EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2014-7030 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

PANAMA

FROM 04 TO 13 FEBRUARY 2014

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

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in Panama, carried out from 4th to 13th February 2014, as part of the published programme of FVO audits on the monitoring of residues in live animals and animal products in European Union (EU) Member States and in 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 EU legislation. Since the authorisation, distribution and use of veterinary medicinal products and feed additives have an impact on the monitoring of residues, the national rules governing the control systems in these areas 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.

With regard to farmed shrimp, the residue monitoring plan (RMP) is in line with the requirements of Council Directive 96/23/EC whereas for finfish, the number of samples taken and the range of substance groups analysed is not yet fully in line with the Directive.

The RMP is generally implemented as planned, supported by good instructions and supervision of implementation. The effectiveness is only slightly compromised by the uneven distribution of sampling during the year or harvesting period.

Though there have been no non-compliant results in the RMP, the system for investigating such results should provide guarantees equivalent to EU requirements.

On the basis of the observed performance of the outsourced laboratory seen in a previous FVO audit, the accreditation status of the laboratory in question and its performance in proficiency tests it is concluded that the competent authority can have confidence in the reliability of the results generated by this laboratory. Notwithstanding this, some methods for analysis of certain residue groups in finfish require full validation and the exceedance of agreed turnaround times has, in the event of a non-compliant result being found, the potential to hinder the effectiveness of follow-up investigations.

The system in place for the authorisation, distribution and use of veterinary medicinal products is broadly similar to that provided for in EU legislation.

Controls on the distribution of veterinary medicinal products cover all importers/wholesalers and feed mills producing medicated feed for aquaculture, as well as on-farm use of veterinary medicines. These controls are generally effective. However, since the central register of veterinary medicinal products is not fully up to date and is difficult to access by local inspectors, this has the potential to reduce the effectiveness of such controls as inspectors cannot readily verify if the veterinary medicinal products found during inspections are still registered at central level.

The report makes a number of recommendations to the Panamanian competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.

Table of Contents

Abbreviations and definitions used in this report

ARAP	*Autoridad de los Recursos Acuaticos de Panama* - Authority for Water Resources
CC alpha / CC beta	Decision Limit / Detection Capability
DEPA	*Departamento de proteccion de alimentos* – Department of Food Protection
DINASA	*Direccion nacional de salud animal* – National Directorate for Animal Health
EU	European Union
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
MIDA	*Ministerio de Desarrollo Agropecuario* - Ministry of Agriculture
MINSA	*Ministerio de Salud* - Ministry of Health
ML	Maximum Level
MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
RASFF	Rapid Alert System for Food and Feed
RMP	Residue Monitoring Plan

1 Introduction

The audit took place in Panama from 4th to 13th February 2014. The audit team comprised two auditors from the Food and Veterinary Office (FVO). The audit was undertaken as part of the FVO's audit programme. The audit covered two scopes, one evaluating the control systems and operational standards in the residues sector and the other evaluating the control systems in place governing the production of fishery products intended for export to the EU. For each scope an individual report is produced. This report covers the evaluation of the residue sector.

Representatives from the central competent authority responsible for control of residues in animals and animal products accompanied the audit team during the audit. An opening meeting was held on 3rd February 2014 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 the authorisation, distribution and use of veterinary medicinal products and feed additives have an impact on the monitoring of residues, the national rules governing the control systems in these areas were also part of the audit. The audit focussed on the roles of the competent authorities at central and regional levels, the legal and administrative measures in place to give effect to the relevant 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
Central	2	Opening and closing meetings with the: Ministry of Health (MINSA); Department of Food Protection (DEPA), Ministry of Agriculture (MIDA); National Directorate for Animal Health (DINASA); Maritime Authority of Panama; Authority for Water Resources (ARAP) and the Panamanian Food Safety Authority.
Regional	3	Meetings at the Regional Competent Authority in two regional MINSA and in one regional MIDA office.
Laboratories	1	Governmental MINSA laboratory for testing in wild caught fish.
Farms	4	Three aquaculture farms for crustaceans and one for fish.
Establishments	6	Three processing plants (two for crustaceans and one for crustaceans and fish): two fishing vessels; one landing site for fish.
Other sites	3	One importer/wholesaler of veterinary medicinal products for aquaculture species and one for other species, one feed mill producing medicated feeding stuffs.

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 Council Directives 85/358/EEC and 86/469/EEC and Council 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 Implementing Decision 2011/163/EU indicates that Panama's residue monitoring plan is approved in accordance with Directive 96/23/EC for aquaculture.

4.2 Summary of previous FVO audit reports

This was the first residues audit carried out in Panama. An audit to evaluate the control systems in place governing the production of fishery products intended for export to the EU took place in 2012 (DG (SANCO) 2012/6469-MR-Final). This report did not evaluate controls of residues of veterinary medicinal products.

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

There have been no RASFF notifications for residues of veterinary medicinal products in aquaculture products exported to the EU since 2009.

4.4 Production and Trade Information

Aquaculture crustaceans/shrimps and finfish are the only foods of animal origin that Panama exports to the EU. Panama produced in 2012 1,998 tonnes of finfish: cobia (300), trout (408) and tilapia (1,290) and 6,734 tonnes of shrimp. Finfish was not exported to the EU but 2,500 tonnes of shrimp were exported. In 2013 4,129 tonnes of finfish: cobia (940), trout (146) and tilapia (3,043) and 7,678 tonnes of shrimp were produced. Two tonnes of finfish (cobia) and 1,980 tonnes of shrimp were exported to the EU.

5 Findings And Conclusions

5.1 Residue monitoring

5.1.1 Competent authorities involved

The *Departamento de proteccion de alimentos* – Department of Food Protection (DEPA), which belongs to the *Ministerio de Salud* - Ministry of Health (MINSA), is the central competent authority responsible for the planning, development, implementation and supervision of the residue monitoring plan (RMP) for aquaculture. Its division of National Plant Inspections and its subdivision for Fishery and Aquaculture Products plan, develop and supervise the RMP at central level. It is implemented through regional or local offices of the MINSA.

The *Ministerio de Desarrollo Agropecuario* - Ministry of Agriculture (MIDA) bears responsibility for authorisation, registration, importation and controls on veterinary medicinal products. MIDA's *Direccion nacional de salud animal* – National Directorate for Animal Health (DINASA) and its registration department is responsible for issuing marketing authorisations for all veterinary medicinal products for food producing animals and for supervising the distribution of veterinary medicinal products in the Panama city region. Supervision of distribution of veterinary medicinal products in all other regions is the responsibility of DINASA's 82 local offices. MIDA's Directorate of Quarantine controls imports of such products into Panama. Lists of authorised veterinary medicinal products and those which are specifically permitted in aquaculture are maintained by DINASA's registration department.

The *Autoridad de Recursos Aquaticos de Panama* - Authority for Water Resources (ARAP) is responsible for aquaculture water and land concessions including taking note of what species may be produced. ARAP, in collaboration with regional MINSA offices and DINASA or local agencies, is responsible for and conducts inspections at aquaculture farms.

The *Autoridad Panamena de Seguridad de Alimentos* - Panamanian Food Safety Authority - is responsible for importation of feed and feed-additives also for aquaculture, however not for medicated feed or any veterinary medicinal products.

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 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 Council Directive 96/22/EC. Articles 3 to 7 of 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 Directive 96/23/EC and Commission Decision 97/747/EC.

Article 11 of Regulation (EC) No 178/2002 of the European Parliament and of the Council, 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 of the European Parliament and of the Council of 23 February 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 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 Decision 2011/163/EC.

Findings

Decree No 84 of June 10, 1996 provides the legal basis for the aquaculture RMP and stipulates that it shall be in line with EU requirements (e.g. Directive 96/23/EC). Resolution No 368 of May 15, 2009 establishes the MLs of toxic residues and contaminants that are allowed in aquaculture products and stipulates that those have to be in line with EU requirements. It is regularly updated to reflect changes with regards to EU legislation.

Aquaculture farms require a land and water concession from ARAP and are also included in the list of establishments supervised by DINASA.

Exports to the EU have taken place until 2012 only for shrimp. In 2013 the first small volume of the finfish cobia was exported. Tilapia and trout have not yet been exported to the EU.

The audit team noted that:

- DEPA planned the 2013 RMP during January and February of the same year. Potential non-compliances and information from the laboratory have to be taken into consideration when drafting the RMP, which is also shared with DINASA for input. However, input from DINASA's veterinary medicinal product registration office has not yet been considered with regard to the type of registered veterinary medicinal products to define the scope of analysis per substance group.

- All aquaculture farms irrespective of the species produced are entitled to export to the EU and no split system for national and export markets exists.

- The annual number of samples to be taken from:

    a.) aquaculture shrimps has been largely based on national production. In 2013, 60 samples were taken based on a 2012 production of 5,524 tonnes. However, the audit team found that while the majority of farms were known and included in the

calculation of the national volume, others were not. The actual production in 2012 was 6,734 tonnes, which should have resulted in 67 samples.

b.) aquaculture finfish was not based on national production but on the production of one farm whereas there are many other farms producing tilapia and trout. Sampling of finfish started for the first time in June 2013; four samples were taken from one farm based on its production of 300 tonnes. However, on a national scale, 1,998 tonnes of finfish were produced in 2012, which should have resulted in 20 samples being taken in 2013. This is not in line with requirements laid down in Annex IV, Chapter 3 to Directive 96/23/EC. DEPA informed the audit team that it intends to base the 2014 RMP sample numbers on national production.

- DEPA had no up-to-date list of aquaculture farms from ARAP or DINASA. A list of aquaculture farms provided to the audit team by ARAP did not include any existing trout and not all tilapia farms, whereas the list of farms supervised by the DINASA was comprehensive covering farms with all species. DEPA informed the audit team that it intends to include all aquaculture farms in its 2014 RMP planning.

- For shrimp, all of the substance groups required by Directive 96/23/EC have been included in the RMPs from 2011 onwards.

- In June 2013, the first finfish samples were analysed for Group B3a and B3c but not for Group A1, A3, B1, B2a, B3d and B3e. This is not in line with regard to the substance groups to be analysed in aquaculture finfish as laid down in provisions of Annex II to Directive 96/23/EC.

- Detailed sample plans are developed at central level and determine in which region, at what time and from which aquaculture commodity and establishment the samples shall be taken. It also determines the substance groups to be analysed for. Sampling is planned to take place during one week in June, August and October.

Conclusions on planning of the residue monitoring plan

With regard to farmed shrimp, the RMP is in line with the requirements of Directive 96/23/EC whereas for finfish, the number of samples taken and the range of substance groups analysed are not sufficient to guarantee equivalence with the Directive.

5.1.3 Implementation of the residue monitoring plan

Legal Requirements

Article 29 of 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 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 Directive 96/23/EC deal with aspects pertaining to the implementation of the residue monitoring plan. Sampling requirements are specified in Annex IV to Directive 96/23/EC and Decision 97/747/EC and Commission Decision 98/179/EC lays down the

rules for official sampling under the residue monitoring plan. EU methods of sampling for the official control a wide range of residues in products of animal origin are laid down in several pieces of EU legislation: Commission Directive 2002/63/EC (pesticides); Commission Regulation (EC) No 1883/2006 (dioxins and dioxin-like PCBs); Commission Regulation (EC) No 333/2007 (certain chemical elements); Commission Regulation (EC) No 401/2006 (mycotoxins).

Findings

DEPA communicates the RMP sampling targets to DINASA and to regional/local MINSA offices in May of each year. The annual RMP sampling plan is subdivided into three sampling periods, with MINSA's regional/local offices taking samples during one week in June, August and October. Detailed instructions have been prepared by DEPA to guide the regional and local offices in their RMP sampling activities. Additional RMP samples can be taken in case of suspicion.

The audit team noted that:

- Staff involved in RMP implementation participated in regular training and were familiar with sampling instructions.

- Suitable sampling materials and a sample report are provided from the central level and used at regional and local level. A uniform national sample report template is used which defines where and from what to take samples. Each sample is subdivided into three tamperproof subsamples. The unique numbers of each subsample-tag were also recorded in the sample report. One subsample remained with the establishment and two were sent to DEPA, which then forwarded one to the laboratory. In this way, DEPA is able to supervise the completion of the RMP.

- Regional and local offices visited took samples in line with the 2011, 2012 and 2013 RMPs respectively. Samples were adequately sealed and transported in cooled containers to ensure sample integrity. Samples in processing plants were taken from the biggest production lot either from frozen or non-frozen shrimp. In aquaculture farms samples were taken from ponds or cages closest to market introduction. No other information, like veterinary medicinal products used, or diseases present on farms were used to follow a risk-based targeting approach of samples. DEPA informed the audit team that it intends to include in the sampling instructions criteria, which will allow participants to base the targeting of samples more on risk.

- Samples remain under official control from the time of sampling through to delivery to the laboratory and analysis also to ensure sample integrity. However, in 2012 around one-third of all samples taken (those during the 3rd sampling period in October) did not reach the laboratory and were not analysed. DEPA informed the audit team that this was due to the fact that the third country customs officials had kept the samples too long, so that they degraded and could not be analysed. DEPA stated further that it could not re-sample the lost samples as many of the companies had ended production for that year. After this incident, the corrective action it implemented included facilitating improved cooperation procedures with the third country custom authority and also requiring Panamanian aquaculture farms and processing establishments to pay in advance for sampling and sample analysis. Thanks to these measures, all samples taken during 2013 arrived on time in the laboratory and were fit for analysis.

- Sampling in June, August and October coincides largely with annual production/harvesting patterns. However, around 15-20% of shrimp are harvested between November and January, and at present no samples are taken during that period. Thus sampling is not spread over the whole year, nor does it take place throughout the harvesting period. This is not in line with requirements laid down in point 2.1. of the Annex to Decision 98/179/EC.

- No suspect sampling took place during the last three years, because there were no non-compliant results.

- Sampling was carried out without prior warning in aquaculture processing plants and largely also in aquaculture farms. In some cases, they were given advance notice of one to two days in order to ensure that staff of the aquaculture farm were present.

- In one out of three processing plants visited, all shrimp farmers delivering products provided a document stating that the shrimp had not been treated with any substances that are forbidden in the EU and that, if treated with an authorised veterinary medicinal product, the required withdrawal periods were observed. The farms submitted to the processing plant copies of official RMP sample results of samples taken at their farms.

Conclusions on planning of the residue monitoring plan

The RMP is generally implemented as planned, supported by good instructions and supervision of implementation. The effectiveness is only slightly compromised by the uneven distribution of sampling during the year or harvesting period.

5.1.4 Follow-up of non-compliant results

Legal Requirements

Article 29 of 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 Directive 96/23/EC.

Findings

The Health Code Law No 66 of November 10, 1947, establishes rules covering the sanitary controls of food on all stages. Executive Decree No 84 of June 10, 1996 lays down all inspection and sanitary control requirements for fish and aquaculture establishments, processing plants and vessels. Executive Decree No 352 of October 10, 2001 determines what penalties/sanctions can be taken in case of offences found. These can include warnings, fines, temporary suspension of activities, closure of establishments and confiscation of products.

DEPA is responsible for follow-up and coordination of follow-up with regard to any RMP non-compliances found. It has drawn up general instructions on what to do in case of RMP non-compliance, though there have been no non-compliant results in the RMP from 2011 to date.

The audit team noted that:

- Instructions on what to do in the event of an RMP non-compliance are in line with key requirements laid down in Article 16 of Directive 96/23/EC.

- The regional and local officials met, who are responsible for follow-up of RMP non-compliance, were familiar with the instructions for following up non-compliant results.

Conclusions on follow-up investigations/actions:

Though there have been no non-compliant results in the RMP, the system for investigating such results should provide guarantees equivalent to EU requirements.

5.2 LABORATORIES

Legal Requirements

Article 29 of 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 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 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 Directive 96/23/EC are laid down in 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 Regulation (EC) No 1883/2006 (dioxins and dioxin-like PCBs in foodstuffs), Regulation (EC) No 333/2007 (chemical elements in foodstuffs) and Regulation (EC) No 401/2006 (mycotoxins).

5.2.1 General description

Findings

All RMP samples are sent for analysis to a laboratory in another country. The laboratory was audited by the FVO in 2012 and it concluded that the methods applied at the laboratory (for testing aquaculture products) were fit for purpose and delivered reliable results.

The audit team noted that:

- The laboratory was accredited according to ISO 17025 by the American Association for Laboratory Accreditation. The accreditation was given on 20 December 2013 and is valid until April 2015. Several methods of importance to the RMP are included in the scope of accreditation for fish/crustacean as matrix ((Group A6 (nitrofurans and chloramphenicol), B1 (fluoroquinolones, tetracyclines, sulphonamides, quinolones, florfenicol), B3a (emamectin, ivermectin), B3c (lead, cadmium, mercury, tin, arsenic), B3e (malachite/leucomalachite green, brilliant green, crystal/leucocrystal violet).

- Methods for analysis for substances in Group A1, Group A3 and Group B3d for finfish are neither included in the scope of accreditation nor are fully validated. The incomplete validation is not in line with the requirements laid down in Decision 2002/657/EC.

However, the laboratory also conducts other internal quality controls for these methods. DEPA informed the audit team that it will ask the laboratory to fully validate these methods prior to the next sample analysis period in June 2014.

- During 2013 the laboratory faced problems in conducting analyses for several RMP substance groups (Group A6, B2a, B3a, B3e) and sent them to four other laboratories for analysis. The audit team found that all these laboratories were accredited according to ISO 17025 and that the methods used for RMP analysis were largely included in the scope of accreditation.

- General target times between sample reception and delivery of results have been agreed between DEPA and the laboratory, and should be 12 days. However, during 2013, the target has regularly been exceeded by up to three months, also for samples which were not sent to other laboratories.

- The laboratory sends a detailed report for each sample analysed quoting the substance analysed, the CC-alpha and the EU MRL. These data are then used by DEPA to determine if a sample result is compliant or not.

- The laboratory successfully participated in several proficiency tests covering the substance groups important for the RMP: Group B1, B3c and B3d. The audit team was informed by the staff of the other country laboratory (which the audit team met in Panama) that the laboratory had tried to participate in proficiency tests for other substance groups in the crustacean or finfish matrix, but that these had not been easily available.

Conclusions on laboratories

On the basis of the observed performance of the outsourced laboratory seen in a previous FVO audit, the accreditation status of the laboratory in question and its performance in proficiency tests, it is concluded that the competent authority can have confidence in the reliability of the results generated by this laboratory. Notwithstanding this, some methods for analysis of certain residue goups in finfish require full validation and the exceedance of agreed turnaround times has, in the event of a non-compliant result being found, the potential to hinder the effectiveness of follow-up investigations.

5.3 Veterinary medicinal products and medicated feedingstuffs

5.3.1 Authorisation, distribution and use of veterinary medicinal products

Legal Requirements

Article 29 of 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 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 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 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 of the European Parliament and of the Council and for certain products authorised on an EU-wide basis, in Articles 30-40 of Regulation (EC) No 726/2004 of the European Parliament and of the Council. 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 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 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.

Findings

Authorisation and registration of veterinary medicinal products: Information on how to apply for authorisation and registration of veterinary medicinal products in Panama is publicly available on the internet. The application, to be sent to the DINASA's registration department, must contain key information, including e.g. the pharmacologically active substances in the veterinary medicinal product. The registration department checks if the product contains any substances prohibited for use in Panama and, if not, conducts a detailed check of all information submitted. If these are in line with veterinary medicinal registration requirements, a specific certificate of registration and a free sale certificate are issued. All registered veterinary medicinal product are included in a national register.

Importation: Importers licensed by DINASA can import any registered veterinary medicinal product. To do so, the importer needs to submit the veterinary medicinal product's certificate of registration and the free sale certificate to MIDA's Directorate for Quarantine. This then issues an importation license and the importer can import the respective veterinary medicinal product, which is again checked at Panama's points of entry by staff of the Directorate of Quarantine.

According to DINASA's registration department, MRLs of registered veterinary medicinal products are in line with those set down in Table 1 of Regulation (EU) No 37/2010.

Distribution: There are two different distribution systems for veterinary medicinal products. One

for aquaculture species and one for all other species. For aquaculture, the importer distributes directly and only to three registered feed mills that produce feed and medicated feed for aquaculture. These feed mills deliver the medicated feed directly to aquaculture farms. For other species the importers sell veterinary medicinal products, excluding those for use in aquaculture, to pharmacies who sell them to veterinarians for use within their practice.

Use: Decree 183, of August 26, 2004 lists all pharmacologically active substances (e.g. antibiotics) which require a prescription by a veterinarian. It also lists all substances banned for aquaculture, which include those listed in Table 2 of the Annex to Regulation (EU) No 37/2010 as well as anabolic substances, dyes and hormones apart from 17-alpha-methyl testosterone, which is used for zootechnical purposes and exclusively in tilapia. Such use is permitted in the EU by Directive 96/22/EC.

Off-label use of veterinary medicinal products in food producing animals is not permitted.

Veterinary medicinal product labels need to mention the registration number, the active pharmaceutical ingredients, the target species, the dosage and usage time as well as the withdrawal period, and in the Spanish language.

The audit team noted that:

- The list of authorised veterinary medicinal products for aquaculture includes pharmacologically active substances currently listed for use in aquaculture species in line with Table 1 of Regulation (EU) No 37/2010, apart from three substances (two antibiotics (toltrazuril and doxycycline) and one anti-protozoal (ormethoprim)). Staff of the Registration Department informed the audit team that these active substances are currently not being used and that their authorisation will end during 2014/2015.

- The certificates to be renewed annually for importers, wholesalers and feed mills that trade in veterinary medicinal products or produce medicated feed were present in all importers, wholesalers and feed mills visited by the audit team.

- The one wholesaler for veterinary medicinal products for aquaculture species, visited by the audit team, delivered veterinary medicinal products for aquaculture to two feed mills and not to any pharmacy selling veterinary medicinal products for other species in line with national rules.

- Three aquaculture veterinary medicinal products sold at wholesalers visited or found at feed mills or farms visited by the audit team were not included in the list of veterinary medicinal products registered in Panama.

- The aquaculture farmers met could obtain veterinary medicinal products through three feed mills processing medicated feed in Panama. To order medicated feed from the feed mill requires the prescription of a veterinarian and records of prescriptions as well as records on which animals were treated must be kept by the farmer. One of the three farms having ordered medicated feed from a feed mill had records of prescriptions, but all farms visited kept records which animals were treated.

- Guides for good practice have been created by the industry in cooperation with competent authorities. These date from 2010 and do not yet include instructions on the national requirement for a veterinary prescription for medicated feed for aquaculture species.

Conclusions on authorisation, distribution and use of veterinary medicinal products

The system in place for the authorisation, distribution and use of veterinary medicinal products is broadly similar to that provided for in EU legislation.

5.3.2 Controls on the distribution and use of veterinary medicinal products

Legal Requirements

Article 29 of 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 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 Directive 90/167/EEC, the rules governing control functions by the competent authorities are laid down in Articles 4, 9 and 13 of said Directive.

Findings

All importers, wholesalers and feed mills dealing with veterinary medicinal products or medicated feed for aquaculture need to be inspected by DINASA's registration department in cooperation with DINASA's 82 local offices at least once a year. For those inspections a detailed checklist has been created to check for example: whether the products present are registered, whether veterinary medicinal products requiring prescription are present, whether corresponding prescriptions exist, whether products comply with labelling requirements (e.g. withdrawal period, species, dosage, active ingredients etc.) or whether storage is appropriate.

According to Article 13 of Decree 183, importers and wholesalers of veterinary medicinal products must have a licensed private veterinarian under contract. These veterinarians licenced by DINASA's registration office have the task of supervising the wholesalers activities once or twice a month, checking among other things the storage, expiry date of veterinary medicinal products and compliance with labelling requirements.

Aquaculture farmers are to be inspected by DINASA's 82 local offices once a year with regard to controls of veterinary medicinal products, again using a comprehensive checklist.

As of 2013, aquaculture farms and feed mills shall, based on sanitary law 66 and 40, also be inspected once a year by a joint inspection team with inspectors from MINSA, MIDA and ARAP.

The audit team noted that:

- In one regional DINASA office visited, the audit team saw evidence that inspections with regard to veterinary medicinal product use took place at least once a year in all aquaculture

farms of the region. Inspection reports were sent monthly to the regional DINASA office. Evidence was presented to the audit team that DINASA had a largely complete list of existing aquaculture farms as well as of feed mills for all regions.

- In one feed mill visited, staff of DINASA's registration department and local office had conducted a comprehensive inspection each year, which checked for compliance with the requirements on the use of veterinary medicinal products. These reports found that medicated feed had been produced without prescriptions for several consecutive years. The audit team was informed that enforcement of the requirement to have prescriptions for ordering medicated feed for aquaculture had only recently started.

- The joint inspections by MINSA, MIDA and ARAP started at the end of 2013 and 12 aquaculture farms had been visited.

- Staff of DINASA, stated that they can quickly rectify non-compliances with regard to veterinary medical products in cooperation with the Consumer Protection Agency (*Autorida Autoridad de Protección al Consumidor*), e.g. the removal of expired or not registered products. MINSA staff met by the audit team stated that they can support DINASA to impose sanctions based on resolution 2 from the 5th January 2012 when found during joint inspections in which staff from MINSA, MIDA and ARAP participate.

- In 2011, there were 12 inspections at veterinary medicinal product wholesalers of which two had a non-compliance. There were also 119 inspections planned at pharmacies, of which six showed non-compliances. In feed mills 18 inspections were done and ten showed non-compliances. There was a similar number of inspections and non-compliances in 2012. Most non-compliances concerned cleanliness and rodent control at the establishments and the presence of expired veterinary medicinal products. From the completed checklists it could be seen that other parameters, like checking of registration and label compliance, were also controlled and were found to be compliant.

- Results of inspections were generally well-documented, often using the respective inspection checklists or writing a summary of findings made. Time limits by when to rectify non-compliances and also if previous non-compliances had been addressed were sometimes included in the reports.

- In both wholesalers visited there was a certificate to wholesale veterinary medicinal products. A licensed veterinarian was under contract and conducted monthly controls, which were recorded in a respective booklet. Key non-compliances found related to keeping the storage area clean, to disposing of expired veterinary medicinal products and to renewing importation certificates in case those were too close to the end of their 10-year validity in line with national rules.

- In one aquaculture farm visited medicine records were complete and in line with national requirements. In another aquaculture farm visited medicine records were largely complete and in line with national requirements. However, medicated feed was provided by the feed mill without any prescription and the withdrawal period of 30 days was not fully respected in three cases during 2011. The shortcoming regarding the withdrawal period had been found during DINASA´s official controls and was immediately rectified by the farmer. DINASA staff met, informed the audit team that official controls on prescription

requirements had not been implemented yet, but will be in future.

- Monthly reports were sent from each local agency to the regional office and those then discussed during meetings at central level.

- The DINASA inspectors met informed the audit team that they have no easy access to an updated list of all veterinary medicinal products registered in Panama in order to verify if veterinary medicinal products used on farm are authorised.

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

Controls on the distribution of veterinary medicinal products cover all importers/wholesalers and feed mills producing medicated feed for aquaculture, as well as on-farm use of veterinary medicines. These controls are generally effective. However, since the central register of veterinary medicinal products is not fully up-to-date and is difficult to access by local inspectors, this has the potential to reduce the effectiveness of such controls as inspectors cannot readily verify if the veterinary medicinal products found during inspections are still registered at central level.

6 Overall Conclusions

With regard to farmed shrimp, the RMP is in line with the requirements of Directive 96/23/EC whereas for finfish, the number of samples taken and the range of substance groups analysed is not yet fully in line with the Directive.

The RMP is generally implemented as planned, supported by good instructions and supervision of implementation. The effectiveness is only slightly compromised by the uneven distribution of sampling during the year or harvesting period.

Though there have been no non-compliant results in the RMP, the system for investigating such results should provide guarantees equivalent to EU requirements.

On the basis of the observed performance of the outsourced laboratory seen in a previous FVO audit, the accreditation status of the laboratory in question and its performance in proficiency tests it is concluded that the competent authority can have confidence in the reliability of the results generated by this laboratory. Notwithstanding this, some methods for analysis of certain residue groups in finfish require full validation and the exceedance of agreed turnaround times has, in the event of a non-compliant result being found, the potential to hinder the effectiveness of follow-up investigations.

The system in place for the authorisation, distribution and use of veterinary medicinal products is broadly similar to that provided for in EU legislation.

Controls on the distribution of veterinary medicinal products cover all importers/wholesalers and feed mills producing medicated feed for aquaculture, as well as on-farm use of veterinary medicines. These controls are generally effective. However, since the central register of veterinary medicinal products is not fully up to date and is difficult to access by local inspectors, this has the potential to reduce the effectiveness of such controls as inspectors cannot readily verify if the veterinary medicinal products found during inspections are still registered at central level.

7 Closing Meeting

A closing meeting was held on 13 February 2014 with representatives of DEPA and other authorities. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities did not express disagreement and stated that they would take whatever actions were necessary in order to address the identified shortcomings.

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 25 working days of receipt of this audit report.

N°.	Recommendation
1.	To base the annual number of RMP samples on the national production of the previous year in line with requirements of Annex IV, Chapter 3 to Directive 96/23/EC.
2.	To ensure that samples drawn from both farmed fish and shrimp are tested for all requisite substance groups in line with the provisions of Annex II to Directive 96/23/EC.
3.	To ensure that sampling is carried out in variable intervals spread over the whole year, in order to provide guarantees at least equivalent to the requirements of the Annex to Decision 98/179/EC.
4.	To ensure that all analytical methods for Group A1, Group A3 and Group B3d used for the RMP of finfish are validated to a standard equivalent to that required by Decision 2002/657/EC.
5.	To improve the effectiveness of official controls in the area of distribution and use of veterinary medicinal products through making the list of veterinary medicinal products publicly available in line with requirements of Article 25(3) of Directive 2001/82/EC.
6.	To provide laboratory results in line with national agreed deadlines in order to be able to start follow-up investigations without delay as required by Article 16 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=2014-7030

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Audits by the Commission Services		
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Food Law		
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Monitoring and sampling of residues in food of animal origin		
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
Dec. 97/747/EC	OJ L 303, 6.11.1997, p. 12-15	97/747/EC: Commission Decision of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products
Dec. 98/179/EC	OJ L 65, 5.3.1998, p. 31-34	98/179/EC: Commission Decision of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products
Approval of residue monitoring plans submitted by third countries		

Legal Reference	Official Journal	Title
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		
Reg. 470/2009	OJ L 152, 16.6.2009, p. 11-22	Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council
Reg. 37/2010	OJ L 15, 20.1.2010, p. 1-72	Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin
Maximum Residue Levels for pesticide residues in food of animal origin		

Legal Reference	Official Journal	Title
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
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

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