actions to be taken.

Ministerial Agreement No 0063-2010 provides instructions on how to handle health alerts with regard to aquaculture products.

In the past years, FSD had applied sanctions which involved quarantine of non-conforming products, cancellation of the operating licenses of establishments and refusal to issue export certificates.

It was noted that:

- The same officials (see 5.1.1) who are responsible for drafting relevant legislation/instructions for the implementation of the national residue control system are also responsible for follow-up investigations. Due to that, there was no need so far to train other staff or to establish guidance documents.

5.1.5.1 Non-compliant results in previous residue monitoring plan

Findings

With regard to aquaculture, in 2007, 2008, 2010 and 2011, there were no non-compliant results under the RMP. In 2009, there were two non-compliant results related to Group B1 (tetracyclines).

With regard to honey, in 2007, 2008, 2009 and 2012, there were no non-compliant results under the RMP. In 2010, there were two non-compliant results, one for tetracyclines and one for

chlorfenvinphos, and in 2011, one non-compliant result related to nitrofurans (furazolidone).

These cases were evaluated and it was noted that:

- With regard to the two non-compliant results in 2009 for aquaculture, one of the non-compliant results (105.6 µg/kg oxytetracycline) was not confirmed by the result of the counter sample, and therefore, the product was used for human consumption in line with national rules.
- The other non-compliant result (1749.6 µg/kg oxytetracycline) was confirmed by the result of the counter sample (576 µg/kg oxytetracycline). The product which had already been exported to the EU before the first result was available, was traced back and detained by the importing company. The importing company decided to destroy the product after it received the second result. As a consequence of the non-compliant result, in 2010 and 2011, the exporting Guatemalan processing plant took establishment own-samples from the respective farm for comprehensive residue testing; all results of this testing were compliant.
- For all non-compliant results related to honey, FSD undertook follow-up investigations (between four and eight weeks after the laboratory result) at the respective establishments or bee keepers. Follow-up activities were: confirmatory analysis, establishing the bee-keepers involved in the non-compliant honey batch, analysis of samples which originated from the individual bee-keepers, detention of the honey and its exclusion from export, training of bee-keepers, and - if necessary – sanctions.
- In 2010, the small quantity of honey which contained chlorfenvinphos (36 µg/kg), was mixed and used for the domestic market. The honey which contained tetracyclines (20 µg/kg) was detained and re-sampled individually for the eight different bee-keepers involved. The honey of one bee-keeper was compliant and eligible for export. The other honey was excluded from export.
- In 2011, the non-compliant honey sample (nitrofuran, screening test result) was detained and re-sampled individually for the five bee-keepers involved. Two out of the five samples were compliant. However, the establishment was not cooperative in relation to the follow-up investigation and therefore, FSD did not permit exportation of the honey and the authorisation (sanitary license) of the establishment was withdrawn and not re-issued up to date.
- In none of the cases, including those in which residues of prohibited substances had been detected, did FSD take samples from other ponds or beehives of the involved aquacultures/apiaries - as provided for in Articles 16 to 19 of Directive 96/23/EC - in order to investigate if other batches contained residues.

5.1.5.2 Non-compliant results reported under the RASFF

Findings

With regard to the two non-compliant results reported for honey under the RASFF (see 4.3), it was noted that:

- With regard to the metronidazole case, the entire consignment was destroyed in an EU Member State. FSD identified the bee-keepers involved and trained them. In addition, since then, FSD has included metronidazole (Group A6) in the scope of the substances to be monitored in the RMP for honey.
- With regard to the oxytetracycline case, FSD did not undertake investigations, as they had

been informed, that a second analysis of the consignment was compliant and that the honey had been released by the respective EU Member State.

Conclusions on follow-up investigations/actions

With regard to the few non-compliant results so far, follow-up investigations and actions – in particular with regard to honey - carried out by the competent authority and the food business operators ensured that non-compliant products were clearly identified and then either excluded from export to the EU or destroyed. Nevertheless, official follow-up is not fully equivalent with regard to the requirements of Articles 16 to 19 of Directive 96/23/EC in that follow-up sampling has not been undertaken by FSD.

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 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 252/2012 (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

At present, all samples under the RMPs for aquaculture and honey are analysed in two foreign private laboratories contracted by MAGA.

Ministerial Agreement No 1128-2001 requires that laboratories designated for analysing samples under the RMP have to be accredited in line with ISO/IEC 17025.

The national governmental laboratory in Guatemala City has started the process to validate relevant methods and to obtain an ISO/IEC 17025 accreditation.

It was noted that:

- FSD has established certain criteria in order to contract an external laboratory. These criteria are: ISO/IEC 17025 accreditation, validated methods under the scope of accreditation and to fill in a checklist provided by FSD. The contracts are informally arranged (including payment) and not formalised in writing.
- The laboratory contracted to analyse aquaculture samples is located in Ecuador and was visited during the 2012 FVO residue audit in Ecuador. The respective report DG(SANCO)2012-6538 has been published on the website of the Directorate – General for Health and Consumers here: http://ec.europa.eu/food/fvo/ir_search_en.cfm.

- This laboratory had not provided a list of its proficiency tests to FSD. However, the representative of the laboratory, who was present at the second day of this audit, showed the results achieved in relevant proficiency tests (proficiency tests in 2010, 2011 and 2012 for chloramphenicol, nitrofurans and (leuco)malachite green) to the auditor. The most recent results for all these substances ranged within the z-score of ± 2.
- The laboratory contracted to analyse honey samples is located in an EU Member State, has been re-accredited on 2 November 2011 by the respective Member States Accreditation Body with an open scope for analyses of honey for all relevant substances under the Guatemalan RMP for honey.
- In 2013, this laboratory provided a list of the proficiency tests in which it has participated in 2010, 2011 and 2012. FSD had not yet evaluated this list. The auditor checked the results of these proficiency tests, and all, except two, were within the z-score of ± 2. The two results which ranged in the z-scores between ± 2 and ± 3, related to proficiency tests for chloramphenicol and sulfonamides. According to the list indicated, corrective actions had been taken for both tests, and the result of a more recent proficiency test for sulphonamides ranged within the z-score of ± 2.
- For the 2013 RMPs, FSD requires from the contracted laboratories a turnaround time of eight working days for all analyses, except for the analysis of dioxins and PCBs for which 30 working days should be achieved. So far, FSD has not monitored turnaround times, but plans to do so in 2013.

5.2.2 On the spot visits in the laboratories

The governmental laboratory in Guatemala City was visited and it was noted that.

- This laboratory is responsible for checking sampling reports, preparing samples before their dispatch to the foreign laboratories and storing counter samples.
- In 2012, the laboratory has drafted three standard operating procedures (SOPs), covering sample reception (shrimps and honey), sample preparation of shrimps, and sample preparation of honey.
- In line with these SOPs, staff check weight, temperature and sample numbers on the packages/jars and record the temperature of the samples at the time of reception.
- Shrimp samples are kept in the freezer until their dispatch by courier to Ecuador. Also counter samples are kept in this freezer. At the time of the audit, no RMP samples were stored, only other official samples. The hygienic conditions of the freezer were inadequate and the freezer needed to be defrosted. The temperature was controlled; however, the respective control chart had been destroyed in course of the on-going reconstruction of the building.

Conclusions on laboratories

The current procedure – to outsource analysing of RMP samples to accredited laboratories with sufficiently sensitive and validated methods available – can ensure that laboratory results for aquaculture products and honey exported to the EU are reliable.

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

The Department of Registration of Supplies for Use in Animals (*Departamento de Registro de Insumos para Uso en Animales* - DRIPUA), of the Animal Health Directorate within VISAR is responsible for issuing marketing authorisations for veterinary medicinal products intended for use in food-producing animals.

The Central American Technical Regulation of Veterinary Drugs and Allied Products; Health Registration Requirements and Control (RTCA 65.05.51:08) is the legal basis for registration of

veterinary medicinal products, and the Central American Technical Regulation of Products used in animal Nutrition; Health Registration Requirements and Control (RTCA 65.05.52:11) for registration and RTCA 65.05.63:11 for production of medicated feedingstuffs.

RTCA 65.05.51:08 contains, inter alia, rules for production, distribution and storage of veterinary medicinal products. Based on this Technical Regulation, a national instruction describes the rules for establishing MRLs, which means that national MRLs for a pharmacologically active substance are to be in line with the MRLs provided for in the Codex Alimentarius, or established by of the United States Food and Drug Administration, the European Medicines Agency, the Food and Agriculture Organization of the United Nations or established by the manufacturer based on his analytical results.

With regard to authorisation of veterinary medicinal products, it was noted that:

- Equivalent to EU legislation, Agreement No 4, annexed to RTCA 65.05.51:08 contains a list of pharmacologically active substances prohibited to be used in food-producing animals (e.g. clenbuterol, dimetridazole, nitrofurans, chloramphenicol, stilbenes, gentiana violet and malachite green).
- In addition, various national legislative acts contain restrictions on the use of pharmacologically active substances in aquaculture and honey: e.g. MAGA Decree 105-2007 prohibits the use of chloramphenicol, nitrofurans and nitroimidazoles in aquaculture, and Ministerial Agreement No 169-2012 contains an updated list of substances prohibited to be used in apiaries.
- Equivalent to EU legislation, RTCA 65.05.51:08 requires a marketing authorisation for all veterinary medicinal products by the competent authority. New authorisations are valid for five years. National legislation does not provide for off-label use of veterinary medicinal products.
- At present, five veterinary medicinal products have a valid marketing authorisation for use in aquaculture. The pharmacologically active substances in these products are florfenicol, oxytetracycline, enrofloxacin and phosphomycin (see 5.1.2). In addition, one product for use in honey bees has a valid marketing authorisation, containing oxalic acid and formic acid, which are listed in the Annex to Regulation (EC) No 37/2010.
- The conceptual framework of the national RMP for aquaculture contains the nationally established MRLs for the pharmacologically active substances tested under the RMP in aquacultured crustaceans. Article 16, table 1, of Ministerial Agreement No 169-2012 provides the nationally established MRLs in honey for pharmacologically active substances that are authorised to treat bees. These national MRLs are the same as those listed in the Annex to Regulation (EC) No 37/2010.
- National labelling requirements for veterinary medicinal products are equivalent to the provisions of Directive 2001/82/EC and withdrawal periods that needs to be respected, are indicated on the labels. However, different days were provided as withdrawal periods for the same product (oxytetracycline) on the various production leaflets of the Mexican manufacturer (after seven days/after ten days no residues in the products will be found, recommended 30 days withdrawal period before harvest of the shrimps) and on the label of the package (eight days). DRIPUA does not include information on the pharmacologically active substance or the withdrawal period on the respective authorisation document for veterinary medicinal product. The list of all authorised veterinary medicinal product maintained by DRIPUA provides also two different withdrawal periods, e.g. seven days and 30 days recommended by the manufacturer for the product containing oxytetracycline (see

also 5.3.2.2).

With regard to distribution and use of veterinary medicinal products, it was noted that:

- In line with RTCA 65.05.51:08, but different to EU legislation (Article 67 of Directive 2001/82/EC), veterinary medicinal products, except psychotropic or narcotic products, can be sold without veterinary prescription. Farmers can buy products directly from importers/wholesalers or retailers/pharmacies.
- In December 2012, DRIPUA wrote to the representatives of the aquaculture farms and told them that a veterinary prescription is needed for veterinary medicinal products intended to be used for the production of medicated feed. In one feed mill, an example of a veterinary prescription could be provided to the auditor. After December 2012, the other feed mill had not yet produced medicated feed for aquaculture.
- All veterinary medicinal products authorised for the use in aquaculture and honey bees are imported. VISAR has to issue an import license for each import.
- VISAR has authorised one importer/wholesaler for the products authorised for use in aquaculture, which are all used to produce medicated feed, mainly at the two authorised feed mills.
- Wholesalers and retailers buying/selling veterinary medicinal products - in addition to their authorisation by VISAR - must have a veterinarian as technical responsible person. VISAR also issues registration documents for the technical responsible persons, which are valid one year.
- Equivalent to Article 10 of Directive 96/23/EC, Article 16 of Ministerial Agreement No 649-2007 requires treatment records (containing veterinary medicinal product administered, date of administration and withdrawal period) to be kept at shrimp farms. The national Manuals for Good Production Practices also include the requirement to keep treatment records (e.g. Good Apiary Practice, applicable for bee-keepers. At all the aquaculture farms and bee-keepers visited, treatment records were demonstrated to the auditor.

Conclusions on authorisation, distribution and use of veterinary medicinal products

In general, national requirements with regard to authorisation of veterinary medicinal products and pre-mixes for medicated feed, their distribution by authorised wholesalers/importers and retailers/pharmacies, and their use are equivalent to EU legislation. However, inconsistent information with regard to the required withdrawal periods has the potential to weaken the system in place.

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.

5.3.2.1 Controls at wholesale level, retail level and farms and veterinary practitioners/zootechnicans

Findings

DRIPUA is responsible for official controls of 48 wholesaler/importers and 83 retailers of veterinary medicinal products. While in 2010, DRIPUA carried out official controls, in 2011 and 2012, no control programme was implemented due to changes of staff.

FSD is responsible for official controls (in order to issue or re-issue operating sanitary licences) of registered shrimp farms eligible to deliver products for export to the EU and of shrimp processing plants and honey collection centres/processing plants authorised for export to the EU. Shrimp farms and processing plants are inspected three times per year.

The Animal Health Directorate within VISAR is responsible for official controls of the only shrimp hatchery in Guatemala.

It was noted that:

- All establishments, farmers and bee -keepers visited had a valid registration or authorisation document.
- The last official control of the wholesaler visited (the only one importing and selling veterinary medicinal products for aquaculture) was on 18 March 2010. DRIPUA used a checklist for this control, which referred mainly to facilities available and their maintenance. The checklist did not contain questions related to compliance with legal requirements for medicines.
- At the veterinary pharmacy visited, which did not sell veterinary medicinal products for aquaculture and honey bees, the packages evaluated were labelled in accordance with national legislation.
- FSD used checklists (aquaculture farms, bee-keepers, honey processing plants) for recording the results of official controls. The checklists for farms/bee-keepers contain one/two question(s) related to the use of veterinary medicinal products. In one of the aquaculture farms visited, since 2010, shrimps were regularly treated. However, only in the last report of the official control in 2013, was the use of veterinary medicinal products recorded. The previous records stated, that there had been no treatments.
- At the aquaculture farms and bee-keepers visited, treatments of animals had been recorded, including the use of medicated feed. Withdrawal periods had been respected for the treatments evaluated by the auditor. Bee-keepers visited used the raw chemical substances formic acid (see 5.3.1), oxalic acid and thymol instead of the authorised veterinary medicinal product containing these substances. Formic acid, oxalic acid and thymol are listed in the Annex to Regulation (EC) No 37/2010 to be used in bees/all food producing species with no MRL required.

- The aquaculture farm visited which used medicated feed, provided a food-chain information sheet to the processing plant, which contained the number of the pond treated, product used, withdrawal period to be respected and dates of treatment.

5.3.2.2 Controls on feed mills (medicated pre-mixes and medicated feedingstuffs)

Findings

DRIPUA is responsible for official controls of registered feed mills producing medicated feedingstuffs.

Two feed mills are authorised in Guatemala to produce feed for aquaculture including medicated feedingstuffs. The Technical Regulations for Central America RTCAs 65.05.52:11 and 65.05.63:11 provide for the basis for national requirements with regard to the production of, inter alia, medicated feedingstuffs, which become applicable in June 2013. The requirements include, inter alia, avoidance of cross contamination, labelling of medicated feed, separate storage of feedingstuffs and pharmacologically active substances or additives. DRIPUA has already started to implement the respective requirements.

The auditor visited both feed mills and noted that:

- The RTCAs 65.05.52:11 and 65.05.63:11 provide requirements similar to the requirements of Directive 90/167/EEC with regard to production and labelling of medicated feed.
- Both feed mills had a valid registration licence (valid for 10 years, under the new RTCA 65.05.52:11 validity will be five years).
- The feed mills used only authorised veterinary medicinal products to produce medicated feedingstuffs, and the respective pharmacologically active substances are listed in the Annex to Regulation (EC) No 37/2010 for use in all food producing animals. The representatives of the feed mills stated that they had not used phosphomycin so far (see 5.1.2). In the last three years, the production of medicated feed was less than 2.5% of the total production of aquaculture feedingstuffs.
- The feed mills kept records providing data for each production of medicated feed: quantity produced, date, name and address of the buyer and veterinary medicinal product used.
- Both feed mills used one production line to produce medicated feed and non-medicated feed. The HACCP concepts of the companies require flushing between the two types of production and one feed mill could demonstrate to the auditor that flushing was implemented and effective.
- In line with the national requirements, veterinary medicinal products (pre-mixes) were stored in a restricted area and separated from other feedingstuff.
- All aquaculture feedingstuffs were packed in sacks and medicated feed was labelled with an additional label of different colour, stating "medicated" and providing the respective withdrawal period. However, the information provided by the Mexican producer of the veterinary medicinal products (pre mixes) on the labels or production sheets were not clear and varied e.g. for oxytetracycline between, seven, eight, ten and recommended 30 days (see also 5.3.1). At one feed mill visited, the label of the pre-mix used to produce medicated feed indicated a longer withdrawal period than the withdrawal period that was indicated by the feed mill on the label of the medicated feed.
- DRIPUA inspected the feed mills at least twice a year and used a detailed and

comprehensive checklist - with references to the respective requirements of RTCA 65.05.52:11 - which serves also to record the findings. Non-compliances noted in the previous official control had been followed-up during the next inspection. The inconsistent information provided with regard to the withdrawal period for veterinary medicinal products was not recorded in the reports of official controls.

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

While official controls on the distribution and use of veterinary medicinal products relevant for crustaceans and honey bees are implemented and farmers/bee-keepers maintain the nationally required treatment records, findings observed during this audit, were not recorded in the reports of official controls by the competent authority, indicating that the official controls in the area of distribution and use of veterinary medicinal products are not as effective as they should be.

6 Overall Conclusions

While planning and implementation of the RMPs for aquaculture crustacean products and honey are generally in line with Directive 96/23/EC, planning of the RMPs is somewhat weakened by the fact, that not all nationally prohibited dyes or nationally authorised pharmacologically active substances for which MRLs have to be respected, are included in the respective RMPs. Current procedures in place to identify and seal residue samples cannot fully ensure their integrity which has potential to weaken the effectiveness of follow-up investigations. In line with EU requirements, traceability to the farm of origin in case of non-compliant residue results is possible and follow-up investigations for the few non-compliant results so far ensured that non-compliant products were not exported to the EU; however, official follow-up sampling has not been undertaken so far.

The two contracted foreign laboratories are accredited and use validated methods and can therefore provide reliable analytical laboratory results.

Although in general, national requirements with regard to authorisation, distribution and use of veterinary medicinal products are similar to EU legislation, inconsistent information with regard to the required withdrawal periods has the potential to weaken the system in place. While official controls on the distribution and use of veterinary medicinal products relevant for crustaceans and honey bees are implemented and farmers/bee-keepers maintain the nationally required treatments records, findings observed during this audit, but not recorded in the reports of official controls indicate that effectiveness of official controls in the area of distribution and use of veterinary medicinal products is not fully ensured.

It is therefore concluded, that the Guatemalan competent authority has implemented residue control systems for aquaculture crustacean products and honey which since 2012, are largely equivalent to EU legislation and where only some areas require further improvements.

7 Closing Meeting

A closing meeting was held on 22 March 2013 with representatives of the central competent authority. At this meeting, the auditor presented the main findings and preliminary conclusions of the audit. The authority did not express disagreement and provided a written statement that they would take what ever actions were necessary in order to address the recommendation provided in the audit report.

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 twenty five working days of receipt of this audit report.

N°.	**Recommendation**
1.	To further strengthen the planning of the RMP by extending the scope of testing, in particular for dyes in aquaculture and authorised antibiotic substances in aquaculture and honey in order to be equivalent to Annex III to Directive 96/23/EC and point 2.2 of the Annex to Decision 98/179/EC.
2.	To further strengthen the implementation of the RMP and follow-up investigations by ensuring integrity of samples after sampling and during their transport to the laboratories in order to be equivalent to Annex III to and Chapter IV of Directive 96/23/EC and point 2.6 of the Annex to Decision 98/179/EC.
3.	To ensure that follow-up investigations of non-compliant residues results are instigated in all farms without undue delay and include in case of illegal treatment, follow-up sampling in order to guarantee equivalence to the requirements of Articles 16 to 18 of Directive 96/23/EC.
4.	To further strengthen the authorisation of veterinary medicinal products with the aim to ensure that farmers, veterinarians/zootechnicans, distributers, retailers and official staff are clearly informed about the withdrawal periods which need to be respected for the respective pharmacologically active substances and to allow food business operators to be equivalent with Article 9 of Directive 96/23/EC.
5.	To further improve effectiveness of official controls in the area of distribution and use of veterinary medicinal products with the aim to fully ensure implementation of relevant national legislation in this area in particular with regard to treatment records or withdrawal periods, in order to be equivalent to Article 10 of Directive 96/23/EC.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6765

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
Reg. 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
Reg. 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
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

Legal Reference	Official Journal	Title
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. 2011/163/EU	OJ L 70, 17.3.2011, p. 40-46	2011/163/EU: Commission Decision of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC
Validation of analytical methods for residues and Minimum Required Performance Limits		
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		

Legal Reference	Official Journal	Title
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
Reg. 396/2005	OJ L 70, 16.3.2005, p. 1-16	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 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

Legal Reference	Official Journal	Title
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
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. 252/2012	OJ L 84, 23.3.2012, p. 1-22	Commission Regulation (EU) No 252/2012 of 21 March 2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006
Sampling methods for pesticides in foodstuffs		

Legal Reference	Official Journal	Title
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