EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2014-7029 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

INDIA

FROM 03 TO 14 MARCH 2014

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 India, carried out from 3 to 14 March 2014, as part of the published programme of FVO audits.

The objective of the audit was to evaluate the performance of competent authorities and other officially authorised entities in their implementation of official controls concerning residues and contaminants in live animals and animal products, in order to assess whether these controls offer adequate assurance that the products and animals concerned, eligible for export to the European Union (EU) do not contain residues of veterinary medicinal products, pesticides and contaminants at concentrations in excess of EU maximum limits. 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. In addition, attention was paid to examining the implementation of corrective actions promised in response to recommendations made in the report of the previous FVO residues audit in India (DG (SANCO)/2011/8861 MR-Final) in May 2011.

Overall, it is concluded that guarantees provided by the residue control system for aquaculture products in India are, with some exceptions, broadly equivalent to those foreseen by EU legislation. The residue monitoring plan is implemented in accordance with planned arrangements and in line with EU rules and meets minimum requirements laid down in EU legislation (for testing of aquaculture shrimp but not finfish). However a relatively narrow range of substances is tested for and no account is taken of the range of substances actually used in fish and shrimp production in the country[1]. As such, guarantees on the residues status of aquaculture products rely to a large extent on the additional pre-harvest and pre-export testing programmes in place and these mitigate to a certain extent the long-standing deficiencies in official controls on farms, and in particular, an almost total absence of official controls on the use of veterinary medicinal products. Nevertheless, the relatively narrow range of substances tested for in those additional programmes also weakens the reliability of those guarantees. With regard to the follow-up of non-compliant results, some improvements have been noted relative to 2011 (for example progress made on the registration of farms), nevertheless, it remains the case that follow-up at primary producer level to identify the root cause of the non-compliance is 'delegated' almost fully to the export establishments which is not in line with EU requirements.

Concerning laboratories, improvements in performance have been noted relative to 2011, though certain deficiencies in quality control and ensuring the analytical integrity of samples have the potential to undermine the effectiveness of the residue monitoring plan.

With regard to veterinary medicinal products, the system for authorisation of, and controls on veterinary medicinal products is deficient in many respects compared to the EU system. Improvements have been made relative to 2011 (introduction of labelling legislation) however, the many non-compliances identified by the audit team in this respect and overall poor awareness and enforcement of the legislation collectively weaken the effectiveness of the residue control system.

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

1 *In their response to the draft report the competent authority noted that data on the range of substances actually used in aquaculture products shall be compiled and considered for inclusion in the 2015 NRCP.*

Table of Contents

Abbreviations and definitions used in this report

Abbreviation	Explanation
AOZ	Marker residue of the nitrofuran drug furazolidone
CAA	Coastal Aquaculture Authority of India
CCα / Ccβ	Decision Limit / Detection Capability
DG(SANCO)	Health and Consumers Directorate-General
EC	European Community
EIA	Export Inspection Agency
EIC	Export Inspection Council
ELISA	Enzyme-Linked Immuno-Sorbent Assay
EU	European Union
FVO	Food and Veterinary Office
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC
HACCP	Hazard Analysis Critical Control Points
ISO	International Organisation for Standardisation
LC-MS/MS	Liquid Chromatography-(Tandem) Mass Spectrometry
ML	Maximum Level
MPEDA	Marine Product Export Development Authority
MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
PET	Pre-Export Test
PHT	Pre-Harvest Test
QC	Quality Control
RASFF	Rapid Alert System for Food and Feed
RMP	Residue Monitoring Plan
SFA	State Fishery Authority
SOP	Standard Operating Procedure

1 Introduction

The audit took place in India from 3rd to 14th March 2014. The audit team comprised five 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 (DG (SANCO) 2014-7136 MR). For each scope an individual report is produced. This report covers the evaluation of the control systems in place governing residues and contaminants in animal and animal products.

Representatives from the central competent authority responsible for the control of residues in animals and animal products accompanied the audit team during the audit. An opening meeting was held on 3rd March 2014 with this central competent authority and representatives of the competent authority responsible for the authorisation of veterinary medicinal products, representatives of the competent authority for the development of marine products and representatives responsible for fishery research. 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 performance of competent authorities and other officially authorised entities in their implementation of official controls concerning residues and contaminants in live animals and animal products, in order to assess whether these controls offer adequate assurance that the products and animals concerned, eligible for export to the European Union (EU) do not contain residues of veterinary medicinal products, pesticides and contaminants at concentrations in excess of EU maximum limits. 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.

Attention was paid to examining the implementation of corrective actions promised in response to recommendations made in the report of the previous FVO residues audit in India (DG (SANCO)/2011/8861 MR-Final) in May 2011.

The principal audit criteria against which fulfilment of the above objective was assessed comprise:

- Regulation (EC) No 882/2004 of the European Parliament and of the Council;
- Council Directive 96/23/EC;
- Directive 2001/82/EC of the European Parliament and of the Council;
- Regulation (EC) No 183/2005 of the European Parliament and of the Council.

Further particulars are listed in each of the 'legal requirements' sections below with details provided in Annex 2.

The table below lists sites visited and meetings held in order to achieve the audit objective.

Meetings/Visits		N	Comments
Competent Authorities	Central	2	Opening and closing meeting with the Export Inspection Council (EIC), the central competent authority for export of fish and fishery products; the Marine Product Export Development Authority (MPEDA); the National Drug Controller General and the Central Institute of Fisheries.
	Regional	4	Meetings with the Export Inspection Agency (EIA) in Chennai, Nellore and Cochin as well as meetings with MPEDA in Nellore and Cochin.
	Local	6	Meetings with local inspectors from MPEDA and EIA as well as district drug controllers in Chennai, Nellore and Cochin.
Laboratories		7	Governmental laboratories: EIA laboratories in Chennai and Cochin; MPEDA laboratories in Cochin and Nellore; Private laboratories in Chennai, Nellore and Cochin.
Farms		2	Two shrimp farms, with representatives of regional and local competent authorities present.
Establishments		2	Two establishments processing crustaceans/shrimp and fishery products for export to the EU. Representatives of regional and local authorities were present in both.
Other Sites		2	Two wholesalers/retailers of veterinary medicinal products.

3 Legal Basis

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

- Article 21 of Council Directive 96/23/EC;
- Article 46 of Regulation (EC) No 882/2004;

A full list of the legal instruments referred to in this audit report is provided in Annex 1 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/EU indicates that India's residue monitoring plan (RMP) is approved in accordance with Directive 96/23/EC for aquaculture products, eggs and honey.

4.2 Summary of previous FVO audit reports

Controls on residues in animals and animal products were audited by the FVO in 2003 DG(SANCO)/9208/2003 MR-Final), 2006 (DG(SANCO)/8015/2006 MR-Final), 2009 (DG(SANCO)2009-8190 MR-Final) and 2011 (DG(SANCO/2011/8861 MR-Final). The reports of these audits (henceforth referred to as the 2003, 2006, 2009 and 2011 FVO reports, respectively) have been published on the website of the Directorate – General for Health and Consumers here http://ec.europa.eu/food/fvo/ir_search_en.cfm

The 2011 FVO audit report concluded that the RMP for aquaculture products fulfilled the minimum requirements of Directive 96/23/EC and was implemented as planned. However, the lack of a legal basis necessary to enable official controls and enforcement action at primary producer level combined with a lack of effective controls on the distribution and use of veterinary medicinal products undermined the ability of the competent authorities to provide guarantees equivalent to those provided for by EU legislation.

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

Between January 2012 and February 2014 around 4,000 consignments of farmed and wild caught shrimp were exported from India to the EU. Of these 400 were sampled at EU Border Inspection Posts and analysed for the presence of residues of veterinary medicinal products resulting in 12 RASFF notifications for residues of veterinary medicinal products of which 10 concerned nitrofuran metabolites (two for nitrofurazone and eight for furazolidone), one concerned chloramphenicol and one oxytetracycline. All of the affected consignments were either rejected or destroyed. For comparison from January 2008 to January 2010 there were 60 RASFF notifications for the presence of nitrofuran metabolites in aquaculture products.

4.4 Production and Trade Information

India exports aquaculture products, mostly shrimp to the EU. Data provided by the Marine Products Export Development Authority (MPEDA) show that in 2013 285 establishments were approved for processing shrimp, fish and fishery products for the EU. During 2012-2013, approximately 29,000 tonnes of brackish water shrimp, 300 tonnes of fresh/saltwater shrimp and 450 tonnes of freshwater fish were exported to the EU.

Commission Decision 2010/381/EU, requires that a Pre-Export Test (PET) must be carried out on official samples from aquaculture products to check for the presence of chloramphenicol, tetracycline, oxytetracycline, chlortetracycline and metabolites of nitrofurans. In addition, EU Member States are also required to carry out official sampling of 20% of aquaculture products consignments presented for import at their Border Inspection Posts to analyse these for residues of the substances listed above. This Decision was amended by Commission Decision 2012/690/EU reducing the sampling of aquaculture consignments from 20% to 10%.

5 Findings And Conclusions

5.1 Residue monitoring

5.1.1 Competent authorities involved

1. The central competent authority is the Export Inspection Council (EIC) under the Ministry of Commerce and Industry. It is responsible for the planning, implementation and supervision of the RMP as well as for the approval, registration and execution of official controls on aquaculture production, processing, trading and export establishments. Notification no. S.O. 497 (E) of 10 March 2011 amended the Export of Fresh, Frozen and Processed Fish & Fishery Products (Quality Control and Inspection and Monitoring) Rules from 1995 giving the EIC the (added) responsibility for approval, registration and implementation of official controls at aquaculture primary production and aquaculture feed-mill level in order to ensure traceability from farm to export establishments.
2. MPEDA which is a statutory body under the same Ministry implements the RMP for aquaculture products under the guidance of the EIC. MPEDA's six regional and six sub-regional offices are responsible for RMP sampling at processing establishment level, whereas its seven regional centres and five sub-centres are responsible for RMP sampling at aquaculture farm level, hatcheries and feed mills.
3. The Coastal Aquaculture Authority of India (CAA) has the responsibility to register aquaculture farms and hatcheries in salt and brackish waters in coastal areas (i.e. within two kilometres of the high tide lines of the coast and rivers). Other aquaculture farms (e.g. inland freshwater farms) are registered by the individual State Fishery Authorities (SFAs).
4. MPEDA has per order EIC/D(Q/C)/T-1/11-12, been appointed as one of the designated authorities for registration of farms supplying aquaculture products for export, as well as of hatcheries and feed mills supplying feed to exporting aquaculture farms. Only farms and hatcheries not under the control of the CAA or SFAs shall be registered by MPEDA. MPEDA has to ensure that registration numbers for farms are unique and not in conflict with any numbering system of other recognised registration authorities (e.g. the CAA, SFAs). MPEDA's National Centre for Sustainable Aquaculture has the task to support small scale aquaculture farm societies with guidance on best practices in order to optimise productivity sustainably and to access export markets.
5. All registered aquaculture farms by any recognised registering authority (MPEDA/CAA/SFA) can supply fish or shrimp to EU approved establishments, provided that they request and pass successfully a Pre-Harvest Test (PHT) for the presence of nitrofurans and chloramphenicol.

5.1.2 Planning of residue monitoring plan

Legal Requirements

Directive 96/23/EC; Council Directive 96/22/EC; Commission Decision 97/747/EC; Regulation (EC) No 178/2002 of the European Parliament and of the Council, Regulation (EC) No 470/2009 of the European Parliament and of the Council; Commission Regulation (EU) No 37/2010; Regulation (EC) No 396/2005 of the European Parliament and of the Council; Commission Regulation (EC) No 1881/2006; Commission Decision 2002/657/EC; Commission Decision 2011/163/EU. (See Annex 2).

Findings and observations

6. The Indian RMP for aquaculture is based on the requirements of Directive 96/23/EC and its elaboration and implementation falls under the responsibility of MPEDA. A draft of the RMP is sent to all regions during October of each year for input after which it is finalised in December when region-specific sampling plans are sent out to the implementing MPEDA offices and centres.

7. The 2013 RMP for aquaculture (shrimp and finfish) includes (as in 2012) all relevant substance groups listed in Annex II to Directive 96/23/EC. However, for some substance groups the scope of testing is still very limited as for example, Group B1 analysis includes only tetracycline, oxytetracycline, chlortetracyline, sulphadiazine, oxolinic acid and Group B2a includes only ivermectin.

8. As described in the 2006, 2009 and 2011 FVO reports, MPEDA does not take into account either sales data or usage patterns for veterinary medicinal products when elaborating the RMP. MPEDA informed the audit team that it will request the sales and usage patterns from the Office of the Drug Controller General with a view to extending the scope of the 2015 RMP.

9. RMP sample numbers are based on 2012 export volumes from coastal states, as no exports have yet occurred from inland states. For the 2013 RMP, the number of samples of aquaculture shrimp and freshwater finfish was calculated in line with requirements of Annex IV Chapter 3 to Directive 96/23/EC with a minimum 10% of MPEDA registered aquaculture farms being sampled. The 2012 production volumes for freshwater fish are based on fish-fillet exports originating from aquaculture and wild freshwater fish, as there are no separate production data for wild and aquaculture freshwater fish. To represent whole fish as required by Directive 96/23/EC, 40% are added to the fish fillet volume.

10. The number of saltwater aquaculture farms and the respective export volume is not known as these premises are not yet registered by MPEDA (see finding 43) and no samples were planned for/taken from saltwater aquaculture finfish farms. This is not in line with requirements of Annex IV Chapter 3 to Directive 96/23/EC. The EIC informed the audit team that little export of saltwater finfish aquaculture has taken place, but that it intends to include sampling of saltwater aquaculture finfish in the 2015 RMP. MPEDA plans to take one residue sample per year from each hatchery either from shrimp seed or larvae.

11. In two of the three states visited by the audit team, the RMP sampling for aquaculture farms was distributed evenly throughout the production period. In the remaining state the RMP sampling activity for processing establishments took place in two months although processing took place almost evenly throughout the year. This is not fully in line with requirements laid down in the Annex to Directive 98/179/EC.

Conclusions on planning of residue monitoring

12. With the exception of finfish, for which there is an absence of sampling for certain production classes, the RMP for aquaculture meets the minimum requirements laid down in EU legislation. Notwithstanding the absence of sampling issue, the fact that neither sales volumes nor usage patterns of veterinary medicinal products are taken into account when planning the overall RMP, potentially limits the effectiveness of residue monitoring in this commodity.

5.1.3 Implementation of the residue monitoring plan

Legal Requirements

Directive 96/23/EC; Decision 97/747/EC; Commission Decision 98/179/EC; Commission Directive 2002/63/EC; Commission Regulation (EU) No 252/2012; Commission Regulation (EC) No 333/2007; Commission Regulation (EC) No 401/2006. (See Annex 2).

Findings and observations

13. RMP samples are drawn by MPEDA staff (see finding 2) and 5% of all RMP samples are drawn jointly by EIA and MPEDA staff and analysed both in EIA and MPEDA laboratories.
14. RMP sampling instructions for aquaculture have been amended to ensure that sampling is unforeseen and unexpected thus **recommendation No 1** of the 2011 FVO audit report has been addressed.
15. According to the results of the 2012 RMP provided to the Commission, all samples were taken and analysed in line with the RMP.
16. The RMP for 2013 which is based on a calendar year, was sent to the MPEDA offices and centres responsible for sampling in December 2012 and sampling started from January 2013.
17. A comprehensive on-line database, which enables the monitoring of the implementation of the aquaculture RMP on an ongoing basis, has been put in place by MPEDA. Any issues such as overdue samples or RMP non-compliances are highlighted in the system and notified to all MPEDA offices/centres as well as to the EIC. MPEDA offices/centres then correct e.g. potential reported RMP under-sampling requesting their staff that missing samples are to be taken.
18. Suitable sampling materials and a uniform sampling report were used when taking RMP samples. The tamper-proof samples were sent to the respective laboratory in suitable tamper-proof packaging.
19. Samples remain under official control from the time of sampling through to delivery to the laboratory and analysis also to ensure sample integrity.

Conclusions on implementation of residue monitoring

20. Implementation of the RMP is in accordance with planned arrangements and in line with EU rules.

5.1.4 Other residues monitoring programmes

Legal Requirements

Directive 96/23/EC. (See Annex 2).

5.1.4.1 Official PHT testing of aquaculture shrimp intended for the export market

Findings and observations

21. S.O. 2714 (E) of 28 October 2009 made it obligatory for EIC-approved export establishments to procure aquaculture products only from farms registered by the CAA, MPEDA or the SFAs (see finding 5). This requirement was also included in S.O. 497(E) of 10 March 2011, which superseded the earlier order, and introduced in addition an obligatory official PHT programme for all aquaculture products sent for processing in EIC-approved export establishments. This PHT programme requires that all aquaculture batches harvested at farm are checked prior to harvest for the presence of chloramphenicol and four nitrofuran metabolites. Testing is performed in an MPEDA network of 20 enzyme-linked immuno-sorbent assay (ELISA) laboratories which are operated by two subcontractors. The costs of screening ELISA tests are paid by farmers whereas MPEDA pays for the cost of any confirmatory tests required.

22. Data provided by MPEDA indicated that 44,000 tests were conducted during 2013 of which 80 were non-compliant after confirmatory testing.

23. MPEDA instructions require that PHT samples need to be collected by ELISA laboratories staff, that farmers need to send a PHT request to the laboratory at least 15 days before the expected harvest date and to provide evidence of the farm's registration by the CAA, FSA or MPEDA. The laboratory representative has to check the original registration certificate on-the-spot and note the farm and pond from which the sample had been taken. However, on one farm visited by the audit team it was not possible to reconcile the pond from which samples were taken with the respective PHT. Samplers also calculate the theoretical production amount based on the size of the pond, the stocking density and the average size of shrimp. That allows to cross-check the calculated volume with the volume received in the processing establishments and minimises the risk that non PHT tested product is added to the volume covered by the original PHT certificate. In the ELISA laboratory visited (see section 5.2.2.5), it was possible to confirm that samples from registered farms were collected by laboratory staff.

24. Documents in both EIC-approved export establishments visited showed that consignments of aquaculture products received during 2012 and 2013 were accompanied by PHT certificates issued by MPEDA ELISA laboratories. This was also checked by EIA inspectors during their inspections of processing establishments.

5.1.4.2 Official PET programme for aquaculture products as required by Commission Decision 2010/381/EU

25. Requirements for PET of consignments of aquaculture origin destined for export to the EU, which are similar to those set down in Decision 2010/381/EU and 2012/690/EU have been included in the EIC-approval scheme since August 2012.

26. In 2012, according to data provided by the EIC, out of 31,000 samples analysed for Group A6 and Group B1, 59 tested non-compliant (25 nitrofurans and 28 chloramphenicol, 1 oxytetracyline and 5 crystal violet). Non-compliant sample results were notified to the relevant EIA office.

27. All PET samples must be, according to EIC staff met by the audit team, collected by staff of the analyzing laboratory. The audit team confirmed that PET samples are collected either by officials or specifically trained representatives of the analyzing laboratory. In two EIC-

approved laboratories visited respective Standard Operating Procedures (SOPs) and training to ensure this was done properly were in place.

28. In two EIC-approved export establishments visited, sample submission forms and certificates of analyses indicated that all samples were collected by staff of EIC-approved laboratories and that all substances set down in Decision 2010/381/EU had been checked. Traceability between each consignment, its analytical result and the export health certificate was assured.

5.1.4.3 Official monitoring in EIC-approved export establishments (EIA monitoring scheme)

29. Establishments approved by the EIC for export are inspected by the EIA every one to three months depending on risk. Every six months samples are collected from all such establishments and tested in an EIC-approved laboratory for the presence of antibiotics including chloramphenicol, nitrofuran metabolites and tetracyclines.

30. Documents seen in two EIA offices visited and in the EIC-approved aquaculture and fishery product export establishment visited, showed that samples of shrimp had been collected and analysed in line with the EIA monitoring scheme.

31. According to EIA staff met, no non-compliant results have been found under the EIA monitoring programme.

5.1.4.4 Establishment own-checks

32. The EIC approval scheme for exporting establishments, as outlined in the EIC executive instructions, requires the operators maintain a Hazard Analysis Critical Control Points (HACCP) programme, to implement special requirements for residue controls and, to keep a register of all suppliers.

33. In two EIC-approved export aquaculture and fishery product establishments visited, HACCP systems were in place and all batches of shrimp arriving at the establishment were tested in the establishments ELISA screening for chloramphenicol and nitrofurans before being accepted. When non-compliances were detected, the product was rejected, the supplier notified and supplies from this source were temporarily suspended.

34. Records which could enable the source of products to be traced were available in both of the EIC-approved export establishments visited and it was seen that all suppliers were registered by either the CAA, MPEDA or SFA.

Conclusions on other residue monitoring programmes

35. Pre-Export testing in line with the requirements of Decision 2010/381/EU and other residue monitoring programmes provide reassurances that aquaculture products containing residues of certain in EU-banned substances or, EU-permitted substances, but exceeding EU maximum residue limits, are less likely to be exported to the EU. However, despite the fact that all products destined for export to the EU undergo 100% pre-harvest testing at farm level, there are still residues of EU-banned substances found both in pre-export testing at exporting processing establishments and during sampling of aquaculture consignments presented at EU Border Inspection Posts (see finding 57), suggesting that controls on the use of veterinary medicinal products are not effective.

5.1.5 Follow-up of non-compliant results

Legal Requirements

Directive 96/23/EC. (See Annex 2).

5.1.5.1 Registration and approval of processing establishments and farms

Findings and observations

36. All processing establishments producing shrimp, fish and fishery products for export require an approval by the EIC. The EIA conducts approval audits of processing establishments, after which the EIC, if satisfied with the outcome of the EIA inspection, will issue an approval number.

37. The MPEDA aquaculture farm registration can be given after a registration inspection by MPEDA staff. MPEDA registration (valid for three years) requires a minimum of two years ownership, free-hold or free-lease. Registration information includes the exact Global Positioning System location of the farm, the pond area and number of ponds in production and what species is produced.

38. All aquaculture farms producing for export are required to be registered (see finding 5) and can apply voluntarily for EIC approval (but such approval is not needed for export). EIC-approval is contingent upon a satisfactory inspection by an assessment panel of experts consisting of EIA, MPEDA staff and other experts. Only EIC-approved farms are subject to EIC official controls and to date, there are only 108 farms approved (< 0.01% of the 48,000 registered by MPEDA). The EIC informed the audit team that it is considering to make the approval of export aquaculture farms compulsory for those wanting to export to the EU. EIC approval is very important for residue controls as only EIC-approved farms fall under EIC official controls and can be inspected for e.g. follow-up investigations of non-compliant RMP-, PET samples or RASFF notifications.

39. EIC approval requirements for processing establishments, hatcheries, aquaculture farms and feed mills are described in the EIC Executive Instructions for Approval and Monitoring of Fish & Fishery Products for Export (hereafter referred to as the EIC executive instructions).

40. For a processing establishment the EIC executive instructions require that an appropriate infrastructure and a HACCP system are in place and that PHT reports from supplying aquaculture farms are kept. For farms and hatcheries they require that only permitted pharmacologically active substances are used under the advice of a veterinary medical practitioner, that withdrawal periods are to be respected, and that records of treatment need to be kept. They also require for farms that harvested shrimp shall be tested for prohibited antibiotics like chloramphenicol and metabolites of nitrofurans and that test results shall be made available to the processing establishment receiving the shrimp for export.

41. There are currently 285 processing establishments producing fish and fishery products for export which are approved by the EIC. Both of the processing establishments visited during the audit had a valid approval and largely followed the provisions of the EIC executive instructions.

42. Around 48,000 aquaculture farms have been registered by MPEDA since March 2011. There are as yet no criteria upon which MPEDA could withdraw a registration and during

the last two years none has been withdrawn. The audit team was informed by MPEDA, that these criteria are currently under development. [2]

43. MPEDA has not yet started to register finfish aquaculture farms or the 244 shrimp hatcheries which are already registered by either the CAA or the FSA. MPEDA staff informed the audit team that they intend to start their registration during 2014. In addition MPEDA registration of aquaculture farms in non-coastal states has not yet started. Staff of the EIC met, informed the audit team that currently no exports of aquaculture products from non-coastal states has occurred. If farms from such states wanted to export, they would require an MPEDA registration and to take part in the PHT.

5.1.5.2 Responsibility for follow-up and general organisation of follow-up

44. The EIC has the overall responsibility for all follow-up investigations. It specifically coordinates follow-up investigations of RASFF notifications, while the EIA is responsible for most other follow-up investigations of non-compliant results under the RMP and the PET programme.

45. No decision has yet been taken which competent authority is responsible for follow-up of non-compliant PHT results and no such follow-up has yet taken place even though there are numerous cases of non-compliant results under this programme.

46. For follow-up of RASFF notifications, the EIC requests the concerned EIA to constitute an assessment panel consisting of EIA, MPEDA and Central Institute of Fisheries Technology experts. The panel is responsible for carrying out a follow-up investigation at the EIC-approved processing establishments and on the implicated aquaculture farms as well as on feed mills producing feed for aquaculture, to identify the root cause of the non-compliances and to take measures to rectify them.

47. The EIC executive instructions include detailed information on what to do in the event of non-compliances with regards to veterinary medicinal products. However, the EIC can legally only conduct official controls on the 108 EIC-approved farms. Thus **recommendation No 3** of the 2011 FVO audit report has only been partially addressed.

48. MPEDA regional and sub-regional offices and centres, EIC and EIA are informed through an electronic alert system of all non-compliant RMP sample results. The EIA is required to carry out enquiries to establish the source of contamination and may collect follow-up samples from the establishment for further analyses.

49. EIC-approved processing establishments and aquaculture farms with non-compliant sample results are subjected to more frequent inspections.

50. Sanctions against EIC-approved processing establishments and farms can range from compulsory residue tests of following consignments, to temporary suspension, fines and revocation of the approval in case of second time violations.

51. Sanctions against MPEDA-registered farmers whose products tested non-compliant in either the RMP or PHT are generally limited to notifying export establishments not to source products from concerned farms.

2 *In their response to the draft report the competent authority noted that they made provisions for registering authorities to initiate the steps to de-register aquaculture ponds in case of violations.*

5.1.5.3 Non-compliant results in the 2012 RMP and the official pre-harvest and pre-export programmes for aquaculture

52. RMP sample non-compliance rates in 2012 and 2013 for Group A6 substances (chloramphenicol and nitrofurans) varied between 53-70% for shrimp hatcheries, 10-16% for shrimp farms and 10.5-12.5% for finfish. RMP non-compliance rates for the limited range of Group B1 substances tested for were below 0.01% for shrimp and varied between 0.5 to 12% for finfish.

53. In 2012 the non-compliance rate for both the PHT and PET was 0.002% (see sections 5.1.4.1. and 5.1.4.2.).

54. Four EIA follow-up investigations of non-compliant RMP samples were checked by the audit team. MPEDA had in each case informed the EIC and the concerned EIA office of the respective non-compliances through the electronic alert system. Investigations and follow-up actions started quickly, with the EIA subsequently informing the processing establishment not to source products from farms where non-compliances were detected or, in case of a non-compliant farm sample, the farmer was informed in writing to not supply non-compliant product to processing establishments.

55. Follow-up samples (drawn at the exporting processing establishment) were taken from the next five consignments immediately where possible, or at the start of the following season. These samples were not targeted at farms which had originally contributed to the consignment causing the RMP non-compliance. The EIC informed the audit team that it will consider targeting follow-up sampling on products coming from farms which have contributed to a non-compliant consignment. Processing establishments were required to provide within 15 days, information to identify the root cause of the non-compliance. They also had contacted the farms concerned, requesting an explanation of the origin of the non-compliance. In not one case was the root cause identified.

56. The EIC executive instructions regarding follow-up investigations require visits to each farm implicated in a non-compliant batch. However, only one out of eight registered farms involved in the four RMP non-compliances had been visited by the EIA (the farm in question had been EIC-approved) and thus was eligible to be controlled by EIA. For the most part the EIA had largely "delegated" the follow-up investigation at farm level to the processing establishment (as has been described in the 2009 and 2011 FVO reports). In this respect the EIC's own executive instructions are not being complied with.

5.1.5.4 Non-compliant results reported under the RASFF

57. Between January 2012 and February 2014 there were 13 RASFF notifications for residues of veterinary medicinal products in aquaculture products of which 11 concerned nitrofuran metabolites, one chloramphenicol and one oxytetracycline. The audit team examined of these during the visits to two EIA offices and two EIC-approved export establishments.

58. The actions taken by the EIA in each case were as set down in EIC executive instructions and were similar to those described above for RMP non-compliances. In one RASFF follow-up investigation (see DG (SANCO) 2014 3176) MR) all farms connected to the RASFF had been visited to identify the root cause. This did not happen in the other RASFF cases examined. In none of these follow-up investigations was the root cause of the non-compliance identified.

Conclusions on follow-up of non-compliant results

59. Procedures for the follow-up of non-compliant results are well described in the EIC executive instructions and, where follow-up takes place, it is done so promptly. Nevertheless, the effectiveness of follow-up is compromised by several factors. The fact that the EIA cannot legally carry out controls on non-EIC-approved farms means that such farms are effectively outside the control of the central competent authority even though they are free to supply products for export to the EU. The delegation of follow-up for the most part to the processing establishment is not in line with EU rules and may be one reason why the root cause of the problem is rarely identified. As a consequence, the measures in place do not provide guarantees equivalent to those provided under Articles 16-18 and 22-27 of Directive 96/23/EC, weakening the effectiveness of controls on residues in aquaculture products.

5.2 LABORATORIES

Legal Requirements

Directive 96/23/EC; Decision 98/179/EC; Decision 2002/657/EC; Regulation (EU) No 252/2012; Regulation (EC) No 333/2007; Regulation (EC) No 401/2006. (See Annex 2).

5.2.1 General description

Findings and observations

60. Official residues testing of aquaculture products is coordinated by the EIC and carried out within four official residue testing programmes: RMP, PHT, PET and EIA monitoring.

61. Laboratories involved in official residues testing are required to obtain an approval under a laboratory approval scheme operated by the EIC. This has been described in the 2009 and 2011 FVO reports.

62. Three MPEDA laboratories located in Bhimavaram, Kochi and Nellore are responsible for analysis of aquaculture samples under the RMP, confirmatory analysis of non-compliant screened PHT samples and monitoring of ELISA laboratories. At the time of the audit this monitoring covered 13 out of the 20 ELISA PHT laboratories.

63. The EIA laboratories have responsibility to carry out the EIA monitoring, PET, testing of returned consignments and to test 5% of RMP samples.

64. There is no nominated national reference laboratory for residues in aquaculture. However, arrangements exist to test in parallel 5% of the RMP samples in both MPEDA and EIA laboratories and a certain percentage of PHT samples is tested in MPEDA laboratories.

65. With regard to RMP, there are no confirmatory methods within the laboratory network for testing residues of stilbenes, steroids and anthelmintics and no contracts are in place to confirm screened non-compliant samples in another laboratory. However, available confirmatory methods are used by the EIA laboratories to analyse the 5% EIA monitoring RMP samples. The MPEDA Nellore laboratory which receives fish samples had no validated methods for stilbenes, steroids and nitroimidazoles in finfish.

66. For testing of dioxins and PCBs under the RMP, a private ISO-accredited laboratory was appointed by MPEDA in 2010 and since then samples are dispatched annually to that laboratory pending receipt of a quotation. The respective analytical methods were included in the accreditation scope.

67. The turnaround times agreed between MPEDA, the EIC and laboratories are 15 days for the RMP samples, 3 days for PHT samples and 7 days for PET samples. Whilst these target times are not monitored it could be seen in the laboratories visited that these turnaround times were generally adhered to.

68. An arrangement is in place to verify residue concentrations in consignments rejected at EU borders. Samples taken from returned consignments are tested in parallel in two laboratories: one belonging to the EIA and one of the private PET laboratories but not the one which carried out PET before the consignment was dispatched to the EU.

69. EIA Kolkata which is involved in PET had not conducted interlaboratory comparisons for chloramphenicol and nitrofuran metabolties but was in process to participate in a proficiency test for these substances.[3]

5.2.2 On the spot visits in the laboratories

70. Two EIA laboratories in Chennai and Kochi, two MPEDA laboratories in Nellore and Kochi, two EIC approved private laboratories involved in PET and one laboratory carrying out PHT were visited.

71. Overall, laboratory documents and records were well maintained and traceable except for the balance records in EIA Kochi.

72. Sample acceptance instructions were in place but samples could be rejected only when deteriorated. Other important criteria for sample integrity and suitability for analysis (packaging, temperature, quantity) were frequently not specified and never recorded.

73. Validation files for chloramphenicol, nitrofuran metabolites, tetracyclines and malachite green were checked in different laboratories visited. All residue methods in use were validated in line with the requirements of Decision 2002/657/EC and the fitness for purpose of those methods was demonstrated with one exception. All validations were performed in shrimp; performance was not verified for fish or hatchery samples (where applicable).

74. With regard to testing for heavy metals accredited methods were available in the laboratories visited. The accredited concentration range and validation files examined were found to be satisfactory with few exceptions.

75. None of the laboratories visited had certified reference materials, control materials or in-house control samples in place. The same standard was used for calibrations and for spiking for quality control purposes. In addition, staff frequently did not understand the difference between certified reference materials and certified standards.

76. Single control samples spiked at the MRPL/Maximum Residue Limit (MRL) were run in every assay series. However, laboratories had no clearly defined criteria for recovery assessment of control samples and consequently acceptance/rejection of analytical runs. No records of recovery assessment for spiked samples were maintained. The staff stated that 50%-120% and 80%-110% recovery criteria for samples spiked at the MRPL and MRL,

3 *In their response to the draft report the competent authority noted that satisfactory results of the proficiency test were received in the meantime for nitrofuran metabolites and chloramphenicol (Z-score 1.3 and -0.5).*

respectively, apply. No assessment against the recovery levels found during validation study or testing results of a representative number of control samples was made.

77. Control charts were not always maintained. The majority of those control charts which were available covered each set of 20 results separately and therefore were not suitable for demonstrating the method performance over an extended period. Due to this and other above mentioned shortcomings related to ensuring sample integrity and calibration of instruments, **recommendation No 2** of the 2011 FVO audit report has only been partially addressed.

78. All three MPEDA laboratories, three EIA laboratories and certain private laboratories involved in PET participate in interlaboratory comparisons for chloramphenicol, nitrofuran metabolites, tetracycline, oxolinic acid, heavy metals, non-dioxin like PCBs and dyes. For the most part, results have been satisfactory.

5.2.2.1 EIA Chennai

79. This laboratory had nine scientific staff and accredited methods for chloramphenicol, nitrofuran metabolites, tetracyclines, sulphonamides, mycotoxins, heavy metals, and non-dioxin-like PCBs. A method for dioxins and dioxin-like PCBs was under development.

80. The Liquid Chromatography-(Tandem) Mass Spectrometry (LC-MS/MS) method for chloramphenicol and the Inductively Coupled Plasma Mass Spectrometry method for cadmium in shrimp were checked by the audit team. Both were adequately validated.

81. For chloramphenicol method a five point matrix-matched calibration curve was run for every assay series and internal standard is used. A control sample was run after every 10 tested samples and control charts were maintained.

5.2.2.2 EIA Kochi

82. This laboratory had five scientific staff and is accredited for testing chloramphenicol, nitrofuran metabolites, tetracyclines, sulphonamides, oxolinic acid, nitroimidazoles and heavy metals in shrimp, fish and fishery products. For chloramphenicol, nitrofuran metabolites and lead the accredited concentration range was equal to respective Minimum Required Performance Limits /Maximum Levels (MRPL/ML) levels. For cadmium the accredited concentration level was higher than the ML for muscle meat of fish as specified in Regulation (EC) No 1881/2006.

83. The audit team was informed that quality requirements for standards used are included in the methods' SOPs. However, the audit team verified that only the standard supplier is indicated. The laboratory had no management policy for standards having no expiry date indicated by a supplier.[4]

84. The LC-MS/MS method for furazolidone (AOZ) was examined by the audit team. Method validation was performed in 2010 at three concentration levels of 1.0; 1.5; and 2.0 µg/kg during two consecutive days. A significant loss of analytical recovery at 2.0 µg/kg was found but results were nevertheless accepted. A third experiment was performed at concentration levels of 0.5; 1.0 and 1.5 µg/kg. The analyst who performed the method validation left the laboratory and the other one who currently operates the method was

4 *In their response to the draft report the competent authority noted that revised SOP for standards/reference material including information e.g. on purity and expiry date as well as the keeping of quality control charts were now newly introduced.*

neither trained in, nor in a position to explain how the method performance parameters have been calculated and he had not performed any method performance verification. A validation file was kept by the quality manager.

85. The CC alpha verification on 22 samples was performed in November 2013 but the laboratory could not demonstrate that independent samples had been spiked with AOZ at that concentration level.

86. The Flame Atomic Absorption Spectrometry method for cadmium was also checked by the audit team. It was validated only at one concentration level of 0.5 mg/kg which is insufficient to demonstrate the suitability of the method for testing cadmium in fish destined for export to the EU. This shortcoming was not noted during the EIC audits. In addition, the experiments carried out in May 2013 to establish limit of detection and quantification of the method to demonstrate its fitness for purpose according to criteria stipulated in Regulation (EC) No 333/2007 had been incorrectly designed and interpreted.

87. A general procedure for assuring quality of test results was available in the laboratory since December 2012 and required to incorporate various Quality Control (QC) checks in each batch of samples but it did not provide guidelines how the QC results should be evaluated. Such guidelines were also not included in the method SOP.

5.2.2.3 MPEDA Nellore and Kochi

88. In both laboratories accredited methods were available for nitrofuran metabolites, chloramphenicol, tetracyclines, sulphadiazine, oxolinic acid, nalidixic acid, ivermectin (Kochi screening only), organochlorine compounds, heavy metals and dyes.

89. MPEDA Kochi is accredited for testing progesterone and diethylstilbestrol (screening only), non-dioxin-like PCBs and mycotoxins. A method for nitroimidazoles was approved by the EIC.

90. In MPEDA Kochi standard for 4-epichlortetracycline was available but neither the purity nor expiry date were specified in the certificate. This was in line with the method SOP where only the supply of standards is indicated but no specific requirements are defined. The laboratory had no policy in place concerning establishing and verification of expiry dates for chemical substances handled.

91. Both laboratories had a policy to calibrate instruments monthly and to use a stored matrix-matched calibration each month without checking the instrument performance and validity of the stored calibration. In addition there was no established sample order for analytical runs.

92. In MPEDA Nellore an Ultra High Performance Liquid Chromatography - Photodiode Array Detector method for tetracyclines and an LC-MS/MS method for malachite green and leucomalachite green were examined by the audit team and both were found to be adequately validated.

93. There was a plan for QC checks for the first half of 2014 comprising, inter alia, replicate testing. The only replicate testing covered analysis of two samples of unknown concentration given for QC by the Technical Manager which were processed on 21 February. However, a job order to analyse the QC samples was not issued and therefore the recovery for those samples was not assessed.

94. In MPEDA Kochi the Ultra High Performance Liquid Chromatography - MS/MS method for tetracyclines and the LC-MS/MS method for chloramphenicol were checked by the audit

team. Both methods were validated but for chloramphenicol the method recovery range was not calculated.

95. During the last two years both laboratories participated in PTs for chloramphenicol, nitrofuran metabolites, tetracyclines (Nellore only), oxolinic acid, organochlorine pesticides, heavy metals and dyes by commercial providers with satisfactory results.

5.2.2.4 EIC approved private laboratories in Chennai and Kochi

96. Both laboratories were adequately equipped and staffed having the EIC approval for PET of aquaculture products. Both had adequate procedures in place and employed specialised staff to collect samples for the pre-export certification schemes. The laboratories were accredited, inter alia, for testing nitrofuran metabolites, chloramphenicol, tetracyclines and a range of sulphonamides.

97. PET reference samples were stored in appropriate and monitored conditions.

98. In Chennai the validated LC-MS/MS method for chloramphenicol was examined by the audit team. An CC alpha / CC beta verification experiment was carried out in May 2013 but no evaluation had been made against CC alpha / CC beta values obtained during method validation. In Kochi the LC-MS/MS method for nitrofuran metabolites was examined by the audit team. It was comprehensively validated and recovery ranges had been set for the acceptance of quality control samples spiked at the MRPL and measured within each analytical run.

5.2.2.5 ELISA Laboratory analysing samples for the official PHT

99. This small laboratory had three staff and carried out PHT using commercial ELISA kits. It is not accredited but is approved under the EIC approval scheme. Of 4,664 samples screened in 2013, three screened non-compliant for nitrofuran metabolites. None of 934 samples processed in 2014 up to the time of the audit were positive. The laboratory was not informed if any of the non-compliant screened samples were confirmed through instrumental analysis.

100. The EIC assessment visit took place in August 2013 and the laboratory was finally approved in February 2014. However, the laboratory had been in operation for PHT since 2009 and the EIC approval scheme had been extended to ELISA laboratories after the 2011 FVO audit.

101. Certified standards with valid and adequate certificates were available.

102. The ELISA reader was calibrated against the standard solutions supplied with the ELISA kit and the calibration was performed with every newly open kit package.

103. The method SOP was available and the validation study was performed in April 2012. It followed the 2010 EU Reference Laboratories guidelines for the validation of screening methods for residues of veterinary medicinal products.

104. Control samples spiked at CC beta level were run after each ten single test samples and last sample in every run was duplicated. The audit team was informed that recovery for control samples should not be lower than 80% and not exceed 120%. However, recovery assessment records were not maintained and there were no criterion established for the maximum readout difference for samples tested in duplicate.

Conclusions on laboratories

105. An improvement in laboratory performance compared to the 2011 FVO residue audit was seen with regard to extension of the EIC approval scheme to all laboratories involved in official residue testing programmes, method validation and introduction of inter-laboratory comparisons. However, shortcomings identified in the area of ensuring sample integrity, calibration of instruments and implementation of quality control have the potential to undermine the reliability of the results produced.

5.3 Veterinary medicinal products and medicated feedingstuffs

5.3.1 Authorisation, distribution and use of veterinary medicinal products

Legal Requirements

Directive 96/23/EC; Directive 96/22/EC; Directive 2001/82/EC; Regulation (EC) No 726/2004; Regulation (EC) No 470/2009, Regulation (EU) No 37/2010; Commission Directive 2006/130/EC; Council Directive 90/167/EEC; Regulation (EC) No 183/2005. (See Annex 2).

Findings and observations

106. The manufacture, import, sale and distribution of drugs and drug products (for animals and humans) are regulated under the Drugs and Cosmetics Act (1940) (hereafter referred to as the Act) and Rules (1945) (hereafter referred to as the Rules). The Office of the Drugs Controller General is responsible for 'inter alia' amendments to national legislation, approval of new drugs, export of new drugs and imports. Once a new drug has been approved for four years a State Drug Control Authority can approve the manufacturing of the drug in their State. A manufacturing license is valid for five years. The central government can prohibit the manufacture and import of a drug considered to be harmful to animals or which does not meet the therapeutic claims registered.

107. Drug manufacturers and retail outlets for veterinary medicinal products must be licenced with the State Drug Control/Licencing authority in the State / State region in which they operate. Licenses need to be renewed every five years. The Drug Controller General stated that there are approximately 600,000 registered drug outlets/pharmacies in India.

108. The Act requires that containers of a medicine for treatment of animals shall be labelled with the words 'Not for human use; for animal treatment only' and shall bear a symbol depicting the head of a domestic animal.' Staff of the State license authorities met in Tamil Nadu and Andhra Pradesh informed the audit team that the head of each animal for which the medicine is approved shall be on the package. However, staff met from the state license authority in Kerala, stated that only one head of a domestic animal is sufficient even if the medication is approved for other species as well.

109. Under the Rules all antibiotics and certain sulphonamides are prescription-only medicines. However, sulphadiazine, sulphaquinoxaline and sulphathiazole (which are authorised for veterinary use) have not been included on the list of prescription-only substances. Products for treatment or prevention of ecto- and endoparasites e.g. containing ivermectin are over-the-counter products while others e.g. containing fenbendazole are prescription drugs. Diclofenac is the only veterinary medicinal product which has been prohibited (2008) in India.

110. Dimetridazole, furazolidone, nitrofurazone, ronidazole and chloramphenicol (listed in Table 2 of the Annex to Regulation (EU) No 37/2010), whilst available in veterinary medicinal products are banned for use in aquaculture.

111. Notification 28 (E) from 17 January 2012 requires the inclusion of withdrawal periods on the labels of veterinary medicinal products. If specific withdrawal periods are not proposed by the manufacturers, generic withdrawal periods in line with those listed in Article 11.2 of Directive 2001/82/EC are to be included on the label. The requirements apply both to all new veterinary medicinal products and those having a licence renewal.

112. Neither staff of the three state licensing authorities met, or staff in wholesalers and pharmacies, were aware of the Notification 28 (E) requirement to show species specific withdrawal periods on the label. Furthermore the audit team found in the wholesalers and pharmacies visited in three states, that labels in at least 50% of cases did not indicate the withdrawal period and in around 10% not the specific species (neither as picture nor as text). Thus **recommendation No 4** of the 2011 FVO audit report has not been addressed.

113. Veterinarians can prescribe veterinary medicinal products for use in aquaculture animals, which is a change vs. the situation observed during the 2011 FVO audit where farmers could not legally obtain e.g. prescription antibiotics.

114. In one wholesaler visited some feed additives contained on the label the words "growth promoters" but it could not be established by the drug control inspector what the substance having a growth promoting effect was or if it was an active pharmaceutical ingredient. Similarly the descriptions of product composition on the labels of some feed additives found on a visited farm did not provide full and accurate information as they were referring, for example, to "other boosters" or "enhancers". The substances covered by these descriptions were not known to the farm business operator or to the authorities met.

115. On one farm visited, an empty package of a feed additive ("natural flavine") was found in the feed storage area. No indication of the product composition was indicated on the label. According to the farm business operator, this additive contains acriflavine, an antiseptic dye, which has been used to treat gill infections in shrimp. The last use was said to have taken place during the last production cycle (ended in Autumn 2013), however this had not been recorded.

Conclusions on authorisation, distribution and use of veterinary medicinal products

116. Whilst there is a system in place for the authorisation and control of veterinary medicinal products, it has several shortcomings in comparison to the EU system. Despite the fact that since 2012 species-specific withdrawal periods on product labels have been required, only around 50% of veterinary medicinal product labels did this and state licensing authority and pharmacy staff had limited awareness of this requirement. Additionally feed additive labels do not always indicate if a pharmacologically active ingredient is included. Consequently veterinarians and farmers do not always have adequate information on the products they are using, and the correct withdrawal periods to apply, to ensure that residues of veterinary medicinal products are not present at concentrations in excess of EU maximum limits in those consignments of fish and shrimp eligible for export to the EU.

5.3.2 Official controls on the distribution and use of veterinary medicinal products

Legal Requirements

Directive 96/23/EC; Directive 2001/82/EC; Directive 90/167/EEC. (See Annex 2).

Findings and observations

117. According to national legislation manufacturers and retail outlets for veterinary medicinal products should be inspected at least annually by the State Drug Control authorities. The State Drug Control authorities are also responsible, inter alia, for taking actions to stop the illegal distribution of antibiotics by so called "shrimp doctors", which are suspected by the competent authorities to be a source of residues in farmed shrimp.

118. Annual or quarterly inspection frequencies of pharmacies and wholesalers set by the State Licensing Authority were complied with in wholesalers and pharmacies visited.

119. Inspections of drug outlets focused on good distribution practice in line with the requirements of the Act and its Rules and samples were collected to check if the content of pharmacologically active substances in medicinal products is in line with label indications.

120. Inspection reports drawn up by the local drug control inspectors were kept by the inspector and copied to the State Drug Controller. Corrective actions, where relevant, would be requested through a letter from the State Drug Controller. Inspections covered license, expiry, storage and label checks. Given that inspectors met by the audit team were not aware that species-specific withdrawal periods needed to be mentioned on the label, no such controls took place and inspection reports did not indicate whether labelling compliance checks actually included checks of withdrawal period labelling requirements.

121. Two wholesalers and pharmacies visited (of both veterinary and human medicinal products) had up-to-date licenses by the State Drug Controller and invoices of purchased products were available as required by national legislation. There is no requirement in national legislation to retain (copies of) prescriptions in pharmacies. The local drug control inspectors interviewed stated that it was only possible to detect a sale without prescription if it took place while the inspectors were present. The drug control inspectors have no way of checking if the name entered under "prescribing doctor" on the sales receipt is a licensed veterinarian/doctor.

122. There is no national legislation equivalent to Directive 90/167/EEC regulating the production of medicated feedingstuffs. According to the Drug Controller General, veterinary medicinal products would be prescribed by a veterinarian for mixing in feed on farm should medication through feed be necessary.

123. State Drug Control Authorities staff met by the audit team stated that they do not conduct official controls on the use of veterinary medicinal products at feed mill or at farm-level. MPEDA does not have responsibility for carrying out controls with regard to correct veterinary medicinal products use and records. EIA compliance controls at farm level on the use, records, and storage of veterinary medicinal products (to ensure that EU residue levels are not exceeded), take place only on the small number of EIC-approved farms. These are inspected by the EIA every six months for the first year and then once a year, as per the EIC executive instructions.

124. Systematic awareness campaigns about the correct use of veterinary medicinal products and about banned pharmacologically active substances were implemented during 2012 and 2013 by MPEDA and aquaculture producer groups. Two aquaculture farmers met knew that certain antibiotics and other substances were banned for use in aquaculture.

125. As in 2009 and 2011, illegal sales of drugs/feed to aquaculture farmers are suspected by the competent authority to be the root cause of residues in aquaculture shrimp. Staff of the State Drug Controller General, the State drug control authorities and the EIC met by the audit team, did not know what (if any) efforts had been made to identify the suspected illegal suppliers ("shrimp doctors") of drugs to aquaculture farms. Thus **recommendation No 5** of the 2011 FVO audit report has not been addressed.

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

126. Despite awareness campaigns about banned substances at farm level and controls at wholesale and pharmacy level, several factors undermine the overall effectiveness of controls on the distribution and use of veterinary medicinal products. There is no evidence that there has been any action by the competent authority to address the reported problem of so-called illegal 'shrimp doctors'. In addition, a significant problem is that only a small fraction of farms eligible to supply aquaculture products to processing establishments (and thence export this product to the EU), are subject to official controls. The existing control system is ineffective in ensuring that veterinary prescription requirements are followed. Combined with the lack of knowledge of official staff and the pharmaceutical industry about veterinary medicine labelling requirements, and a lack of enforcement of these requirements, these factors increase the risk of non-compliant aquaculture products being exported to the EU.

5.4 Follow-up of relevant recommendations made in previous FVO report on residues (DG SANCO 2011-8861 MR Final)

N	Recommendation	Findings
1	Ensure that sampling of aquaculture farms is unforeseen and that samples for the residue monitoring programmes for eggs and poultry are collected throughout the whole production year and where possible not taken from processed products, in order to ensure that guarantees provided about the residue status of products potentially exported to the EU are at least equivalent to those provided under point 2.1 of the Annex to Commission Decision 98/179/EC.	EIC executive instructions indicate that sampling at aquaculture farms needs to be unforeseen and sampling at farms visited by the audit team were found to be unannounced (See finding 14). This recommendation has been addressed.
2	Ensure that the analytical performance of laboratories involved in testing official samples for residues is sufficient to provide reliable assurances that consignments exported to the EU do not contain residues of veterinary medicinal products above limits set down in Commission Regulation (EU) 37/2010.	Although improvements have been made since 2011, shortcomings identified in the area of sample reception, calibration of instruments and quality controls were found in some laboratories (see section 5.2. of this report). Thus this recommendation has only been partially addressed. (See recommendations 3 and 4 of the current report).

3	When non-compliant test results are obtained, ensure effective official follow-up investigations which have an effect at least equivalent to Articles 16-18 and 22 to 27 of Council Directive 96/23/EC.	Whilst follow-up investigations of RMP-, pre-export or RASFF non-compliances take place at EIC-approved processing establishments, relatively few EIC-approved aquaculture farms are subject to official control. Furthermore there is no follow-up in respect of PHT non-compliances (see section 5.1.5. of this report). Thus this recommendation has only been partially addressed. (See recommendation 2 of the current report).
4	Pending the implementation of new legislation, ensure that veterinarians, advisors and farmers have adequate information about the withdrawal periods which should be applied when using veterinary medicinal products in order to ensure that residue levels in animal products intended for the EU market do not exceed EU limits laid down in Commission Regulation (EU) No 37/2010 and Regulation (EC) No 396/2005.	While information campaigns on proper use of veterinary medicinal products directed at farmers took place and a 2011 law requires that species-specific withdrawal periods have to be indicated on the label of veterinary medicinal products, awareness among drug controller inspectors and pharmacists about this law is very low and more than 50% of veterinary medicinal product labels checked by the audit team did not indicate this information (see section 5.3 of this report). This recommendation has not been addressed. (See recommendation 5 of the current report).
5	Prevent the illegal distribution and use of veterinary medicinal products in order to avoid the potential risk that animal products intended for the EU market may contain residues of veterinary drugs exceeding the limits laid down in Commission Regulation (EU) No 37/2010.	No evidence could be presented by the competent authority that efforts had been made to identify the suspected illegal suppliers ("shrimp doctors") of drugs to aquaculture farms (see finding 120). This recommendation has not been addressed. (See recommendation 6 of the current report).

6 Overall Conclusions

Overall, it is concluded that guarantees provided by the residue control system for aquaculture products in India are, with some exceptions, broadly equivalent to those foreseen by EU legislation. The residue monitoring plan is implemented in accordance with planned arrangements and in line with EU rules and meets minimum requirements laid down in EU legislation (for testing of aquaculture shrimp but not finfish). However a relatively narrow range of substances is tested for and no account is taken of the range of substances actually used in fish and shrimp production in the country.[5] As such, guarantees on the residues status of aquaculture products rely to a large extent on the additional pre-harvest and pre-export testing programmes in place and these mitigate

5 *In their response to the draft report the competent authority noted that data on the range of substances actually used in aquaculture products shall be compiled and considered for inclusion in the 2015 NRCP.*

to a certain extent the long-standing deficiencies in official controls on farms, and in particular, an almost total absence of official controls on the use of veterinary medicinal products. Nevertheless, the relatively narrow range of substances tested for in those additional programmes also weakens the reliability of those guarantees.

With regard to the follow-up of non-compliant results, some improvements have been noted relative to 2011 (for example progress made on the registration of farms), nevertheless, it remains the case that follow-up at primary producer level to identify the root cause of the non-compliance is 'delegated' almost fully to the export establishments which is not in line with EU requirements.

Concerning laboratories, improvements in performance have been noted relative to 2011, though certain deficiencies in quality control and ensuring the analytical integrity of samples have the potential to undermine the effectiveness of the residue monitoring plan.

With regard to veterinary medicinal products, the system for authorisation of, and controls on veterinary medicinal products is deficient in many respects compared to the EU system. Improvements have been made relative to 2011 (introduction of labelling legislation) however, the many non-compliances identified by the audit team in this respect and overall poor awareness and enforcement of the legislation collectively weaken the effectiveness of the residue control system.

7 Closing Meeting

A closing meeting was held on 13 March 2014 with representatives of the central competent authority and other authorities. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit.

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.	Ensure that samples are drawn from aquaculture saltwater finfish and tested for all requisite substance groups in line with the provisions of Annex II to Directive 96/23/EC. Conclusion upon which this recommendation is made: 12. Associated findings and observations: 10.
2.	When non-compliant test results are obtained, ensure effective official follow-up investigations which have an effect at least equivalent to Articles 16-18 and 22 to 27 of Directive 96/23/EC. Conclusion upon which this recommendation is made: 59. Associated findings and observations: 38, 42, 45, 47, 52, 53, 55, 56, 59.
3.	Ensure that all laboratories involved in the residue monitoring plan and/or official testing of aquaculture products destined for export to the EU ensure sample integrity in line with requirements of point 2.6 and 2.9 of the Annex to Decision 98/179/EC. Conclusion upon which this recommendation is made: 105. Associated findings and

N°.	Recommendation
	observations: 72, 77.
4.	Ensure that residue testing laboratories improve existing quality control procedures for monitoring the reliable performance of all residue testing in order to provide guarantees with an effect equivalent to that foreseen by Article 5 of Decision 2002/657/EC. Conclusion upon which this recommendation is made: 105. Associated findings and observations: 65, 69, 73, 75, 76, 77, 83, 84, 85, 86, 87, 90, 91, 93, 94, 98, 104.
5.	Ensure that veterinarians, advisors and farmers have adequate information about which withdrawal periods to apply when using veterinary medicinal products in order to ensure that residue levels in animal products intended for the EU market do not exceed EU limits laid down in Regulation (EU) No 37/2010 and Regulation (EC) No 396/2005.Conclusion upon which this recommendation is made: 116. Associated findings and observations: 108, 111, 112.
6.	Ensure that official controls on the distribution and use of veterinary medicinal products are effective in order to ensure that animal products intended for the EU market do not contain prohibited substances listed in table 2, or residues of veterinary medicinal products exceeding the limits of Regulation (EU) No 37/2010. Conclusion upon which this recommendation is made: 35, 126. Associated findings and observations: 22, 25, 57, 117, 120, 123, 125.

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=2014-7029

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
Maximum Residue Levels for pesticide residues in food 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

Legal Reference	Official Journal	Title
Dir. 2006/130/EC	OJ L 349, 12.12.2006, p. 15-16	Commission Directive 2006/130/EC of 11 December 2006 implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription
Reg. 726/2004	OJ L 136, 30.4.2004, p. 1-33	Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
Medicated feedingstuffs and additives		
Dir. 90/167/EEC	OJ L 92, 7.4.1990, p. 42-48	Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community
Reg. 1831/2003	OJ L 268, 18.10.2003, p. 29-43	Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition
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

Legal Reference	Official Journal	Title
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
Horse identification (passport)		
Reg. 504/2008	OJ L 149, 7.6.2008, p. 3-32	Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae
Medicines essential for the treatment of equidae		
Reg. 1950/2006	OJ L 367, 22.12.2006, p. 33-45	Commission Regulation (EC) No 1950/2006 of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae

ANNEX 2 – LEGAL REQUIREMENTS - DETAILED DESCRIPTION

Residue monitoring

Planning

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.

Implementation

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

Other residues monitoring programmes

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.

Follow-up of non-compliant results

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.

Laboratories

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 (EU) No 252/2012 (dioxins, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs), Commission Regulation (EC) No 333/2007 (chemical elements in foodstuffs) and Commission Regulation (EC) No 401/2006 (mycotoxins).

Veterinary medicinal products and medicated feedingstuffs

Authorisation, distribution and use of veterinary medicinal products

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 thereof 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 have been assessed in accordance with the provisions of Regulation (EC) No 470/2009 and 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 their 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.

Controls on the distribution and use of veterinary medicinal products

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.